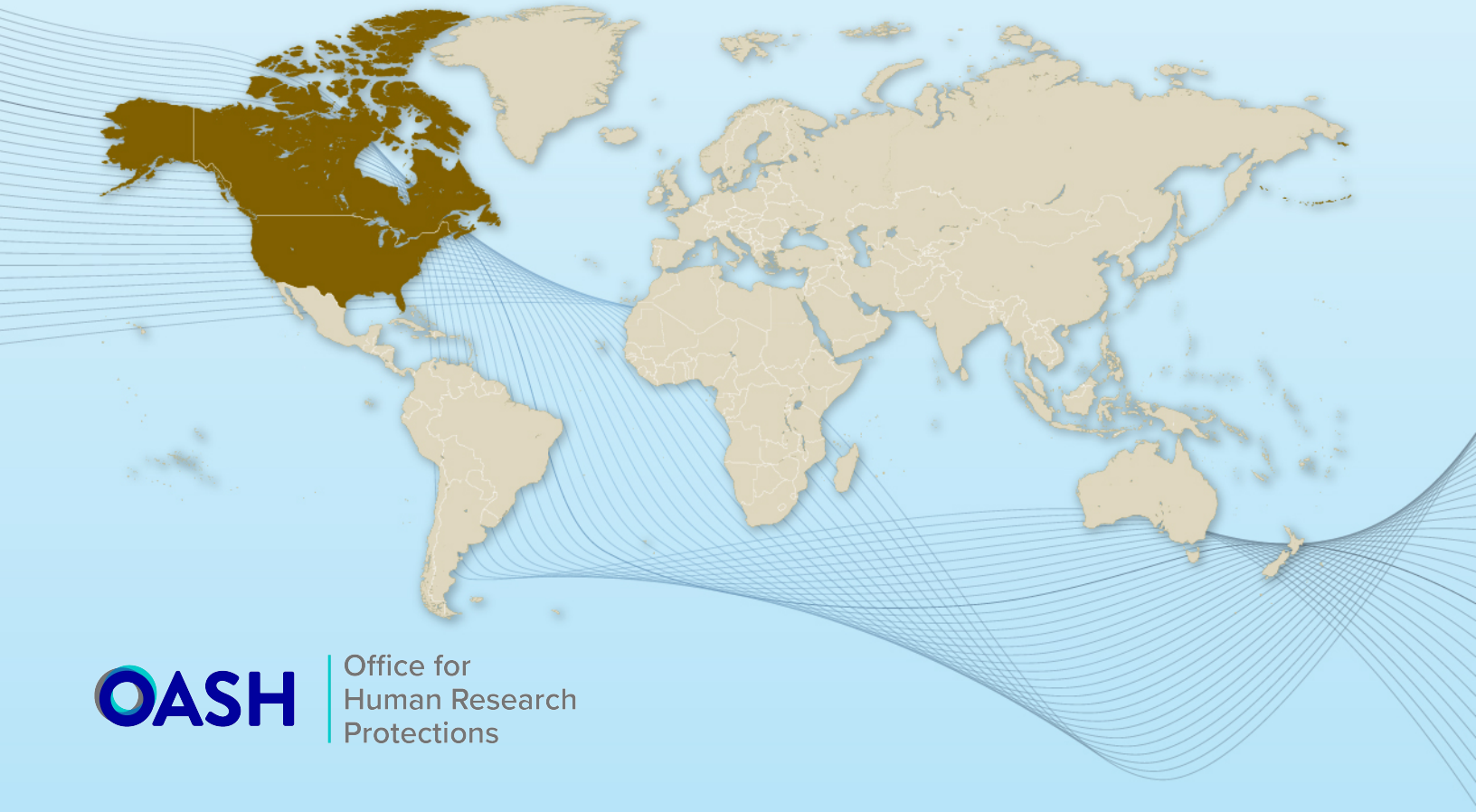
International Compilation of Human Research Standards
2021 Edition

Compiled By:
Office for Human Research 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 human subject protections in 131 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 human subjects research protections around the world.

Collaborators from around the world, some who are acknowledged at the end of the Compilation, provided updates (or confirmations of prior listings), which are reflected in the hundreds of changes entered into this Edition. However, not all countries provided corroboration, so some of the information contain in this document may be outdated or incomplete (please see disclaimer below).

ORGANIZATION

This document only includes North America. To access the complete International Compilation, please visit: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html. You may jump to a specific country by clicking its name in the Table of Contents.

This document is organized by world region in alphabetical order: Africa, Asia/Pacific, Europe, Latin America and the Caribbean, Middle East/North Africa, and North America. Under each region, you will find the countries organized also in alphabetical order. For each country, 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 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 authorize an agency to promulgate human subjects standards, but do not direct the content of those regulations
3. Laws, regulations, or guidelines that are disease-specific or focus on research integrity, clinical bioethics, product liability, clinical trial inspection procedures, intellectual property, good manufacturing practice, bioequivalence testing, or informed consent in clinical practice
4. Ethics codes of academic, medical, or other professional organizations – see the Ethics Codes Collection: http://ethics.iit.edu/ecodes/about
5. 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 provide updated information or report broken links, please contact OHRP-Edu@hhs.gov.

If you would like to provide information for a country not currently included in the Compilation, we would love to hear from you. Please contact 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 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. The information contain in this Compilation may incomplete or outdated. 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.

TABLE OF CONTENTS

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

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
- National Defence and the Canadian Armed Forces, Research Involving Human Subjects (1998): http://www.forces.gc.ca/en/about-policies-standards-defence-admin-orders-directives-5000/5061-0.page
- Correctional Service of Canada: Commissioner's Directive - Research: DCOO9 (2017): http://www.csc-scc.gc.ca/acts-and-regulations/009-cd-en.shtml

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Health Canada, Therapeutic Products 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 Practice, 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)
- 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 Advisory Committee (CBAC): http://www.hc-sc.gc.ca/sr-sr/biotech/role/strateg-eng.php
- Health Canada, Biologics and Genetic Therapies Directorate: 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): http://laws-lois.justice.gc.ca/eng/acts/A-13.4/
- Assisted Human Reproduction (Section 8 Consent) Regulations (2007): 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 Organization and Relevant Standards

- Public Health Service Act (1993): http://history.nih.gov/research/downloads/PL103-43.pdf
- HHS, Food and Drug Administration (FDA) (FDA is not a Common Rule agency): 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
- Other relevant standards by U.S. Federal departments and agencies 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/documents/1864/200mbe.pdf
    2. Central Intelligence Agency: https://www.cia.gov/index.html:
        a. Executive Order 12333, adopting 45 CFR 46 Subparts A, B, C, and D
    3. 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
        b. DoDI 3216.02 (2011): https://rcb.tamu.edu/humans/resources/DOD%20Directive%20321602p.pdf
    4. Department of Education: https://www.ed.gov/
        a. Protection of Pupil Rights Amendment (1974)
        b. Family Educational Rights and Privacy Act (1974)
        c. 34 CFR 98 (1984)
        d. 34 CFR 99 (2000)
        e. 34 CFR 350.4(c) (1991)
        f. 34 CFR 356.3(c) (1991)
    5. Department of Energy: http://science.energy.gov/ber/human-subjects/
        a. DOE Order 443.1B
        b. DOE Order 481.1
    6. Department of Homeland Security: https://www.dhs.gov/
        a. Public Law 108-458, Section 8306
        b. DHS Directive 026-04, Human Subjects Research (2007): https://www.dhs.gov/xlibrary/assets/foia/mgmt-directive-026-04-protection-of-human-subjects.pdf

7. Bureau of Prisons: 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
8. Department of Veterans Affairs:
   a. Office of Research Oversight (ORO): http://www.va.gov/oro/
   b. Office of Research and Development: http://www.research.va.gov
   c. 38 CFR 17.85 (1998)
   d. VA, Policies, Human Research, various: https://www.research.va.gov/resources/policies/human_research.cfm
9. Environmental Protection Agency, Program in Human Research Ethics: https://www.epa.gov/osa/basic-information-about-human-subjects-research-0
   a. Subpart A: Basic EPA Policy for Protection of Subjects in Human Research Conducted or Supported by EPA (Common Rule)
   b. Subpart B: Prohibition of Research Conducted or Supported by EPA Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women (2006)
   c. Subpart C: Observational Research: Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA (2006)
   d. Subpart D: Observational Research: Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA (2006)
   e. Subpart K: Basic Ethical Requirements for Third-Party Human Research for Pesticides Involving Intentional Exposure of Non-pregnant, Non-nursing Adults (2013)
   f. Subpart L: Prohibition of Third-Party Research Involving Intentional Exposure to a Pesticide of Human Subjects who are Children or Pregnant or Nursing Women (2013)
   g. Subpart M: Requirements for Submission of Information on the Ethical Conduct of Completed Human Research (2013)
   h. Subpart O: Administrative Actions for Noncompliance (2013)
   i. Subpart P: Review of Proposed and Completed Human Research (2013)
   j. Subpart Q: Standards for Assessing Whether to Rely on the Results of Human Research in EPA Actions (2013)
   k. Scientific and Ethical Approaches for Observational Exposure Studies (2008): https://nepis.epa.gov/Exe/ZyPDF.cgi/P10012LY.PDF?Dockey=P10012LY.PDF
   l. 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

Drugs, Biologics, and Devices

Drugs and Biologics

Key Organizations

- Food and Drug Administration: https://www.fda.gov/Drugs and https://www.fda.gov/vaccines-blood-biologics

Relevant Standards

- 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: https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials
- FDA, Good Clinical Practice and Human Subject Protection in FDA-Regulated Clinical Trials: 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

Devices

Key Organizations

- Food and Drug Administration, Center for Devices and Radiological Health: https://www.fda.gov/Medical-Devices

Relevant Standards

- Food, Drug, and Cosmetic Act, 21 USC Sections 355 and 371 (2012): https://uscode.house.gov/browse/prelim@title21&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: https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials
- FDA, Good Clinical Practice and Human Subject Protection in FDA-Regulated Clinical Trials: https://www.fda.gov/science-research/science-and-research-special-topics/clinical-trials-and-human-subject-protection
- FDA, Devices, 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: https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fdas-role-clinicaltrialsgov-information
- National Institutes of Health ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/home
- Office of Research Oversight (ORO): http://www1.va.gov/oro/

Relevant Standards

- Food and Drug Administration Modernization Act, Section 113 (1997): https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-modernization-act-fdama-1997
- Food and Drug Administration 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, FAQ: 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

Key Organizations

- Various

Relevant Standards

- Department of Health and Human Services, 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, Handbook 1200.5, Appendix F, Paragraph 2a(11)

Social-Behavioral Research

Key Organizations

- Various

- All Common Rule agencies, 45 CFR 46 and applicable subparts: https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf
- 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
- Department of Health and Human Services (HHS), 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): http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html
- HIPAA Security Rule, 45 CFR parts 160, 162, and 164 (2009): http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/index.html
- HIPAA Breach Notification Rule, 45 CFR §164.400-414: http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/index.html
- HHS, 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
- HHS, OCR, 21st Century Cures Act Research Guidance on Streamlining Authorization (2018): https://www.hhs.gov/sites/default/files/hipaa-future-research-authorization-guidance-06122018%20v2.pdf
- HHS, 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://humansubjects.nih.gov/coc/index
- 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, 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, NIH, Office of Science Policy, Biosafety, Biosecurity, and Emerging Biotechnology Policy Division: https://osp.od.nih.gov/biosafety-biosecurity-and-emerging-biotechnology/
- 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): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-informed-consent-vitro-diagnostic-device-studies-using-leftover-human-specimens-are-not
- FDA, In Vitro Diagnostic (IVD) Device Studies, FAQs (2010): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/vitro-diagnostic-ivd-device-studies-frequently-asked-questions
- 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: https://www.fda.gov/vaccines-blood-biologics/other-recommendations-biologics-manufacturers/references-regulatory-process-office-tissues-and-advanced-therapies
- 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: 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
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ACKNOWLEDGEMENTS

The HHS Office for Human Research Protections thanks the following individuals for providing updates or confirmations of accuracy for the 2021 edition of the International Compilation of Human Research Standards. We are particularly grateful for the assistance provided by **Dr. Carla Saenz** of the Pan American Health Organization, **Dr. Barbara Sina** of the Fogarty Division of International Training and Research, and **Dr. Jonathan Kagan** of the U.S. National Institute of Allergies and Infectious Diseases.

Multinational Organizations:
Comac Medical Ltd.
Pan American Health Organization
The European Council

Africa:
South Africa: Prof. Douglas R Wassenaar
Zambia: Maureen Mupeta Kombe

Asia/Pacific:
Australia: Jeremy Kenner
India: Dr. Nandini K. Kumar
Japan: Dr. Shimon Tashiro, Takashi Tsuchiya
Malaysia: Dr. Nishakanthi Gopalan, Kuenyei Chin
South Korea: Byung-in (B.I.) Choe, Kyoungtae Park,Yoon-Joung Chang, Sang-Min Park, Jinyoung Jeong, Seoyun Hong

Europe:
Global Regulatory Affairs team at Comac Medical Ltd.
Finland: Marko Ahteensuu
Germany: Claudia Leuker
Macedonia: Marija Todorovska
Serbia: Slobodan Zabunovic
Switzerland: The International Society for Biological and Environmental Repositories (ISBER), Daniel Simeon-Dubach, Celeste Sandoval

Latin America and the Caribbean:
Brazil: Pan American Health Organization (PAHO) - Brazil
Chile: Dr. Juan Pablo Beca
Grenada: Cheryl Cox Macpherson
Mexico: M en C Ma. de los Dolores Delgado Ochoa
Panama: Dr. Claude Vergès
Peru: Dr. Carlos Zamudio Fuertes

Middle East/North Africa:
Jordan: Dr. Amal Al Omari and the King Hussein Cancer Center, Amman
Turkey: Dr. Hamdi Akan

OHRP would also like to thank other anonymous colleagues around the world for their invaluable contribution.