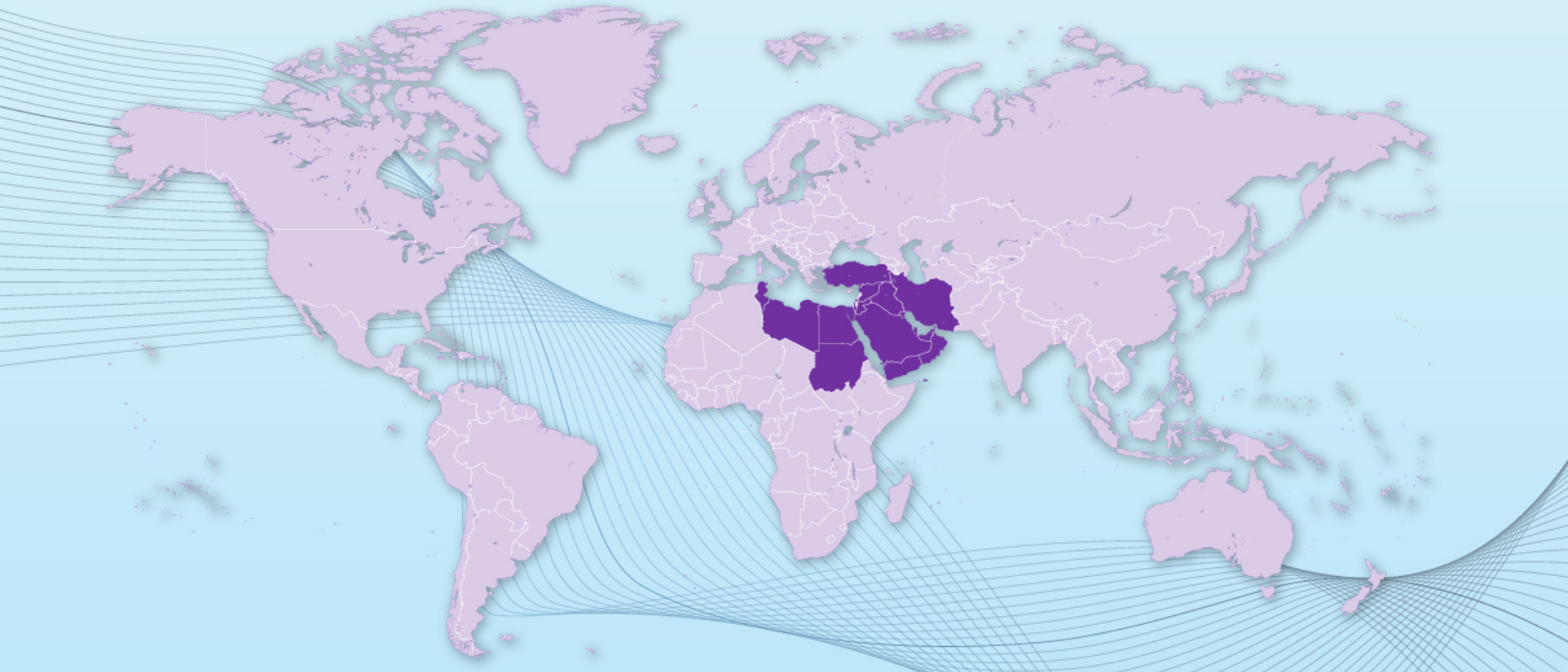
International Compilation of Human Research Standards
2021 Edition

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



OASH | Office for Human Research Protections

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 However, not all countries provided corroboration, so some of the information contain in this document may be outdated or incomplete (please see disclaimer below).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
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

MIDDLE EAST/NORTH AFRICA – Egypt

General

Key Organization

- Medical Professionals Union

Relevant Standards

- Constitution of the Arab Republic of Egypt, Article 43: http://www.sis.gov.eg/Newvr/Dustor-en001.pdf
- 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/

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: 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/

Relevant Standards

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

Clinical Trial Registries

Key Organization

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

Relevant Standards

- Trial Registration: https://www.irct.ir/page/help

MIDDLE EAST/NORTH AFRICA – Israel

General

Key Organization

- Ministry of Health: http://www.health.gov.il/english/

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

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

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

Genetic Research

Key Organizations

- Ministry of Health: http://www.health.gov.il/english/

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)

MIDDLE EAST/NORTH AFRICA – Jordan

Drugs, Biologics, and Devices

Key Organization

- 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): http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/PharmaceuticalStudies/50_211.pdf
- 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%D9%8A%D8%A9.pdf

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 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

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: https://researchportal.moph.gov.qa/_layouts/15/ResearchPortal/RDLogin.aspx?ReturnUrl=%2f_layouts%2f15%2fAuthenticate.aspx%3fSource%3d%252F&Source=%2F
- 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: https://research.moph.gov.qa//DepartmentalDocuments/Guidance%20for%20the%20Use%20of%20Stored%20Data%20and%20Biological%20Specimens%20in%20Human%20Research.pdf?csrt=16566705229134832818
- 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: https://research.moph.gov.qa//DepartmentalDocuments/Guidance%20for%20the%20Design,%20Ethical%20Review,%20and%20Conduct%20of%20Genomic%20Research%20in%20Qatar.pdf?csrt=16566705229134832818
- Guidelines for Gene Transfer Research in Humans: https://research.moph.gov.qa//DepartmentalDocuments/Guidelines%20for%20Gene%20Transfer%20Research%20in%20Humans.pdf?csrt=16566705229134832818
- Human Research Policies & Regulations, various: https://research.moph.gov.qa/en/Pages/HumanResearch.aspx?csrt=16566705229134832818

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

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

MIDDLE EAST/NORTH AFRICA – Saudi Arabia

General

Key Organization

- National Committee of BioEthics: http://bioethics.kacst.edu.sa/?lang=en-US

Relevant Standards

- Law of Ethics of Research on Living Creatures (2016)
- Implementing Regulations of the Law of Ethics of Research on Living Creatures (2016): http://prod.kau.edu.sa/Med/ali/files/Publications/Guide/National_Committe_of_BioEthics-Regulations_of_the_Law_of_Ethics_of_Research_on_Living_Creatures.pdf

Social-Behavioral Research

Key Organization

- National Committee of BioEthics: http://bioethics.kacst.edu.sa/?lang=en-US

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): http://prod.kau.edu.sa/Med/ali/files/Publications/Guide/National_Committe_of_BioEthics-Regulations_of_the_Law_of_Ethics_of_Research_on_Living_Creatures.pdf

MIDDLE EAST/NORTH AFRICA – Sudan

General

Key Organization

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

Relevant Standards

- National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008): http://sites.google.com/site/healthresearchlibrary/national-guidelines
- Accreditation Guidelines for Research Ethics Committees in Sudan (2017): http://snrec.sd/wp-content/uploads/2017/05/Accredition-guidelines.pdf
- Operation Guidelines, Functions, and Procedures (2016)
- NHREC protocol application form: http://snrec.sd/wp-content/uploads/2017/05/NHREC-PROTOCOL-APPLICATION-FORM.pdf

Drugs, Biologics, and Devices

Key Organization

- 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

- 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

- University of Khartoum, Institute of Endemic Diseases: http://iend.uofk.edu/index.php?lang=en

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)
- Oviedo Convention on Human Rights and Biomedicine (2004): https://www.coe.int/en/web/bioethics/oviedo-convention
- Update on the Law of the Support of Research and Development Activities (2016): 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

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 Clinical Trials with Drugs and Biological Products (2015): An Update of 2014 Clinical Trials Regulation: http://www.klinikarastirmalar.org/Detail/1992/ilac-ve-biyolojik-urunlerin-klinik-arastirmalari-hakkinda-yonetmelikte-degisiklik-yapilmasina-dair-yonetmelik-2015
- 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): http://www.resmigazete.gov.tr/eskiler/2016/08/20160810-7.htm

- Bylaw on Clinical Research of Traditional and Complementary Medicine (2019): http://www.klinikarastirmalar.org/Detail/2631/geleneksel-ve-tamamlayici-tip-uygulamalarinin-klinik-arastirmalari-hakkinda-yonetmelik-2019
- 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): http://www.farmakovijilansdernegi.org/files/2015.09.13_Regulation_on_clinical_trials_of_medicinal_and_biological_products.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: 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

Relevant Standards

- Regulation on Research on Medical Devices (2014): https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=20028&MevzuatTur=7&MevzuatTertip=5

Research Injury

Key Organizations

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

Relevant Standards

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2004): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164
- 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)
- Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999): https://www.coe.int/en/web/bioethics/oviedo-convention
- Good Clinical Practice Guidelines for Advanced Therapy Medicinal Products (2011)
- Blood and Blood Products Regulation: https://www.mevzuat.gov.tr/anasayfa/MevzuatFihristDetayIframe?MevzuatTur=7&MevzuatNo=12632&MevzuatTertip=5
- Law on Removal, Storage and Transplantation of Organs and Tissues: https://www.saglik.gov.tr/TR,10372/tarihi29051979--sayisi2238--rg-tarihi03061979--rg-sayisi16655--organ-ve-doku-alinmasi-saklanmasi-ve-nakli-hakkinda-kanun.html

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

- 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: https://www.saglik.gov.tr/TR,10465/organ-ve-doku-nakli-hizmetleri-yonetmeligi.html
- 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 Organization

- 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

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.

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Comac Medical Ltd.
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Global Regulatory Affairs team at Comac Medical Ltd.
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Serbia: Slobodan Zabunovic
Switzerland: The International Society for Biological and Environmental Repositories (ISBER), Daniel Simeon-Dubach, Celeste Sandoval

Latin America and the Caribbean:
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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.