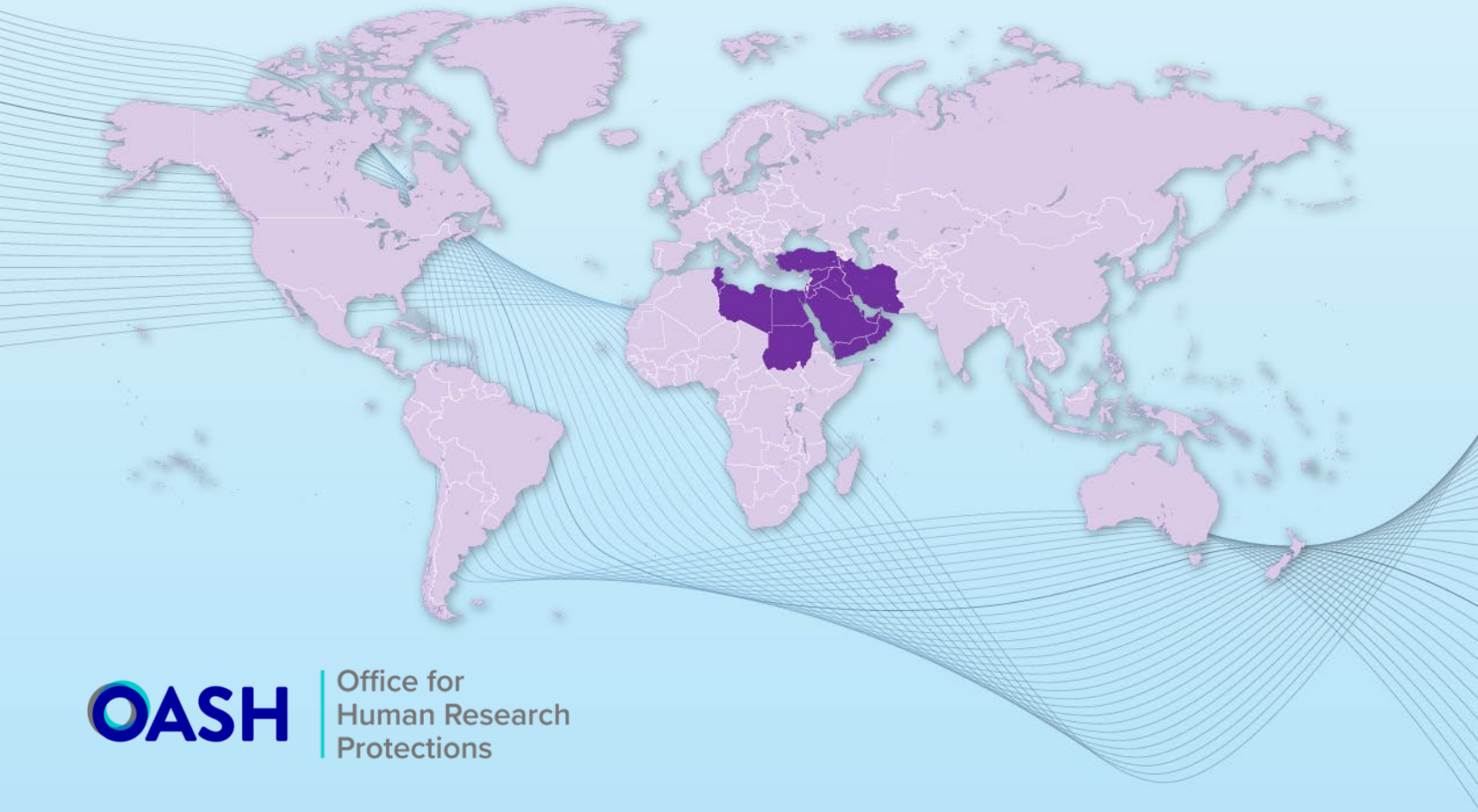
International Compilation of Human Research Standards
2024 Edition

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)

Middle East/North Africa



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MIDDLE EAST/NORTH AFRICA

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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.

TABLE OF CONTENTS

MIDDLE EAST/NORTH AFRICA – Egypt

General

Key Organizations

- Medical Professionals Union
- Supreme Standing Committee for Human Rights (SSCHR): https://sschr.gov.eg/en

Relevant Standards

- SSCHR, Constitution of the Arab Republic of Egypt, Articles 18 and 23: https://sschr.gov.eg/en/the-egyptian-constitution/
- Professional Ethics Regulations, Conducting Medical Research on Human Beings, Articles 52-61 (2003)

Drugs, Biologics, and Devices

Key Organizations

- Egyptian Drug Authority: https://gs1eg.org/eda-egyptian-drug-authority/

Relevant Standards

- Law No. 214 of 2020, Regulating Clinical Research: https://www.edaegypt.gov.eg/media/cyyn0r4r/2020-214.pdf
- Ministerial Resolution No. 436 of 2006, Concerning the Egyptian Code for Evaluating Clinical Trials of Biological Preparations, Serums and Vaccines: https://www.edaegypt.gov.eg/media/wjcjhndl/436-2006.pdf
- Ministerial Resolutions, various: Ministerial Resolutions

MIDDLE EAST/NORTH AFRICA – Iran

General

Key Organizations

- Ministry of Health and Medical Education: https://behdasht.gov.ir/

Relevant Standards

- Protection Code for Human Subjects in Medical Research (1999)

Clinical Trial Registries

Key Organizations

- Iranian Registry of Clinical Trials: http://www.irct.ir/

MIDDLE EAST/NORTH AFRICA – Israel

General

Key Organizations

- Ministry of Health: http://www.health.gov.il/english/
- The Israel Academy of Sciences and Humanities: https://www.academy.ac.il/?nodeId=808

Relevant Standards

- Public Health Regulations (Medical Experiments Involving Human Subjects) (1999)

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health, Pharmaceutical Administration: http://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/Drugs/Pages/default.aspx

Relevant Standards

- Public Health Order (1940)
- Public Health Regulations (Clinical Studies in Human Subjects) (1980) (as subsequently amended)
- Guidelines for Clinical Trials in Human Subjects (2006): https://rnd.sheba.co.il/62382.pdf
- Various procedures: https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/ClinicalTrials/Pages/CTH.aspx
- The Israel Academy of Sciences and Humanities, Committees to Approve Clinical Trials in Humans: https://www.academy.ac.il/RichText/GeneralPage.aspx?nodeId=1417

Privacy/Data Protection

Key Organizations

- The Privacy Protection Authority: https://www.gov.il/en/departments/the_privacy_protection_authority/govil-landing-page

Relevant Standards

- Legislations, various: https://www.gov.il/en/Departments/legalInfo/legislation
- Guidelines, various: https://www.gov.il/en/Departments/General/guidelines_ppa
- The Israel Academy of Sciences and Humanities, Big Data: https://www.academy.ac.il/RichText/GeneralPage.aspx?nodeId=1419

Genetic Research

Relevant Standards

- Genetic Information Law (2000): https://www.jewishvirtuallibrary.org/jsource/Health/GeneticInformationLaw.pdf

- Instruction of the Supreme Committee for Clinical Studies on Humans Regarding Establishment and Usage of Genetic Samples Reservoir (2005)
- Amendment (2007)

Embryos, Stem Cells, and Cloning

Relevant Standards

- Genetic Intervention Prohibition Law (Human Cloning and Genetic Changes in Reproduction Cells) (1999)
- The Israel Academy of Sciences and Humanities, Embryo Research: https://www.academy.ac.il/RichText/GeneralPage.aspx?nodeId=1418

MIDDLE EAST/NORTH AFRICA – Jordan

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health: http://www.moh.gov.jo/en/Pages/default.aspx
- Jordan Food and Drug Administration: http://www.jfda.jo/Default.aspx

Relevant Standards

- Law of Clinical Studies, Law No. 2 (2011): Law No. 2
- Drug and Pharmacy Law No. 12 (2013): Law No. 12
- Narcotic and Psychotropic Law No. 23 (2016): Law No. 23

Research Injury

Relevant Standards

- Regulations for Insurance on Research-Related Injury (2013): http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/PharmaceuticalStudies/22_252.pdf

Embryos, Stem Cells, and Cloning

Relevant Standards

- Stem Cell By-law No. 10 (2014)

MIDDLE EAST/NORTH AFRICA – Kuwait

General

Key Organizations

- Ministry of Health: https://www.moh.gov.kw/en/
- Ministry of Health, Food and Drug Development: https://www.moh.gov.kw/en/Pages/DRUGCA.aspx

Relevant Standards

- Ethical Guidelines for Biomedical Research

MIDDLE EAST/NORTH AFRICA – Qatar

General

Key Organizations

- Ministry of Public Health, Health Research Governance Department: https://research.moph.gov.qa/en/Pages/ResearchHome.aspx

Relevant Standards

- Human Research Policies & Regulations, various: https://research.moph.gov.qa/en/Pages/HumanResearch.aspx?csrt=16566705229134832818
- IRB Registration and Assurance: https://research.moph.gov.qa/en/Pages/IRB.aspx?csrt=16566705229134832818
- Guidelines on Reviewing and Reporting Adverse Events: Guidelines on Reviewing and Reporting Unanticipated Problems Involving Risks to Subject or Others and Adverse Events
- Clinical trials, various: https://research.moph.gov.qa/en/Pages/ClinicalTrials.aspx?csrt=16566705229134832818

Human Biological Materials

Key Organizations

- Ministry of Public Health, Health Research Governance Department: https://www.moph.gov.qa/english/derpartments/policyaffairs/healthresearchgovernance/Pages/default.aspx

Relevant Standards

- Guidance for the Use of Stored Data and Biological Specimens in Human Research: Guidance for the Use of Stored Data and Biological Specimens
- Human Research Policies & Regulations, various: https://research.moph.gov.qa/en/Pages/HumanResearch.aspx?csrt=16566705229134832818

Genetic Research

Key Organizations

- Ministry of Public Health, Health Research Governance Department: https://www.moph.gov.qa/english/derpartments/policyaffairs/healthresearchgovernance/Pages/default.aspx

Relevant Standards

- Guidance for the Design, Ethical Review, and Conduct of Genomic Research in Qatar: Guidance for Genomic Research
- Guidelines for Gene Transfer Research in Humans: Guidelines for Gene Transfer Research

- Human Research Policies & Regulations, various: https://research.moph.gov.qa/en/Pages/HumanResearch.aspx?csrt=16566705229134832818

MIDDLE EAST/NORTH AFRICA – Saudi Arabia

General

Key Organizations

- National Committee of BioEthics: https://ncbe.kacst.edu.sa/en/

Relevant Standards

- Law of Ethics of Research on Living Creatures (2016)
- Implementing Regulations of the Law of Ethics of Research on Living Creatures, Version 3 (2022): Implementing Regulations
- Rules and Regulations, Various: Rules and Regulations

MIDDLE EAST/NORTH AFRICA – Sudan

General

Key Organizations

- Federal Ministry of Health: http://www.fmoh.gov.sd/

Relevant Standards

- National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008)
- Accreditation Guidelines for Research Ethics Committees in Sudan (2017)
- Operation Guidelines, Functions, and Procedures (2016)
- Federal Ministry of Health, Sudan National Health Policy (2017-2030): https://extranet.who.int/countryplanningcycles/sites/default/files/public_file_rep/SDN_Sudan_National-Health%20Policy_2017-2030.pdf

Drugs, Biologics, and Devices

Key Organizations

- National Medicines and Poisons Board: http://www.nmpb.gov.sd/en/

Relevant Standards

- Act on Pharmaceuticals and Poisons (2009) (Arabic): http://www.nmpb.gov.sd/index.php/2015-08-05-11-05-04/regulations/113-laws2009

Human Biological Materials

Key Organizations

- National Council on Biosafety

Relevant Standards

- Human Organs and Tissues Transplant Legislation, Chapter 2, Articles 3 and 4 (1978)

- Act on Biosafety (2010)

Genetic Research

Key Organizations

- University of Khartoum, Institute of Endemic Diseases

Relevant Standards

- Guidelines for Genetics Research on Sudanese Subjects (2005)

MIDDLE EAST/NORTH AFRICA – Tunisia

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Public Health, Institut Pasteur: http://www.pasteur.tn

Relevant Standards

- Conditions of Contract and Specifications Related to Medical or Scientific Experimentation of Medicines Intended for Humans
- Disposals and Director's Principles Related to Good Practices in Clinical Trials

MIDDLE EAST/NORTH AFRICA – Turkey

General

Key Organizations

- Ministry of Health (Turkish): http://www.saglik.gov.tr/

Relevant Standards

- Turkish Constitution, Article 172. Health Services Basic Law No. 3359 (1987)
- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- Update on the Law of the Support of Research and Development Activities (2021): http://www.resmigazete.gov.tr/eskiler/2016/02/2016022-1.pdf
- Regulation on Medical Deontology, Article 11 (1960)
- Bylaw on Patient Rights No. 23420 (1998)
- Guideline on novel Clinical Trials with COVID-19 vaccine Candidates: https://www.titck.gov.tr/duyuru/covid-19-asi-gelistirme-calismasi-yuruten-arastirma-gruplarinin-dikkatine-16032021142718

Drugs, Biologics, and Devices

Key Organizations

- Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr
- Clinical Research Association (CRA): http://www.klinikarastirmalar.org
- Ministry of Health (MoH): http://www.saglik.gov.tr/

Relevant Standards

- Turkish Penal Law, Article 90 (2005)
- Fundamental Law #3359 on Health Services, Supplemental Article 10 (2011)
- Various TITCK legislation: https://www.titck.gov.tr/mevzuat
- Regulation on Clinical Trials with Drugs and Biological Products (2015): An Update of 2014 Clinical Trials Regulation
- Regulation on Efficacy, Safety, and Clinical Trials of Cosmetic Products (2015)
- Update on the Regulation of the Management and Inspection of the Support of Research and Development Activities (2016)
- Draft Regulation on Clinical Research of Traditional and Complementary Medicine Practices (2020): https://shgmgetatdb.saglik.gov.tr/EN-68837/clinical-research-regulation-general-preamble-and-justification-of-articles.html
- Guideline on Phase 1 Clinical Research Centers (2019): https://titck.gov.tr/storage/Archive/2019/legislation/ad316d19-8b9e-420c-86db-3946c56add1d.pdf
- GCP Guideline (2015)
- Guidelines on Application for Good Clinical Practice Inspections (2021): Guidelines on GCP Inspection Application
- Guideline on Risk-Based Good Clinical Practice Inspections (2022): https://titck.gov.tr/storage/Archive/2022/contentFile/Guideline%20On%20Risk-Based%20Good%20Clinical%20Practice%20Inspections_3dbaf7d9-c321-4e85-958b-9b6c63c1bfb1.pdf
- Guideline on the Audit of Pharmacovigilance: https://titck.gov.tr/storage/Archive/2019/legislation/05ef1188-6756-4165-b0d5-bb0a28bbebb3.pdf
- Bylaw on Medical Devices aimed for Invitro Diagnostics
- Regulation on Research on Medical Devices (2014): https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=20028&MevzuatTur=7&MevzuatTertip=5
- New Medical Device Regulations: https://titck.gov.tr/storage/Archive/2021/contentFile/Ek-2.1%20Duyuru%20metni-eng_2e87c6cd-5d45-43d9-9a35-0a94ffee8547.pdf

Research Injury

Key Organizations

- Turkish Medicines and Medical Devices Agency (TMMDA): https://www.titck.gov.tr/mevzuat

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Guidance on Insuring Volunteers in a Clinical Trial (2011): https://titck.gov.tr/storage/Archive/2019/legislation/972bae83-9d23-45ae-b3a3-85b53bd853e1.pdf
- Various other guidance: https://www.titck.gov.tr/mevzuat/liste/k%C4%B1lavuz?page=6

Social-Behavioral Research

Key Organizations

- Yıldırım Beyazıt University Psychiatry and Behavioral Neuroscience Application and Research Center: https://aybu.edu.tr/pdnam
- Istanbul University Consumer Behavior and Behavioral Economics Application and Research Center: https://www.istanbul.edu.tr/tr/_

Relevant Standards

- Istanbul University Consumer Behavior and Behavioral Economics Application and Research Center Regulations: https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=18305&MevzuatTur=8&MevzuatTertip=5

Privacy/Data Protection

Key Organizations

- Personal Data Protection Authority: https://www.kvkk.gov.tr/

Relevant Standards

- Personal Data Protection Law: https://www.kvkk.gov.tr/Icerik/6649/Personal-Data-Protection-Law

Human Biological Materials

Key Organizations

- Ministry of Health (Turkish): http://www.saglik.gov.tr/

Relevant Standards

- Law on Procurement, Preservation, Grafting, and Transplantation of Organs and Tissues, No. 2238 (1979)
- Law on Blood and Blood Products, No. 2857 (1983)
- Regulation on Blood and Blood Products, No. 7314 (1983)
- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98

- Good Clinical Practice Guidelines for Advanced Therapy Medicinal Products (2011)
- Regulation on the Registration of Medicinal Products for Human Use: https://titck.gov.tr/storage/legislation/QEv7VEBH.pdf
- Law on Removal, Storage and Transplantation of Organs and Tissues: Storage and Transplantation of Organs and Tissues

Genetic Research

Key Organizations

- Ministry of Health (Turkish): http://www.saglik.gov.tr/

Relevant Standards

- Regulation on Centers for Diagnosis and Genetic Diseases, No. 23368 (1998): https://www.saglik.gov.tr/TR,10433/genetik-hastaliklar-tani-merkezleri-yonetmeligi.html https://www.resmigazete.gov.tr/arsiv/23368.pdf

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Health (Turkish): http://www.saglik.gov.tr/

Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Regulation on Centers for Medically Assisted Procreation, No. 19551 (1987)
- Regulation on Cordon Blood Banks (2005)
- Circular on Research of Embryonic Stem Cells (2005)
- Guideline on Clinical Research of Non-Embryonic Stem Cells (2006)
- Regulation on Assisted Reproductive Treatment Practices and Assisted Reproductive Treatment Centers: https://www.saglik.gov.tr/TR,10515/uremeye-yardimci-tedavi-uygulamalari-ve-uremeye-yardimci-tedavi-merkezleri-hakkinda-yonetmelik.html
- Regulation on Organ and Tissue Transplantation Services
- Guidelines for Clinical Research and Clinical Trials Using Tissues and Cells: https://shgm.saglik.gov.tr/Eklenti/15612/0/kok-hucre-calismalari-genelgepdf.pdf

MIDDLE EAST/NORTH AFRICA – United Arab Emirates

General

Key Organizations

- Health Authority - Abu Dhabi: http://www.haad.ae/haad/

Relevant Standards

- Healthcare Guidelines, various: https://www.doh.gov.ae/en/resources/guidelines
- Standards, various: https://www.doh.gov.ae/en/resources/standards

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