International Compilation of Human Research Standards

2018 Edition

Compiled By:
Office for Human Research Protections
U.S. Department of Health and Human Services

PURPOSE

The International Compilation of Human Research Standards enumerates over 1,000 laws, regulations, and guidelines (collectively referred to as standards) that govern human subjects research in 130 countries, as well as standards from a number of international and regional organizations. This Compilation was developed for use by researchers, IRBs/Research Ethics Committees, sponsors, and others who are involved in human subjects research around the world.

Content experts from around the world, listed at the back of the Compilation, provided updates (or confirmations of prior listings), which are reflected in the hundreds of changes entered in this Edition. Four new countries are featured in the 2018 Edition: Algeria, Madagascar, Mali, and Saint Lucia. For the first time, this year’s Compilation includes a section on Social-Behavioral Research.

ORGANIZATION

The Table of Contents is on pages 3-4. For each country, the standards are categorized by row as:
1. General, i.e., applicable to most or all types of human subjects research
2. Drugs and Devices
3. Clinical Trial Registries
4. Research Injury
5. Social-Behavioral Research
6. Privacy/Data Protection (also see Privacy International reports: https://www.privacyinternational.org/reports)
7. Human Biological Materials
8. Genetic (also see the HumGen International database: http://www.humgen.umontreal.ca/int/)
9. Embryos, Stem Cells, and Cloning

These nine categories often overlap, so it may be necessary to review the other standards to obtain an accurate understanding of the country’s requirements.

The information is then organized into four columns:
1. Key Organizations – include those groups that issue regulations or guidelines, or serve in a national oversight role for human subjects research.
2. Legislation – encompasses statutes, statutory instruments, and legislative decrees, as well as any pertinent constitutional provisions.
3. Regulations – refer to instruments that are created and issued in the name of governmental administrative bodies.
4. Guidelines – pertain to non-binding instruments.
The year of the document’s most recent version (or date of initial approval, if never amended) is indicated in parenthesis when that information is available, unless the date is part of the document’s title, e.g., Act 46/2012.

**HOW TO ACCESS A DOCUMENT**

Documents can be accessed in four possible ways:

1. Link to the web address (URL).
2. Search for a document at the website of the agency listed in the Key Organizations column.
3. Perform an Internet search on the document title.
4. Request a local research ethics committee to provide the document.

In many cases the documents are available in English. Sometimes the English translation is a non-official version. When the citation links to a non-English document, the language is indicated in parenthesis, e.g., (Spanish).

**TOPICS NOT COVERED**

In order to focus its scope, the International Compilation of Human Research Standards does not include standards from the state, provincial, or local levels. Nor does the Compilation cover:

1. Enabling legislation, i.e., laws that authorize an agency to promulgate human subjects standards, but do not direct the content of those regulations.
2. Laws, regulations, or guidelines specific to research integrity, clinical bioethics, product liability, clinical trial inspection procedures, intellectual property, good manufacturing practice, bioequivalence testing, or informed consent in clinical practice.
3. Ethics codes of academic, medical, or other professional organizations – see the Ethics Codes Collection: [http://ethics.iit.edu/ecodes/about](http://ethics.iit.edu/ecodes/about)
4. 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 report updates or broken links, contact Edward E. Bartlett, PhD, International Human Research Liaison, Office for Human Research Protections, U.S. Department of Health and Human Services: edward.bartlett@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. 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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<td>International Committee of the Red Cross (ICRC): <a href="http://www.icrc.org">www.icrc.org</a></td>
<td>1. Geneva Convention Relative to the Treatment of Prisoners of War, Articles 13 and 130 (1950): <a href="https://www.icrc.org/applic/ihl/ihl.nsf/7c4d08d9b287a4214125673903e636b/6fe854a3517b75ac125641e004a9e68">https://www.icrc.org/applic/ihl/ihl.nsf/7c4d08d9b287a4214125673903e636b/6fe854a3517b75ac125641e004a9e68</a> 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/7c4d08d9b287a4214125673903e636b/f6c8b9ee14a77fde125641e0052b072">http://www.icrc.org/ihl.nsf/7c4d08d9b287a4214125673903e636b/f6c8b9ee14a77fde125641e0052b072</a></td>
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<td>Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice :</td>
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<td>International Air Transport Association: <a href="http://www.iata.org/">http://www.iata.org/</a></td>
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### NORTH AMERICA

#### Canada

Note: Several Canadian provinces and territories also have human subject research standards.

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| United States | All of the following departments and agencies subscribe to subpart A, often referred to as the Common Rule (last updated in 2009), and codified in the relevant section of the Code of Federal Regulations: [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). Some departments and agencies subscribe to additional subparts:  
- Subpart B: Additional Protections for Pregnant Women, Human Fetuses, and Neonates (2001)  
- Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (1978)  
- Subpart D: Additional Protections for Children Involved as Subjects in Research (1991)  
<p>| | Central Intelligence Agency: <a href="https://www.cia.gov/index.html">https://www.cia.gov/index.html</a> | 16 CFR 1028, Subpart A | | |
| | Department of Commerce, National Institute of Standards and Technology: <a href="http://www.commerce.gov/">www.commerce.gov</a> | 15 CFR 27, Subpart A | | |</p>
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4. 34 CFR 350.4(c) (1991)  
5. 34 CFR 356.3(c) (1991) |          |
|        | Department of Energy:  
http://science.energy.gov/ber/human-subjects/ | | 1. 10 CFR 745 (1991), Subpart A  
2. DOE Order 443.1B  
3. DOE Order 481.1 | Various:  
http://www.hhs.gov/ohrp/regulations-and-policy/ |
|        | Department of Health and Human Services, Office for Human Research Protections:  
www.hhs.gov/ohrp/ | Public Health Service Act (1993):  
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html | For studies funded by FDA:  
45 CFR 46, Subparts A, D, and E:  
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html |
|        | Department of Health and Human Services, Food and Drug Administration:  
https://www.fda.gov/ | | | |
|        | Department of Homeland Security:  
www.dhs.gov/ | Public Law 108-458, Section 8306 | 1. 45 CFR 46, Subparts A-D  
|        | Department of Housing and Urban Development:  
www.hud.gov/ | | 24 CFR 60.101, which cites 45 CFR part 46, subpart A. | |
|        | 1. Department of Justice Office of Justice Programs:  
http://ojp.gov/  
2. Bureau of Prisons:  
http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28fr22_main_02.tpl  
3. 28 CFR 46 (1991), Subpart A:  
http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr46_main_02.tpl | |
|        | Department of Transportation:  
www.dot.gov/ | Public Law 108-458, Section 8306 | 49 CFR 11, Subpart A | |
|        | Department of Veterans Affairs:  
1. Office of Research Oversight (ORO):  
http://www1.va.gov/oro/  
2. Office of Research and | | 1. 38 FR 16 (1991), Subpart A  
2. 38 CFR 17.85 (1998) | Various:  
https://www.research.va.gov/resources/policies/human_research.cfm |
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| Development      | Development: [www.research.va.gov](http://www.research.va.gov)                     |                                                                            | 40 CFR 26
1. Subpart A: Common Rule
2. Subpart B: Prohibition of Intentional Exposure Research Conducted or Supported by EPA in Children and Pregnant or Nursing Women (2006)
4. Subpart D: Additional Protections for Observational Research Conducted or Supported by EPA in Children (2006)
5. Subpart K: Regulation of Third-Party Intentional Exposure Research for Pesticides in Non-Pregnant, Non-Nursing Adults (2013)
|                  | Environmental Protection Agency, Program in Human Research Ethics: [https://www.epa.gov/osa/basic-information-about-human-subjects-research-0](https://www.epa.gov/osa/basic-information-about-human-subjects-research-0) |                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                  |
|                  | National Aeronautics and Space Administration: [www.nasa.gov/](http://www.nasa.gov/) |                                                                            | 14 CFR 1230, Subpart A                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                  |
| Drugs, Biologics, and Devices | Drugs and Biologics
2. Public Health Service Act, 42 | 1. 21 CFR 50 (Informed Consent)
2. 21 CFR 312 (Investigational New Drug Application)
3. 21 CFR 56 (Institutional Review Boards)
4. 21 CFR 314 (Applications for Approval to Market a New Drug)
5. 21 CFR 54 (Financial) | General: Good Clinical Practice and Human Subject Protections in FDA-Regulated Clinical Trials: [http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm)
Other: [http://www.fda.gov/Drugs/GuidanceCompliance](http://www.fda.gov/Drugs/GuidanceCompliance)
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<td>Council of Europe, Bioethics Unit: <a href="http://www.coe.int/bioethics">http://www.coe.int/bioethics</a></td>
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2. National Bioethics Committee  
SSFM: Ordinance No. 38-c on Rules for Conducting Morphological Examinations (1999) | |

**General**
- Belgium Advisory Committee on Bioethics (BACB): Law Relating to Experimentation on Humans
- BACB: 1. Opinion No. 13: Regarding
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5. Opinion No. 51: Publication of the Results of Human Experimentation (2012) |
2. Royal Decree of June 30, 2004 Determining the Implementation Measures of the Law  
3. Royal Decree of June 30, 2004 Modifying the Royal Decree of June 6, 1960  
4. Royal Decree of July 15, 2004 Determining Payments for Ethical Opinions or Authorization for the Conduct of a Clinical Trial or Experiment  
<p>| Country          | Key Organizations                                                                                                                                                                                                 | Legislation                                                                                                                                  | Regulations                                                                                                                                     | Guidelines                                                                                                                                                                                                 |
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<td>Keeping the Records of Personal Data Filing Systems and the Pertinent Records Form (2009):</td>
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<td>2. Law on Amendments to the Law on the Protection of Personal Data in Bosnia and Herzegovina, Official Gazette of Bosnia and Herzegovina No. 76/11 (2011):</td>
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<td>**Embryos, Stem Cells</td>
<td>Federation of Bosnia and Herzegovina</td>
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| and Cloning             | Ministry of Health:                                    | http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-
<p>|                         |                                                        | transplantation-organa-i-tkiva-u-svrhu-lijecenja                              |                                                                             |                                                                               |
|                         |                                                        | 2. Law on Blood and Blood Products, Official Gazette of Bosnia and Herzegovina No. 09/10: |                                                                             |                                                                               |
|                         | <a href="http://www.vladars.net/sr-SP-Cyril/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx">http://www.vladars.net/sr-SP-Cyril/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx</a> | <a href="http://www.vladars.net/sr-SP-Cyril/Vlada/Ministarstva/MZSZ/Documents/Zakon%20o%20transplantaciji%20ljudskih%20organa.pdf">http://www.vladars.net/sr-SP-Cyril/Vlada/Ministarstva/MZSZ/Documents/Zakon%20o%20transplantaciji%20ljudskih%20organa.pdf</a> | <a href="http://www.vladars.net/sr-SP-Cyril/Vlada/Ministarstva/MZSZ/Documents/d0%91%80%b0%d0%b2%d0%b8%d0%bb%d0%bd%d0%b8%d0%ba%d0%be%d0%ba%d1%80%d0%b8%d1%82%d0%b5%d1%80%d0%b8%d1%98%d1%83%d0%bc%d0%b8%d0%bc%d0%b0%d0%b7%d0%b0%d1%82%d0%b5%d1%81%d1%82%d0%b8%d1%80%d0%b0%d1%9a%d0%b5%d0%b4%d0%b0%d0%b2%d0%b0%d0%bb%d0%b0%d1%86%d0%b0%d1%99%d1%83%d0%b4%d1">http://www.vladars.net/sr-SP-Cyril/Vlada/Ministarstva/MZSZ/Documents/d0%91%80%b0%d0%b2%d0%b8%d0%bb%d0%bd%d0%b8%d0%ba%d0%be%d0%ba%d1%80%d0%b8%d1%82%d0%b5%d1%80%d0%b8%d1%98%d1%83%d0%bc%d0%b8%d0%bc%d0%b0%d0%b7%d0%b0%d1%82%d0%b5%d1%81%d1%82%d0%b8%d1%80%d0%b0%d1%9a%d0%b5%d0%b4%d0%b0%d0%b2%d0%b0%d0%bb%d0%b0%d1%86%d0%b0%d1%99%d1%83%d0%b4%d1</a> |                                                                               |</p>
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| Human Biological Materials:  | 1. Executive Agency for Transplantation (Bulgarian): http://www2.bgtransplant.bg/bg  
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<td>Note: All websites and documents are in Croatian. For an overview of human subject protections standards in Croatia, see the EFGCP Report: <a href="http://www.efgcp.eu/Downloads/EFGCPReportFiles/Croatia%20definitive%20Updated.pdf">http://www.efgcp.eu/Downloads/EFGCPReportFiles/Croatia%20definitive%20Updated.pdf</a></td>
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<td>1. Agency for Medicinal Products and Medical Devices of Croatia: <a href="http://www.halmed.hr/">http://www.halmed.hr/</a></td>
<td>1. Law on Mandatory Health Insurance (2013): <a href="http://www.hzzo.hr/wp-">http://www.hzzo.hr/wp-</a></td>
<td>Ordinance on Clinical Trials and Good Clinical Practice, Articles 11 and 16, Act 5.8., 6.8. and</td>
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<td>2. Ministry of Health, National Bioethics Committee:</td>
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2. 2003 Amendments: [Link](http://www.dataprotection.gov.cy/dataprotection.nsf/6976708c0004a04a04a0040a0a49/8e24ef90a27f345c2256eb4002854e7/$FILE/37(I)-2003_en.pdf) |                                                                                                |                                                                                                |
| Czech Republic  |                                                                                   | For an overview of human subject protections in the Czech Republic, see the EFGCP Report: [Link](http://www.efgcp.eu/Downloads/EFGCPReportFiles/Czech%20definitive%20Updated.pdf) |                                                                                                |                                                                                                |
2. Act No. 130/2002 Collection on Research and Development Support, as Amended  
3. Act No. 372/2011 on Healthcare Services  
| Drugs, Biologics, and Devices | Drugs                                                                                 | 1. Ministry of Health (MOH) (Czech): [Link](http://www.mzcr.cz)  
MOH: Decree No. 226/2008 on Good Clinical Practices and on Detailed Conditions for Evaluation of Pharmaceutical Products  
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<td>Guidelines for Applications for Authorisation of Clinical Trials of Medical</td>
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<td>1. Ministry of Social affairs and Health (French): <a href="http://www.sante.gouv.fr/">http://www.sante.gouv.fr/</a></td>
<td>1. Law No. 2012-300 of 5 March 2012 on Research Involving Human Persons:</td>
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**Georgia**


| Research Injury | Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001) | |


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<td>2. Central Ethics Committee of the German Medical Association (ZEKO) (German): <a href="http://www.zentrale-ethikkommission.de/">http://www.zentrale-ethikkommission.de/</a></td>
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<td>3. Permanent Working Party of Research Ethics Committees in Germany (German): <a href="http://www.ak-med-ethik-komm.de/">http://www.ak-med-ethik-komm.de/</a></td>
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<td>6. German Research Foundation (DFG), Permanent Senate Commission on Key Questions in Clinical Research (SCCR): <a href="http://www.dfg.de/en/dfg_profile/statutory_bodies">http://www.dfg.de/en/dfg_profile/statutory_bodies</a> senate/clinical_research/index.html</td>
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<td>Act on Medical Devices, Fourth Chapter (2017)</td>
<td>Regulation on Clinical Trials of Medical Devices</td>
<td>FAQs: <a href="https://www.drks.de/drks_web/navigate.do?navigationId=faq&amp;messageEN=FAQ">https://www.drks.de/drks_web/navigate.do?navigationId=faq&amp;messageEN=FAQ</a></td>
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<td>German Clinical Trials Register (DRKS): <a href="https://www.drks.de/drks_web/setLocale_EN.do">https://www.drks.de/drks_web/setLocale_EN.do</a></td>
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<td><a href="http://www.gesetze-im-internet.de/englisch_bdsg/">http://www.gesetze-im-internet.de/englisch_bdsg/</a></td>
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<td>German Society of Human Genetics (GfH): <a href="http://www.gfhev.de/en/gfh/">http://www.gfhev.de/en/gfh/</a></td>
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<td>Central Ethics Committee for Stem Cell Research (ZES): <a href="http://www.rki.de/EN/Content/Institute/Committees/StemCell/StemCell_content.html">http://www.rki.de/EN/Content/Institute/Committees/StemCell/StemCell_content.html</a></td>
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1. Greek Constitution 1975/1986/2001 Article 9.1  
3. Act 2472/1997 on the Protection of Individuals with Regard to the Processing of Personal Data (As Amended by
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### Country: Hungary


**Note:** All webpages and documents are in Hungarian.

#### General

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<td>4. Act LXXXI of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research</td>
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<td>5. Act C of 2012 on the Criminal Code, Chapter XVI Medical Procedures and Criminal Offenses Against the Order of Research, Sections 168-175</td>
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#### Drugs, Biologics, and Devices

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<td>Medical Research Council, Ethics Clinical Pharmacology Ethics Committee (KFEB): <a href="https://ett.aeek.hu/kfeb/">https://ett.aeek.hu/kfeb/</a></td>
<td>Non-Interventional Trials: Act CLIV of 1997 on Health Care, Chapter VIII, Section 164/A:</td>
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3. Government Decree 27/2015 (II.25.) About the National Health Care Service System: [http://njt.hu/cgi_bin/njt_doc.cgi?docid=174246.343548](http://njt.hu/cgi_bin/njt_doc.cgi?docid=174246.343548) | Non-Interventional Trials:  
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<td>3. Withdrawal of Consent: <a href="http://www.vsn.is/en/content/withdrawal-consent">http://www.vsn.is/en/content/withdrawal-consent</a></td>
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<td>5. Advertising to Recruit Participants: <a href="http://www.vsn.is/en/content/advertising-recruit-participants">http://www.vsn.is/en/content/advertising-recruit-participants</a></td>
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<td>2. National Bioethics Committee (NBC): <a href="http://www.visindasidanefnd.is">www.visindasidanefnd.is</a></td>
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<td>2. Regulation on Active Implantable Medical Devices No. 320/2011 (Icelandic): <a href="http://www.stjornartidindi.is/Advert.aspx?ID=506676c-4651-46c2-83b5-ad946f3dee4c">http://www.stjornartidindi.is/Advert.aspx?ID=506676c-4651-46c2-83b5-ad946f3dee4c</a></td>
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<td>3. Regulation on In Vitro Diagnostic Medical Devices No. 936/2011 (Icelandic): <a href="http://www.stjornartidindi.is/Advert.aspx?ID=20b3e4e-ab25-44d3-8c32-e5f42a7b02f0">http://www.stjornartidindi.is/Advert.aspx?ID=20b3e4e-ab25-44d3-8c32-e5f42a7b02f0</a></td>
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| Human Biological Materials | 1. Ministry of Welfare: [Link](http://eng.velferdarraduneyti.is/)  
2. Biobanks: [Link](http://www.vsn.is/en/content/biobanks) |
2. Health Service Executive National Consent Policy, Part 3: [Link](http://www.hse.ie/eng/about/Who/qualityandpatientsafety/National_Consent_Policy/) |                                                                                   |                                                                            |

For an overview of human subject protections in Ireland, see the EFGCP Report: [Link](http://www.efgcp.eu/Downloads/EFGCPReportFiles/Ireland%20definitive.pdf); and see this summary on Clinical Trials Involving Medical Products: [Link](http://health.gov.ie/blog/policy/clinical-trials-involving-medicinal-products/)
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| **Drugs, Biologics, and Devices** | 1. Department of Health: http://health.gov.ie/  
| **Human Biological Materials** | Health Products and Regulatory Authority: https://www.hpra.ie/ | | |
| **Genetic Research**    | Health Products and Regulatory Authority: https://www.hpra.ie/ | | |
| **Italy**               | For an overview of human subject protections in Italy, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Italy%20definitive%20Updated.pdf | | |
2. Italian Medicines Agency (Italian): | 1. Decree of the President of the Republic: Regulations to Simplify the Procedures and to Verify and Check New Systems and Experimental Therapeutic Protocols (September 21, 2001) | 1. Ministerial Decree of 21 December 2007: Directions for Submitting the Request for Authorisation of a Clinical Trial on a Medicinal Product for Human Use to the Competent | |
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| Genetic Research | 1. Instituto Superiore di Sanita (ISS): [http://www.iss.it/chis/?lang=2](http://www.iss.it/chis/?lang=2)  
SIGU: Various: [http://www.sigu.net/show/documenti/5/1/linee%20guida](http://www.sigu.net/show/documenti/5/1/linee%20guida) |


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2. Central Medical Ethics Committee | 1. Law on Pharmacy, Section 26 (2013): [http://www.zva.gov.lv/?id=355&top=333&large=0](http://www.zva.gov.lv/?id=355&top=333&large=0)  
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<td><a href="http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab_Reg_No._891_-Procedures_for_the_Clinical_Trial_of_Medical_Devices.doc">Human Use (2010):</a></td>
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| Human Biological Materials | Central Medical Ethics Committee                                                   | Law on the Protection of Dead Human Beings and Use of Human Organs and Tissue (2008):  
| Genetic Research | 1. Ministry of Health:  
2. Data State Inspectorate:  
http://likumi.lv/doc.php?id=92330 |                                                            |
| Embryos, Stem Cells, and Cloning | 1. Ministry of Health:  
2. Central Medical Ethics Committee | Sexual and Reproductive Health Law, Sections 15-20 (2004):  
| Lithuania     |                                                                                                                                                  |                                                                                       |                                                                                       |                                                 |
|               | Note: All standards are in Lithuanian. For an overview of human subject protections in Lithuania, see the EFGCP Report:  
| General       | Ministry of Health (MOH):  
2. Law on Ethics of Biomedical Research (2016):  
3. Decree on Changes of Law on  
1. V-405, Decree on the Procedure for Keeping a Record of Biomedical Research, Collecting, Storage, and Providing Information on Biomedical Research (2010):  
http://www3.3rs.lt/pls/inter3/dokpaieska.showdoc ?p_id=372121&p_quer y=&p_tr2=  
2. Government of the Republic of |                                                                                       |                                                                                       |                                                 |
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<td>3. V-15, Decree on the Procedure for Calculating and Paying Compensation for the Expenses Incurred Due to Participation in Biomedical Research and the Time Spent (2016):</td>
<td><a href="https://www.e-tar.lt/portal/lt/legalAct/2a0242a0b5fe11e5a6588fb85a3cc84b">https://www.e-tar.lt/portal/lt/legalAct/2a0242a0b5fe11e5a6588fb85a3cc84b</a></td>
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<td>4. V-28, Decree on the Detailed Requirements for the Content of a Person’s Consent to Participate in Biomedical Research and for the Information about the Biomedical Research as well as a Procedure for Giving and Withdrawing the Consent (2016):</td>
<td><a href="https://www.e-tar.lt/portal/lt/legalAct/0f2f1b70b9db11e5a6588fb85a3cc84b">https://www.e-tar.lt/portal/lt/legalAct/0f2f1b70b9db11e5a6588fb85a3cc84b</a></td>
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**Drugs, Biologics, and Devices**

2. State Medicines Control Agency (SMCA): [http://www.vvkt.lt/lit/English](http://www.vvkt.lt/lit/English)
4. Decree No. 435 on the Procedure for Issuing a Favorable Opinion to Conduct a Clinical Trial on Medicinal Products or Approval to Conduct Biomedical Research by the Sponsor of the Clinical Trial on Medicinal Product or Other Type of Biomedical Research (2016): [https://www.e-tar.lt/portal/lt/legalAct/TAR.EF5F8A32BF33B3BF23DD/gRoLvrgCbW](https://www.e-tar.lt/portal/lt/legalAct/TAR.EF5F8A32BF33B3BF23DD/gRoLvrgCbW)
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<td><strong>Opinion to Conduct Clinical Trials on Medicinal Product, Approval for Clinical Trials on Medicinal Product, and Conducting and Controlling Clinical Trials (2017):</strong> <a href="https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TARS.277308/QPLLKpOUKw">https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TARS.277308/QPLLKpOUKw</a></td>
<td><strong>Guidelines to Advertise Clinical Trials, Adopted by the Group of Experts on Biomedical Research of the LBEC (2007)</strong></td>
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<td><strong>V-6, Decree on the Sample Form of the Request to Issue Favorable Opinion to Conduct Clinical Trial on Medicinal Product Form and the Ethical Assessment Form (2016):</strong> <a href="https://www.e-tar.lt/portal/lt/legalAct/b65b5ca0c44011e583a295d9366c7ab3/qcrDrSCSCJ">https://www.e-tar.lt/portal/lt/legalAct/b65b5ca0c44011e583a295d9366c7ab3/qcrDrSCSCJ</a></td>
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2. Decree No. V-659 on the Procedure for Importing of the Stem Cells Taken from the Umbilical Cord or Placenta after the Birth of a Child and the Samples Taken for Genetic Research into the Territory of the Republic of Lithuania and Exporting Therefrom (2017): https://www.e-tar.lt/portal/lt/legalAct/TAR.E2473B1958CA/gEthbNSRzzc |  |
3. Decree on Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/3a2e2c708d8911e7a3c4a5eb10f04386 |  |  |

**Luxembourg**


Note: All websites and documents are available in French.

| General                          | National Ethics Consultative Commission: |  |  |
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**Devices**

2. Drug and Devices Register: [https://lekovi.zdravstvo.gov.mk/](https://lekovi.zdravstvo.gov.mk/)

Law on Medicinal Products and Medical Devices (Official Gazette No.106/2007) and Laws Amending and Supplementing the Law (2010-2016): Click on file folder 1., then open sub-folders: [https://lekovi.zdravstvo.gov.mk/documents/2](https://lekovi.zdravstvo.gov.mk/documents/2)

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### Russia


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1. Ministry of Health Order 433n (July 10, 2015) “On Adoption of the Regulations on Organization of Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment and Rehabilitation (Including Order of Patients’ Assignment for Administering Such Medical Help), Standard Form of Protocol for Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment, and Rehabilitation” (Russian): [http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=183847](http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=183847)  

#### Drugs, Biologics, and Devices

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<td>Various (Spanish): <a href="http://www.aemps.es/actividad/pschb/implantables1.htm#circulares">http://www.aemps.es/actividad/pschb/implantables1.htm#circulares</a></td>
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2. Royal Decree of 19 January 2008 |                                                                            |
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<td>2. Policy Statement Regarding the Assessment of Scientific Studies in which Patients or Healthy Subjects are to Undergo Invasive Operations (2003)</td>
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**Drugs, Biologics, and Devices**

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| **Genetic Research**    | 1. Medical Products Agency: https://lakemedelsverket.se/english/  
| **Embryos, Stem Cells, and Cloning** | 1. Swedish Research Council (SRC): http://www.vr.se/english  

**Access:** http://www.scto.ch/en/News.html
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Note: Most Swiss cantons have enacted laws regarding data collection in the public sector that are similar to the Federal Act on Data Protection.
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3. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305, Articles 22 and 35, and Annexes | |
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United Kingdom

Unless otherwise noted, all laws, regulations, and guidelines listed for England apply to the entire United Kingdom.

For an overview of clinical research regulations in the United Kingdom, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=226

General

England:

2. Integrated Research Application System: https://www.myresearchproject.org.uk/


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<td>3. Data and Tissues Tool Kit: <a href="http://www.dt-toolkit.ac.uk/home.cfm">http://www.dt-toolkit.ac.uk/home.cfm</a></td>
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<td>Human Tissue and Biological Samples for Use in Research (2014)</td>
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<td>(2016), Articles 10, 22, 33, and 48; (Mandarin):</td>
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<td><a href="http://www.sda.gov.cn/WS01/CL0844/10307.html">http://www.sda.gov.cn/WS01/CL0844/10307.html</a></td>
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<td>2. Guideline on Ethical Review of Drug Clinical Trials,</td>
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<td>Appendix 1, Section 6.10 (2010) (Mandarin):</td>
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| Drugs, Biologics, and Devices | 1. Central Drugs Standard Control Organization, Office of Drugs Controller General of India (DCGI): [http://cdsco.nic.in](http://cdsco.nic.in)  
2. Permission for Clinical Trials: General Statutory Rules 63(E)  
3. Ethics Committee Registration: General Statutory Rules 72(E)  
5. Phytopharmaceutical Drug: General Statutory Rules 918(E)  
| Devices | 1. Central Drugs Standard Control Organization, Office of Drugs Controller General of India (DCGI): [http://cdsco.nic.in](http://cdsco.nic.in)  
| Clinical Trials Registry | Clinical Trials Registry – India: [http://ctri.nic.in/](http://ctri.nic.in/) |             |             | Clinical Trials Registry – India:  
FAQs: [http://ctri.nic.in/Clinicaltrials/faq.php](http://ctri.nic.in/Clinicaltrials/faq.php) | Office of Drugs Controller General: |
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<td><strong>Research Injury</strong></td>
<td>1. Central Drugs Standard Control Organization (CDSCO):</td>
<td>Drugs &amp; Cosmetics Act, 1940 (2005):</td>
<td>DCGI:</td>
<td>Registration of Clinical Trial in ICMR Clinical Trial Registry:</td>
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<td><a href="http://www.icmr.nic.in/human_ethics.htm">http://www.icmr.nic.in/human_ethics.htm</a></td>
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<td>1. Compensation and Reporting of SAE timelines GSR 889 (E) 2014 (scroll down to see English version):</td>
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<td>2. Compensation in Case of Injury or Death During Clinical Trial, Schedule Y, Appendix XII (2013) (Scroll down to see English version):</td>
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<td>3. Compensation Formula for Clinical Trial Injury Other than Death (2014):</td>
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<td><a href="http://www.cdsco.nic.in/writereaddata/ORDER%20and%20Formula%20to%20Determine%20the%20quantum%20of%20Compensation%20in%20cases%20of%20Clinical%20Trials%20related%20to%20serious%20Adverse%20Events(SAEs)%20other%20than%20Death.pdf">http://www.cdsco.nic.in/writereaddata/ORDER%20and%20Formula%20to%20Determine%20the%20quantum%20of%20Compensation%20in%20cases%20of%20Clinical%20Trials%20related%20to%20serious%20Adverse%20Events(SAEs)%20other%20than%20Death.pdf</a></td>
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<td><strong>Social-Behavioral</strong></td>
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<td>National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 2.6 (2017):</td>
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| **Genetic Research**         | 1. Department of Biotechnology (DBT): [http://dbtindia.nic.in/](http://dbtindia.nic.in/)  
2. Indian Council of Medical Research (ICMR): [http://www.icmr.nic.in/human_ethics.htm](http://www.icmr.nic.in/human_ethics.htm) | Environmental Protection Act (1986) | DBT:  
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<td><a href="http://law.e-gov.go.jp/htmldata/H17/H17F1900100036.html">http://law.e-gov.go.jp/htmldata/H17/H17F1900100036.html</a></td>
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<td>4. Ministry of Economy, Trade, and Industry (METI):</td>
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2. Order of the MHSD of the RK dated 19.11.2009 No. 744 on the Approval of Regulations on the Conduct of Clinical Trials and/or Trials on Pharmaceutical and Drug Products, Medical Devices, and Medical Equipment  
3. Order of the MHSD Dated 20.05.2014 No.272 on the Approval of Regulations on the Implementation of the New Methods of Diagnostic, Treatment, and Rehabilitation |                                                                                   |
<p>| Korea        | Note: All documents are in Korean.                                                 |                                                                             |                                                                                                                                                                                                             |                                                                                               |</p>
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http://www.mois.go.kr/eng/  
http://www.mohw.go.kr/eng/  
MOIS:  
Personal Information Protection Act No. 14839 (2017):  
http://www.law.go.kr/법령/개인정보보호법  
MOHW:  
Bioethics and Safety Act No. 14839 (2017):  
http://www.law.go.kr/법령/생명윤리및안전에관한법률 | MOIS:  
1. Enforcement Rules to Personal Information Protection Act No. 28211 (2017):  
http://www.law.go.kr/법령/개인정보보호법시행령  
2. Enforcement Decrees to Personal Information Protection Act No. 26140 (2017):  
http://www.law.go.kr/법령/개인정보보호법시행규칙  
MOHW:  
Enforcement Rule of Bioethics and Safety Act No. 419 (2016):  
http://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙 | MOIS:  
http://www.law.go.kr/행정규칙/표준개인정보보호지침 |
http://www.mohw.go.kr/eng/  
2. Ministry of Food and Drug Safety (MFDS):  
http://www.mfds.go.kr/eng  
MOHW:  
Bioethics and Safety Act No. 14839 (2017):  
http://www.law.go.kr/법령/생명윤리및안전에관한법률시행령  
2. Enforcement Rule of Bioethics and Safety Act No. 419 (2016):  
http://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙 | MFDS:  
http://www.mfds.go.kr/index.do?searchkey=contents&searchClass=&searchSubDivision=&searchDivision=&y=0&searchword=유전자재생제품연구용새약제정가요한법률시행규칙 |
http://english.mw.go.kr/  
2. Ministry of Food and Drug Safety (MFDS):  
http://www.mfds.go.kr/eng  
MOHW:  
Bioethics and Safety Act No. 14839 (2017):  
http://www.law.go.kr/법령/생명윤리및안전에관한법률 | MOHW:  
1. Enforcement Decree of Bioethics and Safety Act No. 28211 (2017):  
http://www.law.go.kr/법령/생명윤리및안전에관한법률시행령  
2. Enforcement Rule of Bioethics and Safety Act No. 419 (2016):  
http://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙 | MFDS:  
http://www.mfds.go.kr/index.do?searchkey=contents&searchClass=&searchSubDivision=&searchDivision=&y=0&searchword=유전자재생제품연구용새약제정가요한법률시행규칙 |
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| Note: All websites and documents are in Russian. | 1. Government of the Kyrgyz Republic: [http://www.gov.kg](http://www.gov.kg)  
2. Ministry of Health: [http://www.med.kg](http://www.med.kg)  
2. Ministry of Health, National Bioethics Committee  
2. Technical Regulations on the Safety of Medical Products for Medical Application, Approved by the Governmental Order # 74 from February 1, 2012: |
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<td>2. Ministry of Health, National Bioethics Committee</td>
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<td>Human Biological Materials</td>
<td>1. Ministry of Health, Department of Drug and Medical Devices Provision: <a href="http://www.pharm.kg">http://www.pharm.kg</a></td>
<td>Law on Health Protection of the Kyrgyz Republic (09.01.2005 No. 6): Article 39:</td>
<td>Technical Regulations on the Safety of Medical Products for Medical Application, Approved by the Governmental Order #74 from February 1, 2012:</td>
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**Devices**

| New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz |                                                                             |                                                                            |                                                                            |

**Clinical Trials Registry**

| Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/ |                                                                             |                                                                            |                                                                            |

**Privacy/Data Protection**

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<td>2. Human Tissue Act 2008</td>
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<td>5. Guidelines on Extending the Storage Period of Gametes and Embryos (2012)</td>
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<td>8. Guidelines on Preimplantation Genetic</td>
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**Diagnosis with Human Leucocyte Antigen Tissue Typing (2014)**

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<td>3. PCHRD Special Order No. 146 Series of 2013: Reactivation and Amendment of Functions of the National Ethics Committee</td>
<td><a href="http://nec.pchrd.dost.gov.ph/components/com_ethics/pdf_files/nec_so.pdf">http://nec.pchrd.dost.gov.ph/components/com_ethics/pdf_files/nec_so.pdf</a></td>
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| Singapore                   | 1. Ministry of Health (MOH): [website]  
2. Ministry of Health, National Medical Ethics Committee (NMEC)  
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<td><a href="http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev,loadTime;page=0;query=Id%3A7e3c748b-8089-4699-a4b2-9f66af6f7820;rec=0">http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev,loadTime;page=0;query=Id%3A7e3c748b-8089-4699-a4b2-9f66af6f7820;rec=0</a></td>
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<td>2. Ministry of Health, National Medical Ethics Committee (NMEC):</td>
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<td><a href="https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines.html">https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines.html</a></td>
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<td>2. Ethics Guidelines for Human Biomedical Research (2015):</td>
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Sri Lanka

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<td>Thailand</td>
<td>For an overview of the clinical research regulations in Thailand, see: <a href="https://clinregs.niaid.nih.gov/single_country.php?c_id=213">https://clinregs.niaid.nih.gov/single_country.php?c_id=213</a></td>
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<td>Food and Drug Administration, Medical Device Control Division: <a href="http://www.fda.moph.go.th/eng/medical/pre.htm">http://www.fda.moph.go.th/eng/medical/pre.htm</a></td>
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<td>FAQs: <a href="http://www.clinicaltrials.in.th/index.php?meun=home&amp;smeun=4&amp;task=home&amp;task1=openpage&amp;task2=view&amp;topid=4">http://www.clinicaltrials.in.th/index.php?meun=home&amp;smeun=4&amp;task=home&amp;task1=openpage&amp;task2=view&amp;topid=4</a></td>
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<td>1. Guidelines on Conducting</td>
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<td>Medical Professionals Union</td>
<td>Constitution of the Arab Republic of Egypt, Article 43:</td>
<td>Professional Ethics Regulations:</td>
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<td><a href="http://www.sis.gov.eg/Newvr/Dustor-en001.pdf">http://www.sis.gov.eg/Newvr/Dustor-en001.pdf</a></td>
<td>Conducting Medical Research on Human Beings, Articles 52-61</td>
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<td>(2003)</td>
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<td>Egyptian Drug Authority:</td>
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<td>Ministry of Health and Medical Education, Office for the Study of Humanistic and Islamic Science in Medicine and Medical Ethics:</td>
<td>Protection Code for Human Subjects in Medical Research (1999)</td>
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<td><a href="http://www.irct.ir/">http://www.irct.ir/</a></td>
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<td>Public Health Regulations (Medical Experiments Involving Human Subjects) (1999) (Hebrew)</td>
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<td><a href="http://www.health.gov.il/english/">http://www.health.gov.il/english/</a></td>
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<td>2. 1990 Amendment</td>
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<td><a href="http://www.justice.gov.il/MOJEng/ILITA/">http://www.justice.gov.il/MOJEng/ILITA/</a></td>
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<td>2. Protection of Privacy Law No. 5741, as Amended by Law No. 5745 (1985)</td>
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<td>1. The Instruction of the Supreme Committee for Clinical Studies on Humans Regarding Establishment and Usage of Genetic Samples Reservoir</td>
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2. Drug and Pharmacy Law No. 12 (2013)  
[http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/DrugDirectorate/%D9%82%D8%A7%D9%86%D9%88%D9%86%20%D8%A7%D9%84%D8%AF%D9%88%D8%A7%D9%84%D8%A9.pdf](http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/DrugDirectorate/%D9%82%D8%A7%D9%86%D9%88%D9%86%20%D8%A7%D9%84%D8%AF%D9%88%D8%A7%D9%84%D8%A9.pdf)  
3. Narcotic and Psychotropic Law No. 23 (2016)  
[http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/DrugsAndPsychotropicSubstances/%D9%82%D8%A7%D9%86%D9%88%D9%86%20%D8%A7%D9%84%D8%AF%D9%88%D8%A7%D9%84%D8%A9.pdf](http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/DrugsAndPsychotropicSubstances/%D9%82%D8%A7%D9%86%D9%88%D9%86%20%D8%A7%D9%84%D8%AF%D9%88%D8%A7%D9%84%D8%A9.pdf) | | |
| **Research Injury** | | | | Regulations for Insurance on Research-Related Injury (2013): |

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<td>Ethical Guidelines for Biomedical Research:</td>
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<td>Qatar</td>
<td><strong>General</strong> Supreme Council of Health:</td>
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<td>Various: <a href="https://www.sch.gov.qa/about-sch/departments/research">https://www.sch.gov.qa/about-sch/departments/research</a></td>
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<td><strong>Tunisia</strong></td>
<td>Ministry of Public Health, Institut Pasteur: <a href="http://www.pasteur.tn">http://www.pasteur.tn</a></td>
<td>Conditions of Contract and Specifications Related to Medical or Scientific Experimentation of Medicines Intended for Humans</td>
<td>Disposals and Director’s Principles Related to Good Practices in Clinical Trials</td>
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<td>FAQs: <a href="http://www.tzctr.or.tz/faq.php">http://www.tzctr.or.tz/faq.php</a></td>
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| **Turkey** | **General**  
1. Turkish Constitution, Article 17  
2. Health Services Basic Law No. 3359 (1987)  
1. Regulation on Medical Deontology, Article 11 (1960)  
| **Drugs, Biologics, and Devices** | 1. Turkey Pharmaceuticals and Medical Devices Agency (Turkish) (TITCK): [http://www.titck.gov.tr](http://www.titck.gov.tr)  
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<td>United Arab Emirates</td>
<td>General</td>
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<td>Standard Operating Procedures for Research Ethics Committees (2012): <a href="http://www.haad.ae/HAAD/LinkClick.aspx?fileticket=UL7o8f5mukc%3D&amp;tabid=820">link</a></td>
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<td>Caribbean Public Health Agency: <a href="http://carPHA.org/What-We-Do/Research-Training-and-Policy-Development">http://carPHA.org/What-We-Do/Research-Training-and-Policy-Development</a></td>
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<td><strong>Argentina</strong></td>
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<td><strong>Notes:</strong> Several provinces have their own regulations pertaining to human subjects research. All websites and documents are in Spanish.</td>
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<td>University of the West Indies – Cave Hill / Ministry of Health: <a href="http://www.cavehill.uwi.edu/researchethics/home.aspx">http://www.cavehill.uwi.edu/researchethics/home.aspx</a></td>
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NBC: 1. Requirements for the Evaluation of Research Projects  
2. Code of Ethics and Medical Deontology |
| | | | 1. Regulations on Public Health Research, Chapter V (1978) 2. Rules and Regulations of the National Bioethics Committee | | |
NBC: Projects that Involve Drugs or Therapeutic Products |
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<td>Resolution ANVISA 10/15 - Regulations for Clinical Trials with Medical Devices (Portuguese): <a href="http://pesquisa.in.gov.br/impressa/jsp/visualizar/index.jsp?data=03/03/2015&amp;jornal=1&amp;pagina=73&amp;totalArquivos=140">http://pesquisa.in.gov.br/impressa/jsp/visualizar/index.jsp?data=03/03/2015&amp;jornal=1&amp;pagina=73&amp;totalArquivos=140</a></td>
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**Guinea**


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<td>3. College of Medicine Research and Ethics Committee (COMREC):</td>
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<td>2. Application Form: <a href="https://www.healthresearchweb.org/?action=download&amp;file=SierraLeoneEthicsandScientificReviewCommittee.docx">https://www.healthresearchweb.org/?action=download&amp;file=SierraLeoneEthicsandScientificReviewCommittee.docx</a></td>
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**General**

3. Medical Research Council of South Africa (MRC): [http://www.mrc.ac.za](http://www.mrc.ac.za)


**Drugs, Biologics, and Devices**


Medicines and Related Substances Control Act, 101 of 1965


**Clinical Trials Registry**


**Social-Behavioral Research**

Department of Health


**Human Biological Materials**


National Health Act No. 61, Chapter 8, Sections 53-68 (2003):

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
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<td>Embryos, Stem Cells, and Cloning</td>
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<td>Tanzania</td>
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**General**

1. Ministry of Health (MOH)
2. National Institute for Medical Research (NIMR), National Health Research Ethics Committee (NHREC): [http://www.nimr.or.tz/](http://www.nimr.or.tz/)
3. Tanzania Commission for Science and Technology (COSTECH): [www.costech.or.tz](http://www.costech.or.tz)

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:

COSTECH:

**Drugs, Biologics, and Devices**

**Drugs**

Tanzania Food and Drugs Authority: [http://www.tfda.or.tz/](http://www.tfda.or.tz/)


**Devices**

Tanzania Food and Drugs Authority: [http://www.tfda.or.tz/](http://www.tfda.or.tz/)

Medical Device Act (1988)
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<td>Medicines and Allied Substances Act, Part VI: Regulation of Clinical Trials, 2013:</td>
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<td><strong>Human Biological Materials</strong></td>
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International:
CIOMS: Sue le Roux

North America:
Canada: Hanan Abdel-Akher
United States:
- Consumer Product and Safety Commission: Alice Thaler
- Department of Agriculture: David Klurfeld
- DHHS Agency for Healthcare Quality and Research: Hope Hongzhu He
- DHHS Food and Drug Administration: Carolyn Hommel
- DHHS National Institutes of Health: Pamela Wernett and Jon Kagan
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- Department of Veterans Affairs: Kristina Borror
- Environmental Protection Agency: Daniel Nelson
- National Institute of Standards and Technology: Anne Andrews
- Social Security Administration: Leola Brooks
- United States Department of Agriculture: David Klurfeld

Europe:
Council of Europe: Ramon Prieto Suarez
European Medicines Agency: Calogero Cannavó
Bosnia: Dragana Zaharieva
Bulgaria: Dragana Zaharieva
Croatia: Dragana Zaharieva
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Slovenia: Dragana Zaharieva
Sweden: Stefan Eriksson
Switzerland: Brigitte Meier
Spain: Iñigo de Miguel Beriain
United Kingdom: Clive Collett and Fiona Law

Asia/Pacific:
Australia: Jeremy Kenner
China, People’s Republic of: Yali Cong and Haihong Zhang
India: Nandini Kumar
Japan: Takashi Tsuchiya and Shimon Tashiro
Korea: B.I. Choe, Yuri Hwang, and Seil Jang
Kyrgyzstan: Tamara Kudaibergenova
New Zealand: Lana Lon, Jamie Harknett
Pakistan: Aamir Jafarey
Taiwan: Benjamin Kuo

Middle East/North Africa:
Egypt: Henry Silverman
Jordan: Amal Al Omari
Sudan: Faiza osman
Latin America and the Caribbean:
Caribbean Public Health Agency: Derrick Aarons
Pan American Health Organization: Carla Saenz
Argentina: María del Carmen Díaz
Brazil: Jennifer Braathen Salgueiro, Sergio Rego, and Alessandro Ferreira do Nascimento
Colombia: Elena Rey Lozano, María Consuelo Miranda, and Claudia Ayala Leal
Costa Rica: Yohana Díaz de Valle
Dominican Republic: David Hernandez Martich
Ecuador: Karina Castro
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México: Men C Ma. de los Dolores Delgado Ochoa
Panama: Claude Vergès
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Africa:
Madagascar: Stuart Rennie
Malawi: Khama Kmita
South Africa: Douglas Wassenaar
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Zambia: Maureen Mupeta Kombe
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