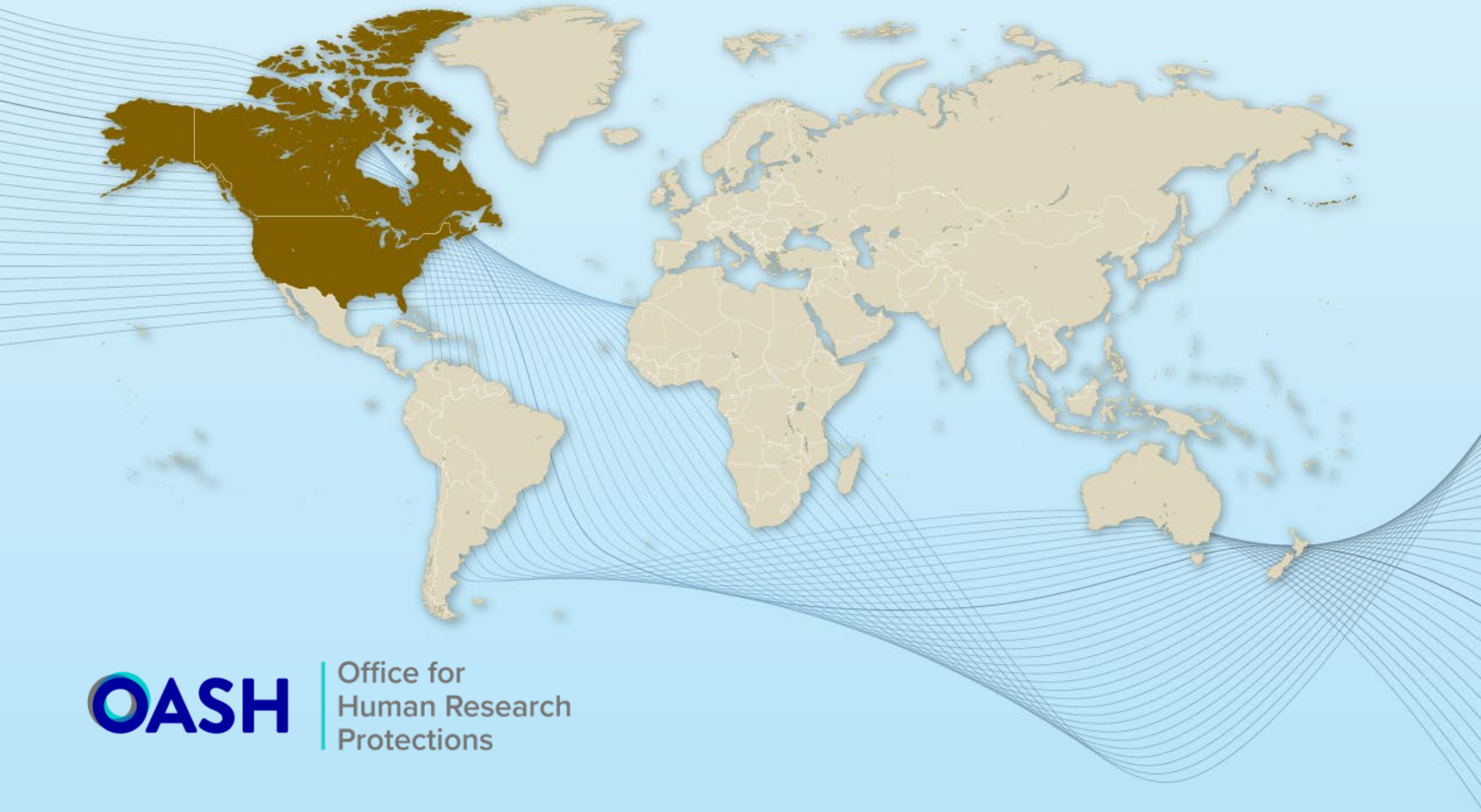
International Compilation of Human Research Standards
2024 Edition

Compiled By:
Office for Human Resource Protections (OHRP)
Office of the Assistant Secretary for Health (OASH)
U.S. Department of Health and Human Services (HHS)

North America



OASH | Office for Human Research Protections

NORTH AMERICA

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PURPOSE

The International Compilation of Human Research Standards enumerates over 1,000 laws, regulations, and guidelines (collectively referred to as "standards") that govern the protection of research participants in more than 130 countries, as well as standards from various international and regional organizations. First published in 2005, the Compilation is intended for use by researchers, IRBs/Research Ethics Committees, sponsors, and others who are involved in the conduct or oversight of research involving human participants around the world.

ORGANIZATION

You may jump to a specific country by clicking its name in the Table of Contents.

This document is organized by country in alphabetical order. Before the world regions, there is a section for standards provided by several international organizations. Under each section, you will find the countries or international organizations organized also in alphabetical order. For each country or international organization, the information is then categorized as it relates to:

1. General (i.e., applicable to most or all types of human subjects research)
2. Drugs, Biologics, and Devices
3. Clinical Trial Registries
4. Research Injury
5. Social-Behavioral Research
6. Privacy/Data Protection
7. Human Biological Materials
8. Genetic
9. Embryos, Stem Cells, and Cloning

These nine categories often overlap, so it may be necessary to review other categories for a more complete understanding of a country's standards. The information under these nine categories is divided into Key Organizations and Relevant Standards. Key Organizations may include governmental and non-governmental organizations. Relevant Standards may include laws, legislations, regulations, guidance, official opinions or positions, etc. Since the meaning of these terms often vary significantly by county, they all have been grouped together under Relevant Standards, regardless as to whether they include mandatory requirements or voluntary guidelines.

Where possible, a link has been provided to specific key organizations and relevant standards. In many cases, the documents and webpages are available in English. When the URL links to a non-English website or document, an online language translator usually can render an English version. Many operating systems may also be able to translate a document or webpage. For example, in Chrome, you may be able to right click a document or page and select "translate to [your native language]."

TOPICS NOT COVERED

In order to focus its scope to human research protections, the International Compilation of Human Research Standards attempts to not include:

1. Standards from the state, provincial, or local levels
2. Enabling legislation, i.e., laws that only authorize an agency to promulgate standards, but that they themselves do not include substantive standards
3. Laws, regulations, or guidelines that are disease-specific or focus on research integrity, clinical ethics, products liability, clinical trial inspection procedures, intellectual property, good manufacturing practice, bioequivalence testing, informed consent in clinical practice, radiation, or environmental safety, etc.
4. Ethics codes of academic, medical, or other professional organizations
5. Working papers, drafts, commentaries, or discussion papers

GENERAL REQUEST FOR PUBLIC INPUT AND COMMENTS

To request that we include a new standard or a new country in the International Compilation, or to let us know of changes to these standards or broken links, please email us at:
OHRP-Edu@hhs.gov.

DISCLAIMER

Although this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or opinion. In addition, because the standards contained in this Compilation may be created, changed, or revoked on a continuing basis, this Compilation is not an exhaustive source of all current standards, and the information provided may be incomplete or outdated. Users of this compilation must not rely only on the information it provides but should also check with local authorities, legal counsel, and/or research ethics committees before commencing research activities.

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NORTH AMERICA – Canada

NOTE: Several Canadian provinces and territories also have human subject research standards. For an overview of clinical research regulations in Canada, see the ClinRegs report:
https://clinregs.niaid.nih.gov/country/canada

General

Key Organizations

- Interagency Advisory Panel on Research Ethics (PRE): https://ethics.gc.ca/eng/home.html
- National Defence and the Canadian Armed Forces: https://www.canada.ca/en/department-national-defence.html
- Correctional Service of Canada: http://www.csc-scc.gc.ca/index-eng.shtml
- Health Canada: https://www.canada.ca/en/health-canada.html

Relevant Standards

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition (2018): http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf
- Defence Administrative Orders and Directives (DAOD) 5061-0, Research Involving Human Subjects (1998): DAOD 5061-0
- Correctional Service of Canada: Commissioner's Directive - Research: DCOO9 (2017): https://www.canada.ca/en/correctional-service/corporate/acts-regulations-policy/commissioners-directives/009.html

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Health Canada, Pharmaceutical Drugs Directorate: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php
- Interagency Advisory Panel on Research Ethics (PRE): https://ethics.gc.ca/eng/home.html

Relevant Standards

- Regulations Amending the Food and Drug Regulations (1024 - Clinical Trials) (2001): http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/1024-eng.pdf
- Health Canada, Good Clinical Practices, various: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices.html
- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 11: Clinical Trials (2018): http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf

Devices

Key Organizations

- Health Canada, Medical Devices: http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php

Relevant Standards

- Medical Devices Regulations (SOR/98-282) (1998): http://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/FullText.html

Clinical Trial Registries

Key Organizations

- Health Canada Clinical Trial Database: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdonclin/index-eng.php
- Interagency Advisory Panel on Research Ethics (PRE): https://ethics.gc.ca/eng/home.html

Relevant Standards

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 11.D. (2018): http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf

Research Injury

Key Organizations

- Interagency Advisory Panel on Research Ethics (PRE): https://ethics.gc.ca/eng/home.html

Relevant Standards

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 3, Article 3.2. (2018): http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf

Social-Behavioral Research

Key Organizations

- Interagency Advisory Panel on Research Ethics (PRE): https://ethics.gc.ca/eng/home.html

Relevant Standards

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 10. (2018): http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf

Privacy/Data Protection

NOTE: Each of the Canadian provinces and territories also has enacted privacy legislation.

Key Organizations

- Office of the Privacy Commissioner of Canada (OPC): https://www.priv.gc.ca/en
- Interagency Advisory Panel on Research Ethics (PRE): https://ethics.gc.ca/eng/home.html
- Canadian Institutes of Health Research (CIHR): http://www.cihr-irsc.gc.ca/e/193.html

Relevant Standards

- Privacy Act, Sections 7-8 (1983): http://laws-lois.justice.gc.ca/PDF/P-21.pdf
- Personal Information Protection and Electronic Documents Act, Articles 5 and 7 (2001): http://laws-lois.justice.gc.ca/PDF/P-8.6.pdf
- OPC: SOR/2001-6, SOR/2001-7, and SOR/2001-8 (September 29, 2014): https://www.canlii.org/en/ca/laws/regu/sor-2001-6/latest/sor-2001-6.html

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 5: Privacy and Confidentiality (2018): http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf
- CIHR Best Practices for Protecting Privacy in Health Research (2005): http://www.cihr-irsc.gc.ca/e/documents/et_pbp_nov05_sept2005_e.pdf

Human Biological Materials

Key Organizations

- Interagency Advisory Panel on Research Ethics (PRE): https://ethics.gc.ca/eng/home.html

Relevant Standards

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 12: Human Biological Materials Including Materials Related to Human Reproduction (2018): http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf

Genetic Research

Key Organizations

- Interagency Advisory Panel on Research Ethics (PRE): https://ethics.gc.ca/eng/home.html
- Canadian Biotechnology Strategy (CBS): http://www.hc-sc.gc.ca/sr-sr/biotech/role/strateg-eng.php
- Health Canada, Biologic and Radiopharmaceutical Drugs Directorate (BRDD): http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/bgtd-dpbtg/index-eng.php

Relevant Standards

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 13: Human Genetic Research (2018): http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf

Embryos, Stem Cells, and Cloning

Key Organizations

- Interagency Advisory Panel on Research Ethics (PRE): https://ethics.gc.ca/eng/home.html

Relevant Standards

- Assisted Human Reproduction Act (2004):
  https://laws-lois.justice.gc.ca/eng/acts/A-13.4/page-1.html
  http://laws-lois.justice.gc.ca/eng/regulations/SOR-2007-137/index.html
- PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 12, Sections E and F (2018): http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf

NORTH AMERICA – United States

For an overview of clinical research regulations in the United States, see the ClinRegs report:
https://clinregs.niaid.nih.gov/country/united-states

General

Key Organizations and Relevant Standards

- Public Health Service Act:
  https://www.govinfo.gov/content/pkg/COMPS-8773/pdf/COMPS-8773.pdf
- HHS, Food and Drug Administration (FDA): https://www.fda.gov/
- Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP): www.hhs.gov/ohrp/
  a. 45 CFR 46, Subparts A (the Common Rule), B, C, D, and E (2018): https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
  b. OHRP, Human Research Protections Guidance, various: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html
- Subpart A of the HHS regulations for the protection of research participants at 45 CFR 46 is often referred to as the Common Rule because various Federal departments and agencies have adopted the same regulations. For a list of U.S. Federal departments and agencies that have adopted the Common Rule and citations to their relevant regulations see: https://www.hhs.gov/ohrp/compliance-and-reporting/common-rule-agencies-contacts/index.html
- Each Common Rule Federal department or agency has jurisdiction over the non-exempt, human subjects research that they support or conduct (FDA is *not* a Common Rule agency). Some of the relevant standards by Common Rules departments and agencies other than HHS include:
  1. Agency for International Development: https://www.usaid.gov/
     a. Protection of Human Subjects in Research Supported by USAID: A Mandatory Reference for ADS Chapter 200 (2015): https://www.usaid.gov/sites/default/files/2022-12/200mbe.pdf
     b. CFR Citation: 22 CFR Part 225
  2. Department of Agriculture: https://www.usda.gov/
     a. Office of the Chief Scientist (OCS), Research, Education and Economics Action Plan (2012): https://www.usda.gov/sites/default/files/documents/usda-ree-science-action-plan.pdf
     b. CFR Citation: 7 CFR Part 1c: https://www.ecfr.gov/current/title-7/subtitle-A/part-1c
  3. Bureau of Prisons, US Department of Justice: https://www.bop.gov
     a. 28 CFR 22 Privacy Regulation (1976): http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr22_main_02.tpl
     b. 42 U.S.C. §3789g Confidentiality of Information (1984): http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap46-subchapVIII-sec3789g.htm
     c. 28 CFR 46 (1991), Subpart A: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr46_main_02.tpl
  4. Central Intelligence Agency: https://www.cia.gov/index.html

a. Executive Order 12333, adopting 45 CFR 46 Subparts A, B, C, and D: https://www.archives.gov/federal-register/codification/executive-order/12333.html

5. Department of Defense, Directorate of Human Research Protections (DOHRP): https://rt.cto.mil/ddre-rt/dd-rtl/hsd/hrp/
   a. United States Code Title 10, Section 980: Limitation on Use of Humans as Experimental Subjects: DOD Title 10, Section 980
   b. DoDI 3216.02: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research (2011): https://rcb.tamu.edu/humans/resources/DOD%20Directive%20321602p.pdf
6. Department of Education: https://www.ed.gov/
   a. Protection of Pupil Rights Amendment (PPRA) (1974): https://studentprivacy.ed.gov/faq/what-protection-pupil-rights-amendment-ppra
   b. Family Educational Rights and Privacy Act (FERPA) (1974): https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html
   c. 34 CFR 98: https://www.ecfr.gov/current/title-34/subtitle-A/part-98
   d. 34 CFR 99: https://www.ecfr.gov/current/title-34/subtitle-A/part-99?toc=1
7. Department of Energy: http://science.energy.gov/ber/human-subjects/
   a. DOE Order 443.1B: https://www.directives.doe.gov/directives-documents/400-series/0443.1-BOrder-b
   b. DOE Order 481.1D: https://www.directives.doe.gov/directives-documents/400-series/0481.1-BOrder-d
   c. CFR Citation: 10 CFR Part 745
8. Environmental Protection Agency: https://www.epa.gov/
   a. EPA, Program in Human Research Ethics: https://www.epa.gov/osa/basic-information-about-human-subjects-research-0
   b. EPA, 40 CFR 26, Human Subjects Research, Various Subparts: EPA, 40 CFR 26
   c. Scientific and Ethical Approaches for Observational Exposure Studies (2008): https://nepis.epa.gov/Exe/ZyPDF.cgi/P10012LY.PDF?Dockey=P10012LY.PDF
   d. EPA Order 1000.17A: Policy and Procedures on Protection of Human Subjects in EPA Conducted or Supported Research (2016): https://www.epa.gov/osa/epa-order-100017-policy-and-procedures-protection-human-research-subjects-epa-conducted-or
9. Federal Bureau of Investigation, Department of Justice:
   https://www.justice.gov/doj/federal-bureau-investigation
   a. Human Subjects Protection: https://nij.ojp.gov/funding/human-subjects-protection
   b. CFR Citation: 28 CFR Part 46; CPD 0737D
10. Department of Homeland Security: https://www.dhs.gov/
    a. Public Law 108-458, Section 8306
    b. DHS Directive 026-04, Human Subjects Research (2018): DHS Directive 026-04
    c. CFR Citation: 6 CFR Part 46
11. Department of Housing and Urban Development: https://www.hud.gov/

a. CFR Citation: 24 CFR Part 60

12. Office of Justice Programs, Department of Justice: https://www.ojp.gov/
    a. CFR Citation: 28 CFR Part 46
13. Department of Labor: https://www.dol.gov/
    a. CFR Citation: 29 CFR Part 21
14. National Aeronautics and Space Administration: https://www.nasa.gov/
    a. Human Research Program (HRP): https://www.nasa.gov/hrp/
    b. CFR Citation: 29 CFR Part 21
15. National Science Foundation: https://www.nsf.gov/
    a. Research Involving Human Subjects: https://new.nsf.gov/funding/research-involving-human-subjects
    b. CFR Citation: 45 CFR Part 690
16. Office of the Director of National Intelligence: https://www.dni.gov/
    a. Executive Order 12333 (2008)
17. Social Security Administration: https://www.ssa.gov/
    a. CFR Citation: 20 CFR Part 431
18. Department of Transportation: https://www.transportation.gov/
    a. CFR Citation: 49 CCFR Part 11
19. Department of Veterans Affairs (VA)
    a. Office of Research Oversight (ORO): http://www.va.gov/oro/
    b. Office of Research and Development: http://www.research.va.gov
    c. CFR Citation: 38 CFR 17.85 (1998)
    d. VA, Policies, Human Research, various: https://www.research.va.gov/resources/policies/human_research.cfm
    e. CFR Citation: 38 CFR Part 16

Drugs, Biologics, and Devices

The Office for Human Research Protections (OHRP) may share jurisdiction with FDA over non-exempt, human subjects research on an FDA regulated product if the research is also supported or conducted by HHS. See, USA-General, supra.

Key Organizations

- Food and Drug Administration (FDA): https://www.fda.gov/drugs
- Food and Drug Administration (FDA), Vaccines, Blood & Biologics: https://www.fda.gov/vaccines-blood-biologics
- Food and Drug Administration (FDA), Center for Devices and Radiological Health: https://www.fda.gov/Medical-Devices

Relevant Standards

- For a search engine of all FDA guidance documents, see: https://www.fda.gov/regulatory-information/search-fda-guidance-documents
- Food, Drug, and Cosmetic Act, 21 USC Sections 355 and 371 (2012): https://uscode.house.gov/browse/prelim@title21&edition=prelim
- Public Health Service Act, 42 USC Section 262 (1998): https://uscode.house.gov/browse/prelim@title42&edition=prelim
- 21st Century Cures Act, Section 3024 (2016): https://www.govinfo.gov/content/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf
- FDA, Regulations, Good Clinical Practice and Clinical Trials, various: regulations-good-clinical-practice-and-clinical-trials
- FDA, Clinical Trials and Human Subject Protection: https://www.fda.gov/science-research/science-and-research-special-topics/clinical-trials-and-human-subject-protection
- FDA, Drugs, Guidance, various: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs
- FDA, Biologics, Guidance, various: https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics
- FDA, Medical Devices and Radiation-Emitting Products, Guidance, various: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products

Clinical Trial Registries

Key Organizations

- Food and Drug Administration (FDA) ClinicalTrials.gov Information: https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fdas-role-clinicaltrialsgov-information
- National Institutes of Health (NIH) ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/home
- Office of Research Oversight (ORO): https://www.va.gov/oro/

Relevant Standards

- FDA Modernization Act, Section 113 (1997): https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-modernization-act-fdama-1997
- FDA Amendments Act, Section 801 (2007): https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-amendments-act-fdaaa-2007
- Clinical Trials Regulation and Results Information Submission, 42 CFR 11 (2016): https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission
- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (2016): https://www.federalregister.gov/documents/2016/09/21/2016-22379/dissemination-of-nih-funded-clinical-trial-information
- FAQs on ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/manage-recs/faq
- Department of Veterans Affairs, FAQs (2015): http://www.research.va.gov/resources/ORD_Admin/clinical_trials/registration-faq.pdf

- OHRP, Clinical Trial Informed Consent Form Posting (45 CFR 46.116(h)): https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html

Research Injury

Relevant Standards

- Department of Health and Human Services (HHS), Sections 116(a)(6) and (7) of the Common Rule: https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf
- Department of Veterans Affairs, 38 CFR 17.85: Treatment of Research-Related Injuries to Human Subjects: https://www.gpo.gov/fdsys/pkg/CFR-2013-title38-vol1/pdf/CFR-2013-title38-vol1-sec17-85.pdf
- Department of Veterans Affairs, Directive 1200.05, Appendix F, Paragraph 2a(11)

Social-Behavioral Research

Relevant Standards

- Department of Health and Human Services (HHS), 45 CFR 46 and applicable subparts: https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf
- All other Common Rule departments and agencies per their adoption of the Common Rule: *See*, USA-General, *supra*
- National Science Foundation, FAQs and Vignettes: https://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp

Privacy/Data Protection

Key Organizations

- Various

Relevant Standards

- All Common Rule agencies, Common Rule at 45 CFR 46.111(a)(7) (2018): https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf
- Department of Justice, Privacy Act, 5 U.S.C. § 552a (1974): http://www.justice.gov/opcl/privacyact1974.htm
- Office for Civil Rights (OCR), Health Insurance Portability and Accountability Act (HIPAA) (1996): https://www.gpo.gov/fdsys/pkg/PLAW-104publ191/content-detail.html
- HIPAA Privacy Rule, 45 CFR parts 160 and 164, Subparts A and C (2002): https://www.hhs.gov/hipaa/for-professionals/privacy/index.html
- HIPAA Security Rule, 45 CFR parts 160, 162, and 164 (2009): https://www.hhs.gov/hipaa/for-professionals/security/index.html
- HIPAA Breach Notification Rule, 45 CFR §164.400-414: https://www.hhs.gov/hipaa/for-professionals/breach-notification/index.html
- OCR, 21st Century Cures Act Research Guidance on Activities Preparatory to Research (2017): https://www.hhs.gov/sites/default/files/remote-access-research-12-15-17.pdf

- OCR, various: https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html and https://www.hhs.gov/hipaa/for-professionals/faq/research-uses-and-disclosures
- Confidential Information Protection and Statistical Efficiency Act (CIPSEA) (2002): http://www.eia.gov/cipsea/cipsea.pdf
- Health Information Technology for Economic and Clinical Health (HITECH) Act (2009): https://www.gpo.gov/fdsys/pkg/PLAW-111publ5/pdf/PLAW-111publ5.pdf
- NIH Policy on Certificates of Confidentiality (2017): https://grants.nih.gov/policy/humansubjects/coc.htm
- NIH, HIPAA Resources, various: http://privacyruleandresearch.nih.gov/
- Agency for Healthcare Research and Quality (AHRQ), Confidentiality in AHRQ-Supported Research (2018): https://grants.nih.gov/grants/guide/notice-files/NOT-HS-18-012.html
- E-Government Act of 2002, Public Law 107-347: https://www.gpo.gov/fdsys/pkg/PLAW-107publ347/pdf/PLAW-107publ347.pdf

Human Biological Materials

Key Organizations

- Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/

Relevant Standards

- Guidance, various: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/biological-materials-and-data/index.html

Genetic Research

Key Organizations

- FDA, Office of In Vitro Diagnostic Device Evaluation and Safety: https://www.fda.gov/medical-devices/products-and-medical-procedures/vitro-diagnostics
- FDA, Center for Biologics Research and Evaluation (CBER): https://www.fda.gov/about-fda/fda-organization/center-biologics-evaluation-and-research-cber
- HHS, Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/
- HHS, National Institutes of Health (NIH), Office of Science Policy: https://osp.od.nih.gov/
- HHS, Office for Civil Rights (OCR): https://www.hhs.gov/hipaa/for-professionals/special-topics/genetic-information/index.html

Relevant Standards

- Genetic Information Nondiscrimination Act (GINA) (2008): https://www.gpo.gov/fdsys/pkg/PLAW-110publ233/content-detail.html
- All Common Rule agencies: Common Rule at 45 CFR 46: https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf
- FDA, Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable (2006): guidance-informed-consent-vitro-diagnostic-device-using-leftover-human-specimens

- FDA, In Vitro Diagnostic (IVD) Device Studies, FAQs (2010): vitro-diagnostic-ivd-device-studies-faqs
- FDA, Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products. October 14, 1993. 58 FR 53248: https://www.fda.gov/media/76647/download
- FDA, CBER-Specific, various: other-recommendations-biologics
- OHRP, Research on Transplantation of Fetal Tissue, Public Law 103-43 (1993): http://www.hhs.gov/ohrp/regulations-and-policy/guidance/public-law-103-43/index.html
- OHRP, Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards (2009): http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2019): https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf
- OCR, HIPAA Privacy Rule Provisions Implementing GINA Requirements at 45 CFR 160.103; 45 CFR 164.502(a)(5)(i); 45 CFR 164.514(g); and 45 CFR 164.520(b)(1)(iii)(C)

Embryos, Stem Cells, and Cloning

Key Organizations

- National Academy of Sciences (NAS): http://www.nasonline.org/
- National Institutes of Health (NIH) Stem Cell Information: http://stemcells.nih.gov/

Relevant Standards

- Executive Order 13505, Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Executive Order 13505 (2009): https://www.gpo.gov/fdsys/pkg/DCPD-200900136/pdf/DCPD-200900136.pdf
- Research on Transplantation of Fetal Tissue. Public Law 103-43 (1993): https://www.hhs.gov/ohrp/regulations-and-policy/guidance/public-law-103-43/index.html
- NAS 2010 Final Report of the National Academies Human Embryonic Stem Cell Research Advisory Committee and 2010 Amendments to the National Academies Guidelines for Human Embryonic Stem Cell Research: http://www.nap.edu/catalog.php?record_id=12923
- NIH, Guidelines on Human Stem Cell Research (2009): https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research
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