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)

Middle East/North Africa
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 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 However, not all countries provided corroboration, so some of the information contained in this document may be outdated or incomplete (please see disclaimer below).

ORGANIZATION

This document only includes the Middle East/North Africa. 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](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.
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## MIDDLE EAST/NORTH AFRICA – Egypt

### General

**Key Organization**
- Medical Professionals Union

**Relevant Standards**
- Professional Ethics Regulations, Conducting Medical Research on Human Beings, Articles 52-61 (2003)

### Drugs, Biologics, and Devices

**Key Organization**
- Egyptian Drug Authority: [https://www.edaegypt.gov.eg/](https://www.edaegypt.gov.eg/)

**Relevant Standards**
- Law No. 214 of 2020, Regulating Clinical Research: [https://www.edaegypt.gov.eg/media/cyyn0r4r/2020-214.pdf](https://www.edaegypt.gov.eg/media/cyyn0r4r/2020-214.pdf)
- Ministerial Resolutions, various: [https://www.edaegypt.gov.eg/ar/%D8%A7%D9%84%D9%82%D9%88%D8%A7%D9%86%D9%8A%D9%86-%D9%88%D8%A7%D9%84%D9%82%D8%B1%D8%A7%D8%B1%D8%A7%D8%AA-%D9%88%D8%A7%D9%84%D9%82%D9%88%D8%A7%D8%B9%D8%AF-%D8%A7%D9%84%D9%85%D9%86%D8%B8%D9%85%D8%A9/%D8%A7%D9%84%D9%82-%D8%B1%D8%A7%D8%B1%D8%A7%D8%AA-%D8%A7%D9%84%D9%88%D8%B2%D8%A7%D8%B1%D9%8A%D8%A9/](https://www.edaegypt.gov.eg/ar/%D8%A7%D9%84%D9%82%D9%88%D8%A7%D9%86%D9%8A%D9%86-%D9%88%D8%A7%D9%84%D9%82%D8%B1%D8%A7%D8%B1%D8%A7%D8%AA-%D9%88%D8%A7%D9%84%D9%82%D9%88%D8%A7%D8%B9%D8%AF-%D8%A7%D9%84%D9%85%D9%86%D8%B8%D9%85%D8%A9/%D8%A7%D9%84%D9%82-%D8%B1%D8%A7%D8%B1%D8%A7%D8%AA-%D8%A7%D9%84%D9%88%D8%B2%D8%A7%D8%B1%D9%8A%D8%A9/)

## MIDDLE EAST/NORTH AFRICA – Iran

### General

**Key Organization**
- Ministry of Health and Medical Education: [https://behdasht.gov.ir/](https://behdasht.gov.ir/)

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

### Clinical Trial Registries

**Key Organization**
- Iranian Registry of Clinical Trials: [http://www.irect.ir/](http://www.irect.ir/)
Relevant Standards
  - Trial Registration: https://www.irct.ir/page/help

MIDDLE EAST/NORTH AFRICA – Israel

### General

**Key Organization**

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

### Drugs, Biologics, and Devices

**Key Organization**
- Ministry of Health, Pharmaceutical Administration: [http://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/Drugs/Pages/default.aspx](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)
- Various procedures, [https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/ClinicalTrials/Pages/CTH.aspx](https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/ClinicalTrials/Pages/CTH.aspx)

### Privacy/Data Protection

**Key Organizations**

**Relevant Standards**

### Genetic Research

**Key Organizations**

**Relevant Standards**
- 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)

MIDDLE EAST/NORTH AFRICA – Jordan

Drugs, Biologics, and Devices

Key Organization

Relevant Standards
- 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%D8%A1%20%D9%88%D8%A7%D9%84%D8%B5%D9%8A%D8%AF%D9%84%D8%A9.pdf
- 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%D9%85%D8%AE%D8%AF%D8%B1%D8%A7%D8%AA%20%D9%88%D8%A7%D9%84%D9%85%D8%A4%D8%AB%D8%B1%D8%A7%D8%AA%20%D8%A7%D9%84%D8%B9%D9%82%D9%84%D8%A9.pdf

Research Injury

Relevant Standards

Embryos, Stem Cells, and Cloning

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

MIDDLE EAST/NORTH AFRICA – Kuwait

General

Key Organization
- Ministry of Health, Kuwait Institute for Medical Specialization: http://www.kims.org.kw/
Relevant Standards

- Ethical Guidelines for Biomedical Research

**MIDDLE EAST/NORTH AFRICA – Qatar**

### General

**Key Organization**

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

**Relevant Standards**


### 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](https://www.moph.gov.qa/english/derpartments/policyaffairs/healthresearchgovernance/Pages/default.aspx)

**Relevant Standards**


### Genetic Research

**Key Organizations**

- Ministry of Public Health, Health Research Governance Department:
  [https://www.moph.gov.qa/english/derpartments/policyaffairs/healthresearchgovernance/Pages/default.aspx](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:
- Guidelines for Gene Transfer Research in Humans:
- Human Research Policies & Regulations, various:

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Public Health, Health Research Governance Department:

Relevant Standards

- Human Research Policies & Regulations, various:

MIDDLE EAST/NORTH AFRICA – Saudi Arabia

General

Key Organization


Relevant Standards


Social-Behavioral Research

Key Organization


Relevant Standards

- Implementing Regulations of the Law of Ethics of Research on Living Creatures, Expedited Research (Article 10.18g) and Categories of Social-Behavioral Research That do not Require Continuing Review (Article 10.32) (2016):
MIDDLE EAST/NORTH AFRICA – Sudan

General

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

Relevant Standards
- Operation Guidelines, Functions, and Procedures (2016)

Drugs, Biologics, and Devices

Key Organization

Relevant Standards

Human Biological Materials

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

Relevant Standards
- Guidelines for Genetics Research on Sudanese Subjects (2005)

MIDDLE EAST/NORTH AFRICA – Tunisia

Drugs, Biologics, and Devices

Key Organization
- Ministry of Public Health, Institut Pasteur: 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 Organization

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

Relevant Standards

- Turkish Constitution, Article 172. Health Services Basic Law No. 3359 (1987)
- Regulation on Medical Deontology, Article 11 (1960)
- Bylaw on Patient Rights No. 23420 (1998)

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Turkey Pharmaceuticals and Medical Devices Agency (Turkish) (TITCK): http://www.titck.gov.tr
- Clinical Research Association (CRA): 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 TMMDA legislation: https://www.titck.gov.tr/mevzuat
- Regulation on Efficacy, Safety, and Clinical Trials of Cosmetic Products (2015)
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- Guideline on the Audit of Pharmacovigilance: [https://titck.gov.tr/storage/Archive/2019/legislation/05ef1188-6756-4165-b0d5-bb0a28bbebb3.pdf](https://titck.gov.tr/storage/Archive/2019/legislation/05ef1188-6756-4165-b0d5-bb0a28bbebb3.pdf)
- Bylaw on Medical Devices aimed for In Vitro Diagnostics: [https://www.resmigazete.gov.tr/eskiler/2021/06/20210602M1-1.pdf](https://www.resmigazete.gov.tr/eskiler/2021/06/20210602M1-1.pdf)

**Devices**

**Key Organizations**
- Turkey Pharmaceuticals and Medical Devices Agency (TITCK): [http://www.titck.gov.tr](http://www.titck.gov.tr)

**Relevant Standards**

**Research Injury**

**Key Organizations**
- Turkish Medicines and Medical Devices Agency (TMMDA): [https://www.titck.gov.tr/mevzuat](https://www.titck.gov.tr/mevzuat)

**Relevant Standards**
- Various other guidance: [https://www.titck.gov.tr/mevzuat/liste/k%C4%B1lavuz?page=6](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](https://aybu.edu.tr/pdnam)
- Istanbul University Consumer Behavior and Behavioral Economics Application and Research Center: [https://www.istanbul.edu.tr/tr/_](https://www.istanbul.edu.tr/tr/_)

**Relevant Standards**
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)
- Good Clinical Practice Guidelines for Advanced Therapy Medicinal Products (2011)

Genetic Research

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

Relevant Standards

Embryos, Stem Cells, and Cloning

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

Relevant Standards
- Regulation on Centers for Medically Assisted Procreation, No. 19551 (1987)
- Regulation on Cordon Blood Banks (2005)
- Circular on Research of Embryonic Stem Cells (2005)
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- Guideline on Clinical Research of Non-Embryonic Stem Cells (2006)

MIDDLE EAST/NORTH AFRICA – United Arab Emirates

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

**Relevant Standards**
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