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Prawne aspekty badań naukowych z udziałem człowieka. Kontekst Zjednoczonych Emiratów Arabskich

Abstract

Legal Aspects of Human Subjects Research. A case study of the United Arab Emirates

Research involving human subjects is relatively new to the United Arab Emirates (UAE), however since 2012 there has been a sharp increase in the number of human research publications from this country, and from the GCC (Gulf Cooperation Council) region in general. The collaboration with western health care providers triggered the transformation of the research status, regulations, and ethics.

The paper aims to provide a brief review of ethical guidelines and codes regarding human subjects research in the healthcare system in the MENA region and in the UAE.

Keywords: human subjects research, United Arab Emirates, law, ethics, health care

Background

The descriptions and characteristics of human subjects research vary across the globe, however, in its broadest definition, it is a scientific investigation that involves human beings as research subjects. The nature of this investigation can be either medical (clinical) or non-medical (social science), and it involves both the collection (using interventional or observational

methodologies) and analysis of data.[1] The type of human subjects research that is especially heavily regulated is the clinical trial, which evaluates drugs, vaccines and medical devices. The research into psychology, anthropology, and other social science fields, has also become more formalized, largely due to abuses of human subjects in the past.

Ethical guidelines and national codes that regulate the use of human subjects in research are a fairly new construct not only in the Middle East, which is the focus of this paper, but worldwide.

The oldest documents dealing with the ethics of human experimentation and consumer protection laws were *the Code of William Beaumont* (issued 1833) and *Pure Food and Drug Act* (enacted in 1906) respectively.[2] Both documents stemmed from the United States. However, ethical guidelines did not truly appear until after World War II.

After World War II, twelve trials were held in the U.S. occupied zone in Nuremberg, Germany. In all of these trails German physicians were accused of conducting inhumane and unethical human experiments in Nazi concentration camps. A memorandum outlining six points for legitimate research on human subjects was submitted by the expert medical advisers for the prosecution. In the summer of 1947, the judges delivered their verdict against 23 physicians. The verdict also reiterated the six points of the memorandum and added four additional. The ten points became known as *the Nuremberg Code.*[3] This document was the actual beginning of established national ethical codes governing human subjects research. It was followed by *the Declaration of Helsinki,* established 1964 by the World Medical Association (WMA). Both documents are considered to be the most important milestones in the history of clinical research ethics and global human rights, and to date they inspired the creation of over 1,000 laws, regulations and guidelines that govern human subjects research in 130 countries. The recommended, fundamental set of rights relating to human subject protection includes: (1) voluntary, informed consent, (2) respect for persons and the right to be treated as autonomous agent, (3) the right to end participation in

1 *Activities that Require IRB Review*, https://research.uci.edu/compliance/human-research-protections/researchers/activities-irb-review.html (accessed: 15.02.2019).

2 J. Young, *Pure Food: Securing the Federal Food and Drugs Act of 1906*, Princeton, N.J: Princeton University Press, 1989, p. 98.

3 MA. Grodin, *Historical origins of the Nuremberg Code*, (in:) *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation*. Annas, GJ and Grodin, MA (eds). Oxford University Press, Oxford, 1992, p. 15.

research at any time, (4) the right to safeguard integrity, (5) benefits should outweigh cost, (6) protection from physical, mental and emotional harm, (7) access to information regarding research, (8) protection of privacy and well-being.[4] There are currently fifteen key international organizations developing global guidelines and standards related to human subjects research, these are: (1) Council for International Organizations of Medical Sciences (CIOMS), (2) World Medical Association, (3) World Health Organization, (4) United Nations Educational, Scientific and Cultural Organization (Bioethics Program), (5) UNAIDS, (6) Office of the United Nations High Commissioner for Human Rights (OHCHR), (7) International Committee of the Red Cross (ICRC), (8) International Conference on Harmonization (ICH), (9) International Medical Device Regulators Forum (IMDRF), (10) International Standards Organization, (11) International Committee of Medical Journal Editors, (12) International Air Transport Association, (13) International Society for Biological and Environmental Repositories, (14) Human Genome Organization, (15) International Society for Stem Cell Research. The question arises whether, and to what extent, such international guidelines are applicable to different regions, including the Middle East.

An Overview of Human Subjects Research Regulations in the MENA Region

The MENA (Middle East and North Africa) region includes territories stretching from Morocco to Iran. However, due to the lack of standardized definition of MENA, international organizations and academia tend to define the term differently[5]. The commonly included countries are: Algeria, Bahrain, Egypt, Iran, Irak, Israel, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, Palestine, Qatar, Saudi Arabia, Syria, Tunisia, United Arab Emirates and Yemen.

There are various factors that contribute to the attractiveness of the MENA region for clinical research projects. One of the key factors is a significant patient diversity. Other important aspects are: good medical

4 World Medical Association, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects,* JAMA 2013. No. 310 (20): 2191–2194, http://www.wma.net/en/30publications/10policies/b3/index.html (accessed: 15.02.2019).

5 The World Bank, *Middle East and North Africa*, http://www.worldbank.org/en/region/mena (accessed: 28.02.2019).

facilities and infrastructure (especially in the Gulf Cooperation Council (GCC) countries – Oman, Kingdom of Saudi Arabia, United Arab Emirates, Qatar, Kuwait and Bahrain) and significant cost advantages. Between 2006 and 2010 there was a 4% rise in the number of drug trials conducted in the Middle East, which was the largest recorded increase in any region of the world.[6] As a result of this increase, ethicists, medical practitioners and researchers are currently facing new challenges with regards to ethical issues involving the use of human subjects.

Analyzing the historical context, the first locally developed ethical guidelines started appearing almost five decades after their European counterparts. The first attempt at crafting regulations related to human subjects research came from Lebanon (1994)[7], followed by Saudi Arabia (1998)[8], and Egypt (2003)[9]. The document that can be considered as the biggest milestone in promoting the concept of legal protection of human subjects in research in the MENA region, was the Jordanian "Law of Clinical Studies" (2001). The document not only was the first national law aimed at regulating the conduct of clinical research in the Greater Middle East but also the first one in the region that directly referred to international guidelines – the Declaration of Helsinki and the International Conference of Harmonization – Guidelines for Good Clinical Practice (ICH-GCP)[10].

The table below includes all national codes, regulations or guidelines from the MENA countries available online and written in Arabic, English, French or Hebrew (in case of Israel) that address research ethics (exclusively or partially). It also shows the total number of such documents in each country.

Country	Documents	Total number
Algeria	1. Order No. 387 of 31 July 2006 Relating to Clinical Trials 2. Order No. 00200 of 25 July 2009 Amending Order No. 112 of 22 October 1995 Setting the Rules of Good Clinical Practice	2

6 Alahmad et al., *Review of national research ethics regulations and guidelines in Middle Eastern Arab Countries*. BMC Medical Ethics 2012, p. 3.

7 *Ibidem*.

8 *Ibidem*.

9 *Ibidem*.

10 *Ibidem*.

Country	Documents	Total number
Bahrain	Ethical Guidelines for Health Research (2009)	1
Egypt	1. Constitution of the Arab Republic of Egypt, Article 43 2. Professional Ethics Regulations: Conducting Medical Research on Human Beings, Articles 52–61 (2003)	2
Iran	1. Protection Code for Human Subjects in Medical Research (1999) 2. Iranian Registry of Clinical Trials (FAQs)	2
Iraq	No document	0
Israel	1. Public Health Order (1940) 2. Privacy Protection Act No. 5741 (1981) 3. Protection of Privacy Law No. 5741, as Amended by Law No. 5745 (1985) 4. Genetic Information Law (2000) (Hebrew) 5. Genetic Intervention Prohibition Law (Human Cloning and Genetic Changes in Reproduction Cells) (1999) 6. Public Health Regulations (Medical Experiments Involving Human Subjects) (1999) (Hebrew) 7. Public Health Regulations (Clinical Studies in Human Subjects) (1980) 8. Guidelines for Clinical Trials in Human Subjects (2006) 9. The Instruction of the Supreme Committee for Clinical Studies on Humans Regarding Establishment and Usage of Genetic Samples Reservoir (2005)	9
Jordan	1. Law of Clinical Studies, Law No. 2 (2011) 2. Drug and Pharmacy Law No. 12 (2013) 3. Narcotic and Psychotropic Law No. 23 (2016) 4. Stem Cell By-law No. 10 (2014) 5. Regulations for Insurance on Research-Related Injury (2013)	5
Kuwait	Ethical Guidelines for Biomedical Research (2001)	1
Lebanon	Law of Medical Ethics No. (288) for the Year 1994	1
Libya	No document	0

Country	Documents	Total number
Morocco	No document	0
Oman	No document	0
Palestine	No document	0
Qatar	Guidelines, Regulations and Policies for Research Involving Human Subjects (2009)	1
Saudi Arabia	1. I Clinical Trial Requirement Guidelines (2005–2008) 2. II Ethics of the Medical Professions (1998–2007) 3. III System of ethics of research on living subjects (2010) 4. Law of Ethics of Research on Living Creatures (Arabic) 5. Implementing Regulations of the Law of Ethics of Research on Living Creatures (2016) 6. 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)	6
Syria	No document	0
Tunisia	1. Conditions of Contract and Specifications Related to Medical or Scientific Experimentation of Medicines Intended for Humans 2. Disposals and Director's Principles Related to Good Practices in Clinical Trials	2
United Arab Emirates	1. Guidance for conducting Clinical Trials Based on Drugs/Medical Products & Good Clinical Practice (2006) 2. Standard Operating Procedures for Research Ethics Committees (2012)	2
Yemen	No document	0

There are major differences in terms of whether the MENA countries have research guidelines. The countries with the most specific national research ethics guidelines are Israel, Saudi Arabia, Qatar, Bahrain, Kuwait, the UAE and Jordan. The countries with generic documents that only

mention research ethics in some paragraphs are Egypt and Lebanon. Finally, seven out of nineteen MENA countries do not have any guidelines. These countries are: Libya, Morocco, Syria, Oman, Palestine, Iraq, Yemen.

Human Subjects Research in the United Arab Emirates

Established in 1971, the United Arab Emirates (UAE) is a federation of seven emirates (Abu Dhabi, Ajman, Dubai, Fujairah, Ras Al Khaimah, and Umm Al Quwain). The discovery of oil in the early 1960s drove significant economic growth in the country, which has impacted the demographic landscape of the nation. Population growth in the UAE is reported to be among the highest in the word, with census data recording a seven-fold increase in population between the years of 1975 and 2005[11]. The country's population is very diverse, with only 11,6% UAE nationals[12]. The remainder is made up of expatriates.

By the time the Ministry of Health (MoH) was established in 1972, the country hosted a total of seven public hospitals. Federal law gave the MoH the role of licensing all health care providers, regulating medical practices (including research on human subjects), and managing health care services[13]. In 2001, the government of Abu Dhabi established the General Authority of Health Services (GAHS) to oversee all matters related to public health institutions in the emirate. The GAHS was later restructured and divided into two entities – the Health Authority – Abu Dhabi (HAAD), responsible for regulating policy, and the Abu Dhabi Health Services Company (SEHA), created in order to manage the government-owned health care facilities[14]. During the restructuring of GAHS in the emirate of Abu Dhabi, ruler of Dubai, Sheikh Mohammed bin Rashid Al Maktoum launched the Dubai Health Authority (DHA) with the objective of improving health care infrastructure and encouraging health care investment and research in Dubai[15].

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11 Sheikh Saud bin Saqr Al Qasimi Foundation for Policy Research, *Public Health in the United Arab Emirates and Ras Al Khaimah*, Fact Sheet, 2015, p. 1.

12 CIA, *The World Factbook*, https://www.cia.gov/library/publications/the-world-factbook/geos/ae.html (accessed: 15.02.2019).

13 U.A.E. National Societies of Public Welfare. (n.d.). Federal Law No. 1 of 1971.

14 Latham & Watkins, *Healthcare regulation in the United Arab Emirates*, 2013, p. 11, https://www.lw.com/upload/pubContent/_pdf/pub3951_1.pdf (accessed: 15.02.2019).

15 Dubai Health Authority (DHA), *DHA: Our history*, https://www.dha.gov.ae/en/Aboutus/pages/history.aspx (accessed: 15.02.2019).

In addition to the government-provided DHA, the Dubai Health Care City (DHCC), a health care free zone was launched in 2002 in order to oversee the development of medical and paramedical colleges, universities, research centers, specialized health care facilities, and pharmaceutical companies. As a result of the above mentioned developments in Abu Dhabi and Dubai, the focus of Ministry of Health (MoH) was shifted to the northern and less affluent emirates (Ajman, Fujairah, Ras Al Khaimah, Sharjah, and Umm Al Quwain). In 2011, the MoH launched a strategic plan to increase preventive action through community awareness, to enhanvce standards of health care, and last but not least, to encourage medical and scientific research[16].

The UAE developed two documents pertaining to human subjects research: (1) Guidance for conducting Clinical Trials Based on Drugs/Medical Products & Good Clinical Practice (2006) and(2) Standard Operating Procedures for Research Ethics Committees (2012). The former document contains chapters such as a glossary, principles, requirements for the approval of clinical trials, goals, medical institutes, protection of subjects participating in the clinical trial, and responsibilities of the investigator. It states six ethical protections: (1) informed consent, (2) ethics committee, (3) scientific validity, (4) confidentiality, (5) benefits and risks of participation, and (6) limitations of risk of research on incapables. Unlike its Qatari counterpart (see: table above), the Emirati document does not mention protections related to compensation, research involving children, vulnerable persons, consent of incapables and ethical review of externally sponsored research. There are two external references mentioned in the Emirati document, these are: (1) the Declaration of Helsinki and (2) ICH-GCP. What seems interesting, considering the fact that Islam plays a major role in shaping Emirati society and culture, is that Islamic values are not mentioned as a reference in the document. Standard Operating Procedures for Research Ethics Committees issued on February 20, 2012 is a 77-page-long document developed by the Health Authority – Abu Dhabi (HAAD). The document provides guidance for "compliance with relevant laws and HAAD policies regulating health research in the Emirate of Abu Dhabi"[17]. The procedures mentioned in the document apply to: (1) Clinical

16 U.A.E. Ministry of Health. (2011). *About the ministry: Strategy*, https://www.mohap.gov.ae/en/Aboutus/Pages/Strategy.aspx (accessed: 15.02.2019).

17 Health Authority – Abu Dhabi, *Standard Operating Procedures for Research Ethics Commitees. Version 1.0*, 2012, p. 5, https://www.haad.ae/HAAD/LinkClick.aspx?fileticket=UL7o8f5mukc%3D&tabid=820 (accessed: 15.02.2019).

Trials of Investigational Medicinal Products (CTIMPs), (2) any research involving vulnerable persons, (3) all other research involving human participants, (4) research that does not involve human participants but has ethical considerations. However, they do not apply to: (1) CTIMPs for gene therapy, (2) Phase I CTIMPs and (3) any research exclusively involving animal subjects.

Conclusion

Research ethics regulations are relatively new phenomenon in the MENA region. The new regulations contain either all or only some of the protections provided in the international guidelines. The most advanced documents from the MENA region related to human subjects research can be found in Israel, Saudi Arabia and Qatar. Most of the Gulf Cooperation Council (GCC) countries made visible progress in developing their guidelines compared with non-GCC countries. The discrepancies between the countries can be viewed as a result of the significant differences in the levels of financial support for health care and research, and also of differences in the levels of social and political stability.

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Abstrakt

Prawne aspekty badań naukowych z udziałem człowieka. Kontekst Zjednoczonych Emiratów Arabskich

Artykuł porusza problematykę badań naukowych z udziałem człowieka na Bliskim Wschodzie, ze szczególnym uwzględnieniem kontekstu Zjednoczonych Emiratów Arabskich. Autorka przedstawia tło historyczne związane z badaniami z udziałem człowieka (ang. Human Subjects Research), a następnie pokazuje jak ta stosunkowo młoda gałąź prawa, związana z etyką badań klinicznych (i nie tylko klinicznych), uwidacznia się w państwach Bliskiego Wschodu poprzez tworzone w tych państwach regulacje.

Słowa kluczowe: badania naukowe z udziałem człowieka, Zjednoczone Emiraty Arabskie, prawo, etyka, służba zdrowia