

**Ethics and Law  
in Biomedicine and Genetics:  
An Overview of National Regulations  
in the Arab States**



# ETHICS AND LAW IN BIOMEDICINE AND GENETICS: AN OVERVIEW OF NATIONAL REGULATIONS IN THE ARAB STATES












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© UNESCO Cairo Office 2011  
Published by the United Nations Education,  
Scientific and Cultural Organization  
8, Abdel Rahman Fahmy st., Garden City,  
Cairo 11541, Egypt.  
cairo@unesco.org  
EG/2011/SS/PI/01  
ISBN 978-92-3-104211-9

Cover design & Layout by Hany Al ashkar, Orange Creation Company

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## Acknowledgements

This publication was realized through the excellent contributions of many people in the region. In addition to **Dr Fouad N. Boustany** (Professor of Medicine in Chronic Care Centre, Secretary General, Secretary General in Ethics Advisory Committee for Health and Life Science, Member of the National Council for Scientific Research, Former President of the Lebanese Order of Physicians and Member of IBC, Beirut, Lebanon), who analyzed the collected survey data and wrote a report on it, the editors express their profound gratitude to the following experts in the region for conducting thorough research and providing us with valuable legal information on their countries;

**Dr Faisel Abu-Duhier** (*Dean, Faculty of Applied Medical Science, University of Tabuk.(previous) General Director, General Administration for Medical Research, Ministry of Health, Riyadh, Saudi Arabia*);

**Dr Khalid Alali** (*Director, Foundation Program, Qatar University, and Member of COMEST, Doha, Qatar*);

**Dr Khedidja Allia** (*Chemical Engineering Professor and Research Director and President of the Scientific Committee of Chemical Engineering department - USTHB, Algiers, Algeria*);

**Dr Asya Al-Riyami** (*Director of Research and Studies, Department of Research and Studies, Ministry of Health, Muscat, Sultanate of Oman*);

**Dr Jassim Ali Salem Al-Shamsi** (*Dean, Faculty of Law, United Arab Emirates University, United Arab Emirates*);

**Dr Mahoud Attia** (*Research and Studies adviser, Department of Research and Studies, Ministry of Health, Muscat, Sultanate of Oman*);

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**Dr Mariam Abdulla Ghuloom Dashti** (*Director, Aljawhara Hospital for Fertility and Genetic Diagnosis, Aljawhara Center for Molecular Medicine, Genetics and inherited Diseases, Assistant Professor, College of Medicine (CMMS), Arabian Gulf University*);

**Dr Jamila Ibrahim El Megresi** (*Legal Advisor, Tripoli, Libya*);

**Dr Mustafa Khidir Mustafa Elnimeiri** (*Associate Professor of Preventive Medicine and Epidemiology-Certified Trainer on Research Ethics, Coordinator of the Post-graduate Medical Studies, National consultant of RH & HIV/AIDS, Faculty of Medicine and Health Sciences, Elneelain University, Khartoum, Sudan*);

**Dr Guessous -Idrissi, Nouzha** (*Independent researcher & Consultant, in Bioethics and Human Rights, Emeritus Professor at the Hassan II University of Casablanca, Morocco*);

**Dr Mohamed Abdulla Hadi** (*Head of Community of Medicine & Public Health Department, Faculty of Medicine, Aden University, Aden, Yemen*);

**Dr Asem Khalil** (*Director of the Ibrahim Abu-Lughod Institute of International Studies, Assistant Professor of Law at Birzeit University, Palestine*);

**Dr Ibrahim Ramahi** (*Consultant of Forensic Pathology and Clinical Forensic Medicine, National Institute of Forensic Medicine, Prince Hamza Hospital and Vice Chair of Research Ethics Committee-MoH , Amman, Jordan*)’

**Dr Fawaz Saleh** (*Professor of Private Law in University of Damascus, Professor and Secretary-General of the Higher Institute of Business Administration, Head of Legal Affairs, University of Damascus, Member and Secretary-General of the Syrian Bioethics Committee and member of IBC, Damascus, Syria*);

**Dr Magdi Gebril Shehata** (*Professor of medical Entomology, Head of Entomology department, Faculty of Science, Ain Shams University and Secretary General, Research Ethics Council- Academy of Scientific Research and Technology, Cairo, Egypt*), and;

**Dr Majed Zemni** (*Professor of Legal Medicine and Medical Law, University of Medicine of Sousse - Tunisia. Member and president of Technical Section of National Committee of Medical Ethics Tunisia*).

## Preface

UNESCO's work in the field of ethics started in the 1970s and since then UNESCO has been leading the international community in addressing ethical questions that have arisen throughout the development of biomedicine, natural sciences, and technology.

The work of UNESCO in the field of bioethics was bolstered in the 1990s by the establishment of the International Bioethics Committee (IBC) in 1993 and the Intergovernmental Bioethics Committee (IGBC) in 1998. This coincided with the period when ethical concerns related to rapidly progressing genetics research were emerging in the international community. In 1990 the human genome mapping project—an attempt to decode the “book of life”—was launched in cooperation with scientists from all over the world. The outcome of this research gave us high expectations of enriching our knowledge and understanding of the mechanisms of life, health, and disease. That being said, because genes possess fundamental information about individuals, communities, and all of humanity, they must be treated with proper consideration from ethical, cultural, social, and economic perspectives.

In response to the international community's urgent need to establish international legal instruments to guide each society to develop appropriate laws and regulations; the General Conference of UNESCO adopted the Universal Declaration on the Human Genome and Human Rights in 1997. UNESCO's subsequent activities in standard setting resulted in the adoption of the International Declaration on Human Genetic Data in 2003 and the Universal Declaration on Bioethics and Human Rights in 2005.

These three declarations provide evidence of the international community's strong commitment to tackling these ethical issues and following their adoption UNESCO's mandate was to support Member States in implementing, at the regional and the national levels, the principles enshrined in these declarations. In 2007, it was decided that the UNESCO Cairo Office serves as the focal point for implementing bioethics and ethics of science and technology projects in the UNESCO Arab region and various projects have been launched since then.

As in other regions, bioethics is quite a new concept for many of the Arab countries. Additionally, certain ethical issues related to the most advanced technologies are not relevant to developing countries. Nevertheless, countries of the region have shown a great deal of interest in bioethics and UNESCO has carried out many projects in coordination with National Commissions for UNESCO, regional and international organizations, and with many experts in the Arab region. The survey included in this book was conducted from September 2007 to May 2009 in 17 Member States of the UNESCO Arab region and in cooperation with experts in each country. Ten important issues in bioethics were identified and legal documents in each country regulating each issue were collected. This is the first exhaustive study that gives an overview of the regulations on bioethical issues in the Arab region.

I believe that the research results enrich our knowledge of the existing regulations in the Arab countries, the similarities and differences in the ways that certain issues are approached in the region and in the world, as well as the challenges facing the region. The benefits of this study may go beyond academics working on bioethics, but also benefit decision makers, researchers in the natural and social sciences, students, and the general public.

One of the missions of UNESCO's bioethics programme is to serve as a clearinghouse for the



Member States and hence a system of ethics databases called the “Global Ethics Observatories” (GEObs) was launched in 2005. Currently, the GEObs consist of six databases: GEObs 1 (individual experts in ethics); GEObs 2 (institutions, centres, commissions, and committees in the field of ethics); GEObs 3 (descriptions of existing teaching programmes in the field of ethics); GEObs 4 (descriptions of ethics-related legislation and guidelines); GEObs 5 (codes of conduct for the field of ethics); and GEObs 6 (resources in ethics). The information contained in the GEObs can be viewed online at following address:

[www.unesco.org/shs/ethics/geobs](http://www.unesco.org/shs/ethics/geobs)

The survey conducted in the Arab region complements the GEObs and, along with the GEObs, the information contained in this book is expected to offer valuable information in the field of bioethics and regulations in the Arab region to the Member States of UNESCO.

**Tarek Shawki**

Director

UNESCO Cairo Office

## General Introduction

As biotechnology and medical treatments rapidly develop all over the world, there is a growing need to establish regulations on conducting research and applying new medical treatments all over the world. However, the systems and policies regulating bioethical issues differ from one country to another. In some countries, most medical practices are regulated by professional guidelines. Other countries have written legislation or governmental guidelines concerning certain issues. Other countries have developed comprehensive legislative frameworks to regulate bioethical issues. In this globalized world, bioethical issues can have significant impact beyond national borders. Researchers and patients who pursue certain research or medical treatments can travel around the world in order to find a place where there are fewer restrictions or no restrictions at all on the services they seek. In order to safeguard human dignity and human rights, regardless of the time and space, it is crucial that a regulatory system for research and medical treatment be synchronized and harmonized at the international level.

Each country may have established different regulations on certain issues due to their different cultural and religious contexts. Nevertheless, universal principles such as respect for human dignity and human rights should be provided for in all regulations. Several international studies have been conducted to collect and compile worldwide legislation related to medical and health issues (e.g. “International Digest of Health Legislation” by the World Health Organization, “International Encyclopaedia of Laws: Medical Laws” edited by N. Herman, and Global Ethics Observatory by UNESCO). UN agencies have made a number of other efforts to collect information on specific issues (e.g. “Abortion Policies: A Global Review” by United Nations Population Division and “National Legislation Concerning Human Reproductive and Therapeutic Cloning” by UNESCO). Nevertheless, a comprehensive survey of bioethical regulations in the Arab region had not yet been conducted. Therefore a project to collect legal information was designed with the goal of contributing to the international community by: presenting an overview of the regulatory provisions on bioethical issues in the region; identifying needs that must be met in order to further promote bioethical discussions and regulations; and facilitating dialogue in the region towards creation of international harmonization on bioethical issues.

In order to collect comparative data from the countries surveyed, a standardised survey sheet was developed and used for research. One expert was identified in each country and s/he worked independently or with colleagues to collect information in their countries. The information requested concerned: laws (adopted laws, draft laws, constitution, decrees, etc); national guidelines and codes; regulations of professional associations and societies; and any other documents that indicate the government’s position on various issues (e.g. opinions of and reports by national bioethics committees). The experts were also requested to refer directly to the original text of laws, draft laws, and regulations as they analyzed the situation in their countries.

This was not an easy task, particularly because such a survey requires expertise in multiple fields of medicine, biology, law, religion, and bioethics. Despite the difficulties, all the experts who cooperated in this project provided UNESCO with comprehensive and thoroughly analyzed reports on their countries within a relatively short period of time. The first phase of the survey was conducted from 2007 to 2008 and a second phase was conducted from 2008 to 2009 in order to include more countries in the study. The results of the research reveal that regulations on some of the issues addressed in this study are changing rapidly and that some issues require further discussion and awareness-raising efforts in order to establish regulations in this region.

Part I of this book consists of a report by Dr Fouad N. Boustany analyzing the raw survey data collected from 17 Arab countries. He also provides an introduction to bioethics in the context of Arab culture and Islam. Part II contains the original survey sheets, which offer rich and complete information on all issues in each country. Experts in some countries (Libya, Kuwait, Oman and Qatar) voluntarily provided a country report which gives an overview of the regulatory system and current situation in their countries. These reports are attached in a CD rom. It is helpful to understand the current practices and development of bioethical discussion on establishing regulations in these countries where regulations on many issues have yet to be developed.

It is my hope that this publication will provide useful information on regulations in the Arab region, contribute to the international harmonization of regulations, and promote further discussion on bioethics.

**Orio Ikebe**

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# Report of Mapping Bioethics Regulations in 17 States in the Arab region

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Member of the IBC

# Introduction

For the past 50 years it has been essential to reflect on ethical behaviour because throughout the world we have the same objective: safeguard the human being in all situations where s/he faces a menace. Bioethics has developed most prominently in the fields of life sciences and health due to the rapid progress in biological research and advanced medical techniques. It is to be noted that all that can be attained scientifically is not necessarily desirable for the human being and has the potential to dehumanize him/her.

Ethical thinking is above all personal and each person pursues it in his/her profession according to his/her convictions and competence, but it is also a collective concern because people live together and are collectively responsible for preserving humanity. To this end, over the past decades, national, regional, and international committees for bioethics have developed progressively in human societies throughout the world. This may be called the “worldwide institutionalization of bioethics”.

On the national level, this institutionalization is accomplished in each country in different contexts. Tristan Engelhardt writes: “Bioethics in the United States is an element of a secular culture and the daughter of the philosophy of the enlightenment” (philosophie des lumières). Daniel Callahan states: “The first thing that persons involved in bioethics should do is to put religion aside”. Nevertheless, this does not mean that bioethics have not benefited from the principles of religious morality.

In Europe, Louis Seve summarizes the consensus attained by the Comité Consultatif National d’Ethique in France in these terms: “In the case of France [and certain other European countries] bioethics have found in existing laws favourable circumstances that previously existed: the existence of laws of secular character that have permitted different trends and opinions in bioethics to come together if not to agree”. Despite the pertinence of this statement, the majority of the European countries have become aware of the benefits of including representatives of their religious communities in their bioethics committees.

# 1. Bioethics and Multi-denominational Arab Societies

From October 2007 to 2009 UNESCO's regional office in Cairo conducted a survey to evaluate the state and the evolution of bioethics in most of the Arab countries (Algeria, Bahrain, Egypt, Jordan, Kuwait, Lebanon, Morocco, Oman, Palestine, Qatar, Sudan, Syria, Saudi Arabia, Tunisia, Libya, the United Arab Emirates, and Yemen). UNESCO requested answers from parties working in the field of bioethics to questions concerning ten subjects of debate in bioethics:

- Human reproductive and therapeutic cloning
- Embryonic stem cell research
- Genetic testing
- Human genome and gene analysis
- Research involving human subjects
- Organ transplantation
- Assisted reproductive technologies
- Pharmaceutical research
- Medical practice
- Abortion

The report represents the examination and comparison of their responses, which reveals the depth and density of the work accomplished in the Arab world in the field of bioethics, as well as the disparity between regulations and legislations in each of these countries.

In some countries of the Mashreq, Maghreb, and the Arabian Peninsula where Islam is predominant, bioethics are practiced in a context different from that of the West. These countries have not experienced the process of secularization that profoundly impacted the West for centuries. Many of the Arab states are relatively homogeneous with regard to their beliefs and are less disposed to pass laws in a field with which they are not familiar and wherein so-called "universal values" may conflict with the values of their various religious communities, despite the fact that in 2005 they approved the universal principles of bioethics proclaimed in the UNESCO Universal Declaration on Bioethics and Human Rights. Some people in the Arab world are not comfortable with western-style bioethics and want bioethical considerations to conform to Islamic principles. The necessity to articulate ethics compatible with religion is often underlined by Muslim authors. Abd-Al-Haqq Guiderdoni writes: "To present the fundamental principles of ethics in Islam requires raising the question of Islamic anthropology which is entirely defined by man's relationship with God".

It should be noted that this conviction is upheld not only by Islam, but is shared by the three "religions of the book" (Islam, Judaism, and Christianity) in the region, even though each may understand a human's autonomy and the basis of his/her dignity in its own way.

Thus, in the region, bioethical thought is often expressed at the level of religious dignitaries. Indeed, the First International Conference of Medicine (held in Kuwait in 1981) ended with the

publication of the “Islamic Code of Medical Ethics”. Furthermore, the first Congress of Islamic Sciences (held in Cairo in 1985) and the subsequent positions upheld at the annual sessions of the Councils of the Fiqh Academy, as well as the numerous fatwas (decisions on practices deemed to conform to the *Sharia*, which is Islamic law or jurisprudence) issued by religious Islamic authorities, fully support the above position.

On many occasions, Christian and Jewish religious authorities have also stated similar stances regarding the values they deem fundamental to human moral ethics.

## 2. Bioethics and Monotheistic Religions

The behaviour of the followers of the three “religions of the book” is profoundly influenced by the presence of God in their lives. This behaviour is also influenced by their membership in a community of people with shared beliefs, which, in the case of Islam, is called the *Umma*. The behaviour of these communities is also based on religious texts and interpretations that are sometimes imposed upon them. Monotheistic religions attach great importance to their sacred books; however, the influence of these books varies in the three major religions of the region as their emphasis on the interpretation of the scriptures and traditions varies.

Muslims believe that the Qur’an is the word of God, which was revealed to the Prophet Mohammed and proclaimed by him. Because the Qur’an is believed to be the direct, precise, and unaltered word of God, great emphasis is placed on the texts of the religion in determining appropriate behaviour and ethical practice. Henri Lammens writes: “The Qur’an is for the believer the epitome of the sacred and secular history, a manual of prayer, a code for behaviour in religious and social life, a guide for daily behaviour”.

In the Arab world, where, as abovementioned, Muslims are in the majority, one must take into consideration the instances in which religious values are the basis of bioethics. That being said, Islam does not have a hierarchical authority that determines Muslim orthodoxy. Orthodox Islam is concerned only with the recognition of the uniqueness, transcendence, and omnipotence of God. In other words, the spirit of Islam is quite liberal. A number of ethical questions are addressed in the Qur’an and the *Hadith* (the sayings of the Prophet Mohammed) and other contemporary issues are resolved by the issuance of fatwas by religious leaders or institutions, most notably the Academies of Fiqh. Influential fatwas sometimes offer support for various medical practices and facilitate the articulation of laws that regulate these practices.

The questions that must be addressed are: Can a comprehensive analysis of these religious values in and of itself constitute a complete set of bioethical practices? Can a set of bioethical guidelines consisting of the shared values of Islam, Christianity, and Judaism be developed?

While religion affects the ethical behaviour of its followers in many Arab countries, it is not the sole determinant of people’s practices and behaviour. Mohamed Arkoun writes: “The Qur’an does not impose definitive solutions to the problems of human existence. It attempts to instigate man to look upon himself and the world, the verses constitute for all men a metaphysical horizon”. People must find solutions to problems inherent to human existence together, as there are no standards that prescribe proper behaviour in all circumstances and contexts. Thus, in homogenous as well as in multi-denominational Arab countries, it is essential to articulate a set of shared ethical guidelines that are based on human rationality and are multi-denominational and multidisciplinary. All the while, people’s freedom of choice must be preserved.



### 3. Bioethics and Law in the Arab Countries

The problems raised by sensitive bioethics issues including, among others, voluntary termination of pregnancy, medical assistance in procreation, embryonic research, and organ transplantation constitute problems that, in the region, fall in the domain of “personal status”. In western countries, laws concerning bioethics are included in the Civil Code or in the Codes of Public Health. Most of the Arab countries do not have codes of public health. As for Civil Codes, they are Codes of Personal Status, and, in most Arab countries, they are under the jurisdiction of religious courts. This makes resolving ethical issues complicated and prevents them from having a serious impact on legislation.

In Algeria and Morocco, *Sharia* is codified in the Personal Status Code, but all legislation must respect the procedures followed by civil jurisdictions and institutions. Tunisia and Lebanon, whose legal systems were inspired by the French system, follow a different practice. Tunisian reforms are based on a re-reading of *Sharia*, the central idea being that Islam can evolve and the spirit must prevail over the text. In Islam there is the possibility of innovation (*Ijtihad*) through reasoning by analogy (*Qyas*) or by consensus of the scholars (*Itimaa*) in the service of public interest (*Maslaha*). This partially explains the 1991 foundation of the Tunisian National Committee of Medical Ethics, which is very active.

In the Mashreq (not including the countries of the Arabian Peninsula where *Sharia* is the law), Egypt, Syria, and Lebanon are countries with a pluralistic outlook on the Personal Status Code. In Egypt and Syria, where *Sharia* is a component of the constitution, the rulings of the different denominations must respect the procedures followed by civil jurisdictions. The Personal Status of the different denominations in Lebanon is on equal footing and none has the character or nature of civil law. The Lebanese Constitution renders the state responsible for respecting this autonomy and the state is not subject to the religious convictions of any denomination. The Lebanese National Consultative Committee of Bioethics is a product of Lebanese civil society and has assumed its responsibilities more rapidly than the political institutions that created it.

In most of the Arab countries where bioethical committees exist, political and above all religious authorities present their concerns about the problems resulting from the rapid progress in biological sciences directly to the committees. Often, they propose resolutions or fatwas to these committees, which, in turn, usually have to respect them because of the predominance of *Sharia* in the laws of the state.

## 4. Modernity and Bioethics (*la Modernité Bioéthique*)

The search for bioethics with a universal scope (*modernité éthique*) is a concern shared by different national, regional, and international institutions, first and foremost, UNESCO. Clearly, the Arab world must make a contribution. In 1999, the president of the *Académie de la langue arabe* stated in Algeria: “The gap in Muslim countries between scientific research and an adapted legal framework, or in case of absence of the same, an ethical thought is enormous. It is urgent to remedy this.” In 2001, the Secretary General of the Lebanese National Consultative Committee of Bioethics stated that there is no legal framework for bioethics in most of the Arab countries, and that national ethics committees that were recently formed on a consultative basis should study the bioethical issues and, if necessary, the legal texts.

## 5. Morals and Ethics

Morals and ethics are synonyms, one of Latin etymology, the other of Greek. The use of Latin in the West over a long period gave a religious connotation to the word “moral” that reflects, rightly or wrongly, a system of principles evoked by a Christian religious authority. When the West rediscovered the Greek philosophers, the word “ethics” replaced the word “morals”. Thus, the religious connotation progressively disappeared and the term became secular.

Ethics were adopted specially for professional problems that did not have ready-made answers due to their complexity and newness. This change in vocabulary is a voluntary manifestation of liberty from religious authorities and the traditions for which they stand. This led to a modern bioethics code that seeks to establish the “liberty to judge by oneself what is ethical and what is not”. This liberty also reflects the Kantian notion of the “liberty of others” and the precept that you must “always act in a manner that you treat humanity as you treat yourself as well as the others”.

Believers in Islam, however, cannot totally disregard the principles of the Qur’an, which they believe is a gift from God that illuminates their lives and the lives of all believers.

## 6. Bioethics, Medical Ethics, and Deontology

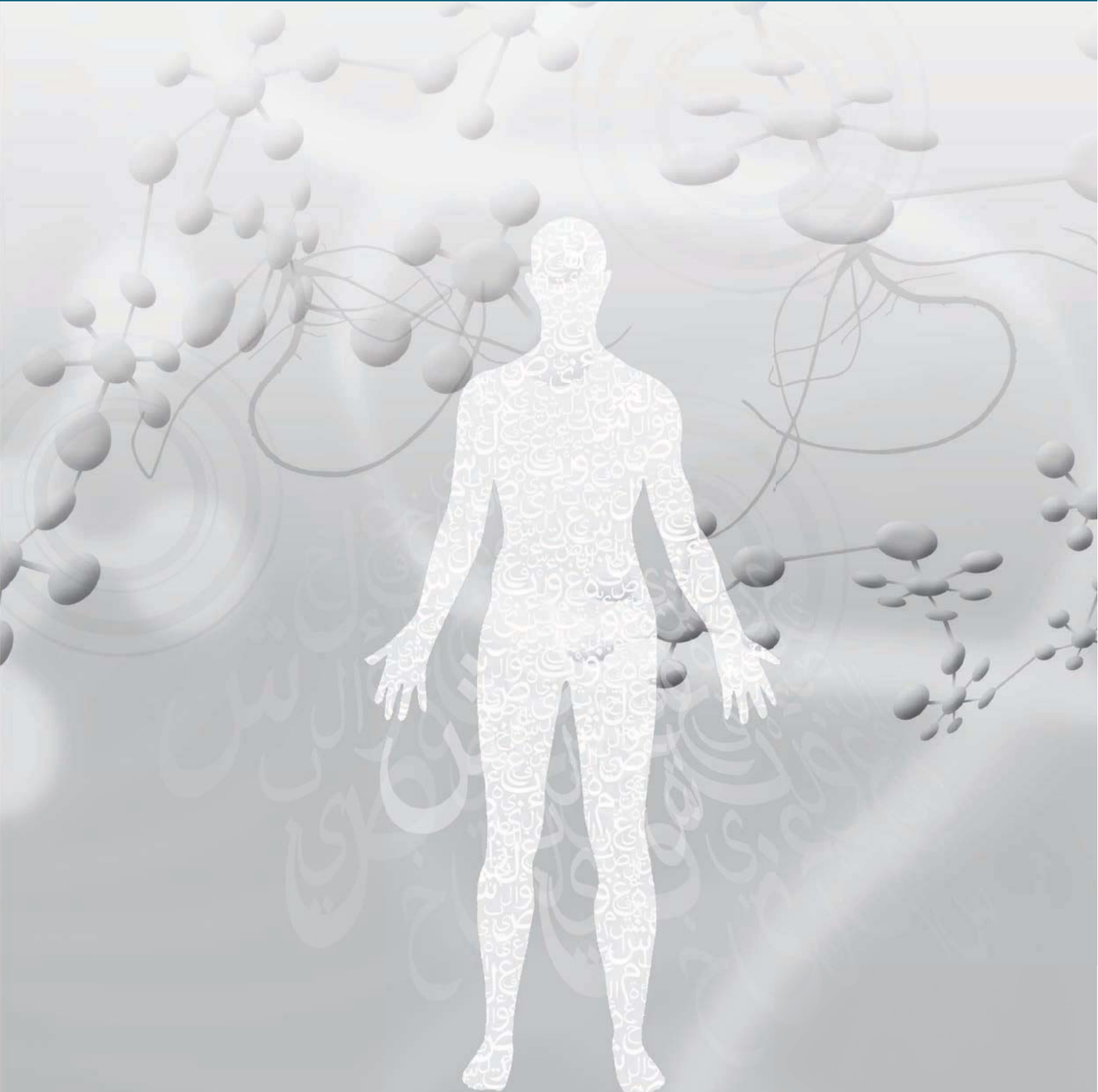
The relationship between bioethics, medical ethics, and deontology is both complex and controversial. This is confirmed by the ambiguity in the answers received from several Arab countries concerning certain questions asked by the Cairo office of UNESCO. It would appear that there is nearly no distinction made between these three disciplines in existing laws and recommendations.

For some people, bioethics is just a new term for medical ethics, which is traditionally the only recognized discipline. For others, bioethics includes medical ethics, which constitute an

important chapter in medical history dating back to the Hippocratic oath. The first position tends to confirm medical power as a traditional ethical monopoly that has become more important as medical techniques rapidly advance. The second position underlines the necessity of a multidisciplinary and pluralistic focus in which laymen have a say in biomedical discussions. This dualism will increase as the “doctor-patient” relationship and the newly recognized rights of the patient (health rights, consent, right to procreate, etc.) decentralize the problems of bioethics and render people more autonomous from the medical power.

Medical ethics, on the other hand, remain very close to medical deontology, which is a special form of professional ethics and imposes a number of duties on an individual in the exercise of his/her profession. Many of the questions that one encounters in bioethics are more significant than all deontology and overlap the limits of any profession, as they concern humanity at large. Furthermore, this indicates that experts from different disciplines and, in addition to the medical corps, members of civil society should serve on biomedical committees.

# Laws and Regulations in the Arab Countries



# 1. Human Reproductive and Therapeutic Cloning



# 1. Human Reproductive and Therapeutic Cloning

*Among the 17 UNESCO Arab member states that participated in UNESCO's survey, only four (Algeria, Egypt, Tunisia, and Lebanon) have addressed the issue of human reproductive and therapeutic cloning in official regulations. The other 13 countries either ignore it or address it under recommendations that are not legally binding, such as those issued by the Islamic Organization for Medical Sciences (IOMS). This organization plays a significant role in addressing numerous science-related issues in many Muslim countries. Kuwait, for example, has tackled the issue of human reproductive and therapeutic cloning under the recommendations of the 9th Fiqh Medical Seminar. It should be noted that although these countries may respect the guidelines and regulations of IOMS, the fact remains that they are not legally binding and are not considered official laws.*

*The IOMS recommendations prohibit ordinary human cloning; however, they have left some room for exceptional cases that may emerge in the future, to be considered on an individual basis as to their benefits and compliance with Sharia. They also reflect the widespread fear of promotion or misuse of human cloning in Muslim countries by foreign research institutes and organizations and request legislation to prevent this from happening. There were also recommendations to call upon IOMS and similar bodies to monitor all scientific developments in the field of cloning and to set up specialized committees that would prepare a document on foetal rights as a prelude to formulating legislation.*

## **Jordan**

Jordan, for instance, has no regulations on this matter, but has signed the Muslim World League Declaration formulated in Mecca, Saudi Arabia in 2003, without officially endorsing it, since cloning and related research are not currently practiced in the country. Therefore, Jordan only abides by a reference to prohibit both reproductive and therapeutic cloning.

## **Qatar**

Although it has no regulations on this matter, Qatar was one of the 84 countries that voted in favour of the United Nations Declaration on Human Cloning, adopted on 8 March 2005, according to which all forms of human cloning that are contrary to human dignity are prohibited. According to the survey provided by the expert in Qatar, this could be interpreted as the official position of Qatar on cloning. Although there are no specific Qatari national laws or institutional regulations for cloning at this point, the Gulf Co-operation Council (GCC) is preparing regulations on the issue of cloning.

## **Palestine**

In Palestine, the Basic Law and the Draft of the Palestinian Constitution are both silent on the issue of human cloning. However, according to the 2003 Draft Law on Human Organ Transplantation (Art. 17): "It is forbidden to perform cloning on humans or carry out research, experiments, and applications related to cloning on humans". In practice, however, until the abovementioned draft law is endorsed, the issue of cloning remains outside legal regulation.

## **Bahrain**

In Bahrain there are no regulations on this matter and the only partial reference to it is found in

the Draft Guidelines for the Regulations on Assisted Reproductive Technologies (p. 10, pt. 12), which stipulates that the technique of human reproductive cloning cannot be used for fertility treatment, unless it is justified by *Sharia*.

### Libya

This issue has not yet been addressed in laws or regulations in Libya; however, many workshops on cloning in the past, present, and future have been held by the Biotechnological Research Centre and the National Institution of Scientific Research, which issued Decision No. 386/2003. These workshops resulted in recommendations that encourage establishing an official legal framework for cloning, using modern technologies in the field of cloning, and organizing research on cloning.

*The responses from Oman, Morocco, Syria, Yemen, and Sudan show that none of these countries has developed regulations on human reproductive and therapeutic cloning because this issue has not yet arisen.*

### UAE

In the UAE two draft laws that refer to the prohibition of reproductive and therapeutic cloning are currently being developed.

### Saudi Arabia

In 2002, the Saudi National Committee on Biomedical Ethics (NCBE) rejected human reproductive cloning and all its applications saying that the risks exceed the benefits (No. 4/14/23).

### Algeria

In Algeria, the Minister Instruction No. 300 (12 May 2001) determining good practice in assisted reproductive techniques, mentions that *in vitro* conception of an embryo for study, research, or experimental purposes is prohibited, but that exceptions can be made for therapeutic objectives.

### Egypt

As for Egypt, cloning is prohibited by Art. 60 of Decree No. 238/2003 of the Ministry of Health and Population on the regulation of professional ethics, which states that researchers are prohibited from conducting or participating in research and practices that involve the mixing of lineages. This article also mentions that researchers are prohibited from carrying out or participating in any research that aims at cloning a human being.

### Tunisia

In addition to the Tunisian National Committee for Medical Ethics' prohibitions in Opinion No. 3 on cloning (22 May 1997) and Opinion No. 5 on therapeutic cloning (4 July 2002), it is clearly stated in Art. 8 of Law No. 93/2001 (7 August 2001) that cloning is strictly forbidden in reproductive medicine.

### Lebanon

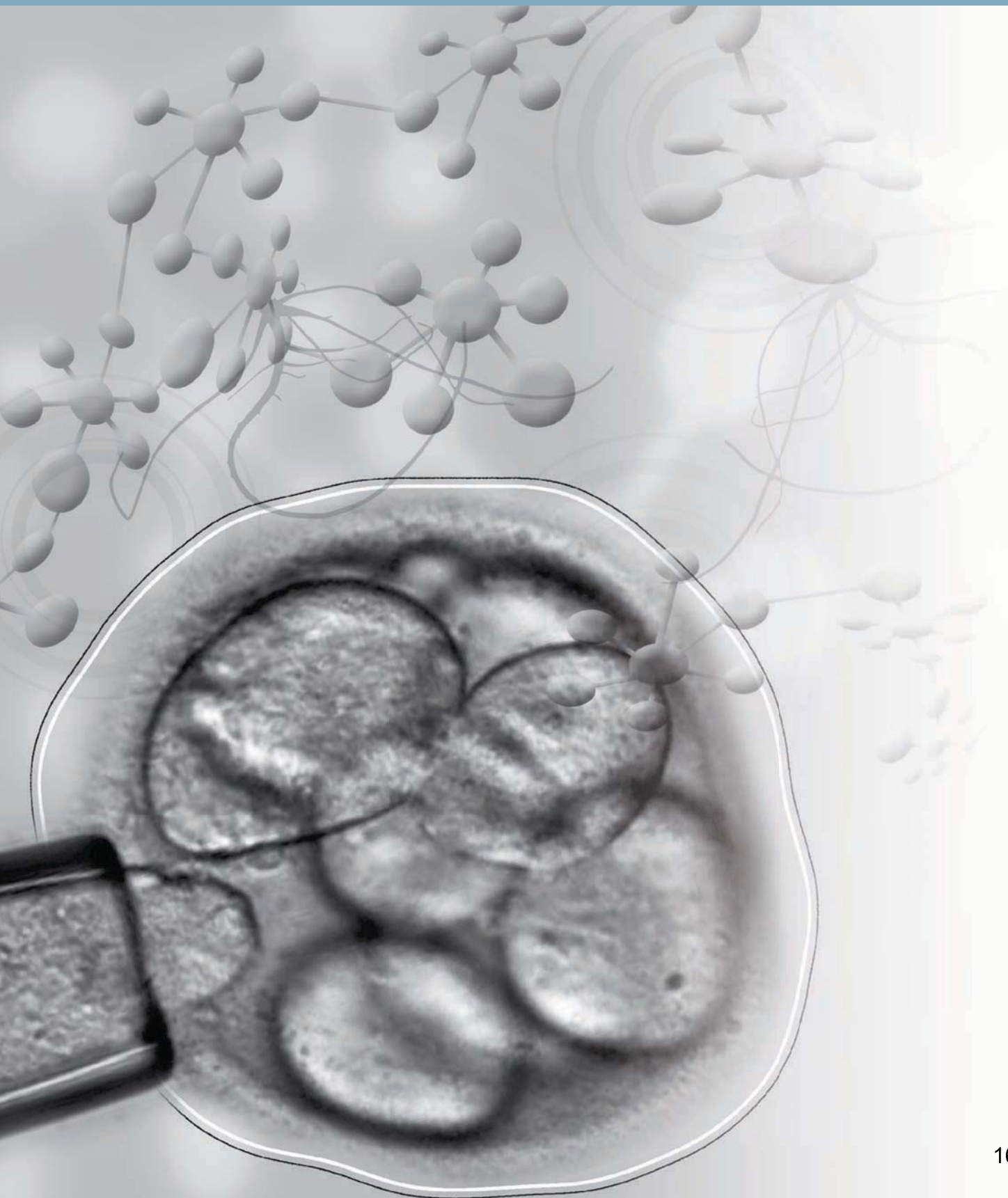
Lebanon also prohibits reproductive and therapeutic cloning in Art. 4 of Law No. 625 regarding human genetic testing, in Art. 8 of the Draft Law for Assisted Human Reproductive Techniques,

and in national guidelines considering such practices inconsistent with preserving the dignity of the human being.

*In conclusion, among 17 countries, there is no country which permits human reproductive cloning and some countries explicitly or implicitly prohibit such practice by national guidelines, or by virtue of an international declaration. However, almost all the countries expressed the need to further develop this issue and regulate it through well informed legislation. For example, at the 58th Session of the General Assembly of the United Nations in 2003, most Muslim-majority countries decided to follow the proposal to postpone consideration of the International Convention against Reproductive Cloning of Human Beings until the 60th General Assembly, which appear to have marked a turning point of the discussion in the United Nations. Apparently, although the Arab countries have argued strongly against reproductive cloning, they preferred the adoption of the text by consensus not by vote.*



## 2. Embryonic Stem Cell Research



## 2. Embryonic Stem Cell Research

*In the Arab countries, embryonic stem (ES) cell research is still considered a new biomedical issue, as most of these countries lack suitable facilities and equipment for research in this field. Only Egypt, Algeria, Tunisia, and Saudi Arabia have a few non-comprehensive stipulations referring to ES cell research, whereas the other 13 countries have not yet tackled this issue. It is important to highlight once again the role that religion plays in decision-making in the Arab world. There are key ethical issues regarding ES cell research that are nearly impossible to solve, such as the status of the embryo as a human being and the acceptability of research on ES cells if this means the destruction of the embryo.*

*In Sudan, Syria, Kuwait, Oman, Yemen, Lebanon, Jordan, Libya, and the UAE there is no national legal framework, nor are there regulations concerning ES cell research. However, stem cells are being extracted from the umbilical cord in Lebanon, Jordan, and the UAE for future therapeutic uses, a practice that is gaining popularity for its potential future benefits.*

### Jordan

Extracting ES cells from embryos created by Somatic Cell Nuclear Transfer (SCNT) or from aborted fetuses is a delicate procedure that requires logistical and laboratory facilities not yet available in Jordan and there are no officially recorded procedures of the sort in Jordan. However, a project was established in June 2005 under the name “Baby Cord Blood Jordan” and its task is to extract stem cells from umbilical cord blood. The programme was launched in private hospitals in Jordan that are affiliated with the New England Cord Blood Bank (NECBB) in Boston, USA. In 2005, the Ministry of Health approved the procedure, which consists of collecting the cord blood in Jordan and sending it to the affiliate NECBB.

Guidelines need to be established in accordance with the conclusions of the Muslim World League on its 17th session in Mecca, Saudi Arabia (13-17 December 2003). The session’s conclusions, which were deemed in harmony with Islamic precepts, proclaim that it is acceptable to obtain embryonic cells, preserve them, and conduct testing on them for scientific research and treatment, if the source of the specimen is legitimate. Legitimate sources are: adults who have provided written consent (if the procedure does not constitute a threat to their health); children whose legal guardians have provided written consent (if the procedure does not constitute a threat to their health); the placenta or umbilical cord with parental written consent; aborted fetuses, provided that abortion laws are respected, with parental written consent; and *in vitro* fertilization (IVF) embryos donated for research. Therefore, the study and use of ES cells is prohibited if obtained from an illegal source, such as illegally aborted fetuses, intentional fertilization from donated specimens, and therapeutic cloning.

### Qatar

Although there are no regulations specifically pertaining to embryonic stem cell research in Qatar, the Qatari national stance on this issue is as follows: ES cells used for research are available either from the creation of embryos or from leftover fertilized embryos. However in Qatar, there would be no embryos to be used for research since embryos fertilized by IVF are either transferred directly to a woman’s uterus, or frozen only to be transferred to her uterus in the next cycle. Defective embryos have to be destroyed.

Thus, ES cell research is de facto prohibited in Qatar.

## Libya

There is no governmental position on ES cells in Libya; however, on 7 January 2007, the Biotechnological Research Centre convened a scientific workshop in cooperation with the Libyan Albeit Therapeutic Services Company on stem cells and their role in the treatment of diabetes. The workshop recommended that Libya start carrying out scientific research in order to develop such technology. The Department of Stem Cells was established in the Biotechnological Research Centre to perform this research following the approval of the Permanent National Committee for Biological Ethics and Vital Safety.

## Bahrain

In Bahrain, there are no regulations at this time. However, there is a brief reference to ES cells in the Bahraini Draft Guidelines for Regulation of Assisted Reproduction (pg. 10, pt. 13) that mentions that ES cells extracted or obtained from a person are not to be used for fertility treatment in another person. A special joint committee of the Arabian Gulf University and the Ministry of Health will prepare a draft law after they discuss this matter with the authorities.

## Morocco

In Morocco Art. 1 of Decree No. 2-01-1643 (2 January 2003) related to the application of Law No. 16-98, which concerns the donation, removal, and transplant of organs and tissues, deals indirectly with ES cells, as the list of organs and human tissues that can be donated for medical or research purposes excludes cells related to reproduction. Thus, it can be surmised that it is not permitted to use oocytes, spermatocytes, or supernumerary embryos for any research purposes.

## Palestine

Although Palestinian legal provisions are silent on issues related to ES cell research, it is possible to interpret, according to the expert in Palestine, Palestine's endorsement of basic human rights and willingness to join international declarations related to human rights, as prohibiting such activities. It is also possible to conjecture that ES cell research is prohibited if one can interpret the provisions related to abortion to mean that the embryo is considered a human being, based on the absence of commentary distinguishing the legality of abortion at different phases of pregnancy. If the embryo is considered a human being, then it is "unlawful to conduct any medical or scientific experiment on any person without prior legal consent" (Basic Law, Art. 16).

*As opposed to the abovementioned countries, Egypt, Saudi Arabia, Algeria, and Tunisia have some stipulations on this issue.*

## Egypt

Resolution (Decree) No. 238/2003 of the Egyptian Ministry of Health and Population on the regulation of professional ethics clearly states in Part 3 (Conducting Medical Research and Experiments on Human Beings): "It shall be prohibited to use human organs, tissues and cells, and human embryos for commercial purposes. Under no circumstances shall the physician be allowed to take part in these operations, otherwise s/he shall be subject to disciplinary action."

According to the Egyptian Fatwa Council: Research Issues on Human Organ Transplantation, May 2007 (Chapter 4, “Stem Cell Transfer in Egypt”), it is allowed to obtain and use stem cells for research or therapeutic purposes provided that no damage is inflicted on the person from whom the stem cells originated. It is, for example, permitted to use stem cells from surplus embryos and legally aborted fetuses, provided that the parents’ consent is obtained.

### Algeria

Algerian Ministry Instruction No. 300 (12 May 2001) on good clinical and biological practices in assisted reproductive technology states that the conception of embryos *in vitro* for study, research, or experimental purposes is prohibited. However, it permits research on embryos for therapeutic purposes provided that no damage is done to the embryo and stipulates that in all cases permission must be granted by the authorities.

### Saudi Arabia

Articles 41-44 of the Saudi Arabian National Committee of Biological and Medical Ethics guidelines on “Organizational System for Research Practices on Living Beings” prohibit the creation of embryos, donation of sperm or reproductive cells, use of ES cells from fertilized embryos or from embryos created by SCNT, and the storage of fertilized eggs for research purposes. The import and export of ES cells for research purposes is not permitted except after obtaining the approval of the national committee, which allows (as in the UAE and Jordan) research on stem cells extracted from the umbilical cord (Recommendation No. 3/13/23).

### Tunisia

In Tunisia, the conception and conservation of supernumerary embryos is permitted solely for reproductive purposes and it is forbidden to create embryos for research purposes (Art. 9 and 12 of Law No. 2001-93 on the medicine of reproduction). Furthermore, Art. 7 of this same law also forbids the import and export of ES cells. The Tunisian National Committee of Medical Ethics’ Opinion No. 5 on therapeutic cloning (5 July 2002) proposes an alternative, which is “to develop research on adult stem cells, even if they are currently less rich in potential”. This opinion is in line with the conclusions of the 17th Session of the Muslim World League (Mecca, Saudi Arabia, 13-17 December 2003). The Tunisian National Committee of Medical Ethics also considers that adult stem cells “must be a preferred source, avoiding the use of the embryo, for therapeutic cloning....It is also necessary to consider other new technologies for obtaining stem cells from genetically compatible sources for therapy. Adult stem cells exist in the bloodstream and do not pose any ethical problems”.

# 3. Genetic Testing



### 3. Genetic Testing

*The issue of genetic testing is insufficiently addressed in regulations in the Arab world. Only Lebanon has written a law specifically formulated to regulate it (No. 625 of 2004). Bahrain, Tunisia and the UAE have referred to genetic testing in some stipulations, but the other 13 countries have ignored this issue completely, or are working on draft guidelines, or have formulated simple guidelines that partially regulate genetic testing.*

*Sudan, Morocco, Yemen, Kuwait, Palestine, Syria, Algeria, Saudi Arabia, Libya, and Oman have no regulations whatsoever concerning genetic testing.*

#### **Algeria**

We can deduce from Art. 4 of the Algerian Executive Decree 05-438 (10 November 2005) that genetic testing is permissible for prenatal research.

#### **Palestine**

Palestine has legal provisions that can be seen as indirectly addressing genetic testing. A Draft Law on Forensic Medicine was presented in 2003 by the Council of Ministers. It states that part of the mission of the forensic doctor is to perform genetic tests (Art. 13). This draft law remains in the phase of general discussion. It is worth noting as well that a council for Forensic Medicine was created by Decision No. 24 of 1994.

#### **Syria and Morocco**

Despite the absence of regulations in Syria and Morocco, there are many laboratories performing genetic tests, which creates a serious need for a legal framework regulating this practice in these two countries.

#### **Saudi Arabia**

In Saudi Arabia, there are no regulations on genetic testing; there are only draft guidelines such as the “Organizational System for Research Practices on Living Beings” issued by the National Committee on Biomedical Ethics (NCBE). These guidelines are only partially respected and some institutes are bypassing them, particularly the stipulation that a gene bank database be established at King Abdelaziz City for Science and Technology. Instead, samples are sent abroad.

Art. 66-84 of these draft guidelines include some important stipulations concerning the use of genetic testing in medicine. They stipulate that genetic testing is permitted for medical, research, and forensic purposes, for prenatal diagnosis, and for pre-implantation genetic diagnosis (PGD). They also state that genetic counselling is recommended and confidentiality is mandatory. They mention tests on minors and disabled persons under the general guidelines for research on minors and they do not allow the discrimination between subjects on a genetic basis.

#### **Oman**

Oman has no regulations on genetic testing, but has formulated guidelines that are not yet in practice: “Guidelines for Collection, Transfer, and Exchange of Human Genetic Data, Proteomic

Data, and Biological Samples”. The Oman Genetic Material Task Force was formed by the Dean of the College of Medicine & Health Sciences of Sultan Qaboos University (SQU) on 10 March 2006. The task force examined the principles set out in the International Declaration on Human Genetic Data and recommended that these principles serve as a basis for human genetic work in Oman. These general guidelines stipulate that genetic tests may be carried out for screening, diagnosis, and forensic purposes, that no discrimination is permitted, and that confidentiality must be respected, as is the case in Saudi Arabia. They also state that prior, free, informed, and specific consent without pressure or inducement by financial or other personal gain should be obtained for the collection and storage of genetic data, proteomic data, and biological samples. The guidelines state that such consent must be obtained without coercion and that the person has the right to decide whether or not s/he is informed about research results.

It must be noted that whatever is not mentioned in the prior consent is decided in Oman by Medical Research and Medical Research Ethics Committees. Since these guidelines are not yet being implemented, the Oman Genetic Material Task Force also recommends the establishment of an independent committee to be in charge of monitoring and enforcing the implementation of the recommended guidelines and of keeping accurate records.

### **Kuwait**

Although Kuwait has no regulations concerning this issue, it respects the recommendations and final statement of IOMS’ “Genetics, Genetic Engineering, Human Genes, and Genetic Treatment: An Islamic perspective”. These recommendations stress the importance of the broad scale provision of genetic counselling and the confidentiality of results. They allow genetic testing for therapeutic and forensic purposes. The recommendations confirm the necessity of obtaining the written consent of the person undergoing the tests or that of his/her guardian in the event s/he is unable to provide consent and affirm his/her right to choose whether or not to be notified of the test results.

### **Libya**

There are no regulations on genetic testing in Libya. The issue of confidentiality has been addressed in a general way under Medical Liability Law No. 17/1986, which states that patients’ information is to be kept confidential. Recommendations to preserve the confidentiality of patients’ hereditary data were the only results of workshops and symposiums.

### **Jordan**

In Jordan, by virtue of the Institutional Review Board (IRB), genetic studies are conducted to diagnose hereditary diseases through prenatal diagnosis. Genetic analysis for insurance and employment purposes is not permitted, and genetic research is conducted on minors and the disabled only after obtaining written consent from their legal guardians and providing genetic counselling for the family.

Genetic testing is conducted for forensic purposes in all judicial cases upon appeal from the District Attorney or by a court order in order to determine genetic matching with evidence found on a crime scene, or with the deceased, or in other legal circumstances. The data obtained is considered highly classified and is not revealed to any of the parties except under court order.

Genetic studies for families or individuals are conducted upon their own request to identify hereditary diseases. Genetic testing is also carried out in legal paternity cases. All research conducted in genetic studies must be submitted for review by the IRB, the approval of which should be granted prior to the implementation of the study. Said committee also supervises the research and evaluates the results.

Thus, except for the guidelines applied by the IRB, there is no regulation on this issue even though it should be the subject of defined regulations to address the growing research in this field.

### **Qatar**

In Qatar, issues related to genetic testing are regulated by the Shafallah Genetics Medical Centre (SGMC), by virtue of its document issued in March 2007 entitled “Research Policies, Procedures, and Guidelines” for regulating research in the field of medical genetics. This document adopts the “Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services,” in which WHO presents its recommendations. This document, or more specifically WHO’s international guidelines, is the only document that regulates genetic testing issues in Qatar in a straightforward manner. The document states that genetic data should not be given to insurance companies, employers, schools, or governments, except after obtaining the full informed consent of the person tested. Prenatal diagnosis should be offered to those who need it, but without applying any pressure on parents to agree to such testing. Minors and disabled persons must be provided with all the protection provided to others plus additional protection (e.g. seeking the child’s consent after describing to him/her the potential harms and benefits of testing in a simple manner appropriate to his/her age). Genetic counselling should be given in a compassionate and professional manner, offering guidance and allowing individuals and families to make an informed choice.

The Department of Biomedical Research in the Supreme Council of Health in Qatar is in the process of drafting policies, rules, and regulations for human research involving genetics and molecular genetics, as well as for the use of the stem cells.

### **Egypt**

The National Research Centre, which operates according to national guidelines, and some private clinical genetics centres in Egypt provide services in clinical diagnosis of congenital malformations and genetic diseases associated with chromosomal abnormalities or mutations in single genes, among others. Collaborative efforts between departments of gynaecology and obstetrics and clinical genetics have resulted in the creation of facilities for prenatal diagnosis and PGD for assisted reproductive technologies. This is to provide better medical care, reduce risks, and help individuals to make informed decisions about their future. Genetic tests are also carried out in Egypt for forensic purposes and paternity cases are sometimes solved by DNA examination upon the request of the court.

Genetic testing has also played a role in research in the field of Egyptology and is helping researchers better identify and study Pharaonic relics. Accordingly, Egypt’s Supreme Council of Antiquities announced its collaboration with Applied Biosystems and the Discovery Channel to establish the first such laboratory in Egypt, located in the Egyptian Museum in Cairo, in order



to test samples from ancient royal mummies.

### **Bahrain**

Bahrain's Law No. 11 (2004) regarding premarital genetic screening for both genders, permits premarital genetic counselling and genetic testing for certain blood disorders based on biochemical analysis as part of the Ministry of Health's services offered to the public.

As Bahrain states in the questionnaire provided by the UNESCO, prenatal diagnosis and all other issues are subject to international standards and need to be adapted to suit the Bahraini terms of regulations prescribed by the Ministry of Health. The laboratory facilities for prenatal testing involving karyotyping have not been optimized yet, so such tests are referred to specialized labs abroad. A special interest is focused on this service, but official documentation on its regulation does not yet exist.

### **UAE**

The UAE does not have comprehensive guidelines for genetic testing and addresses the issue in the following draft law. Article 15 of proposed Federal Law concerning the licensing of fertility treatment centres in the country states: "Without prejudice to the provisions of Art 14 of this Act, it is permitted upon the written consent of the couple to perform pre-implantation genetic diagnosis for the purpose of identifying genetic diseases provided that all necessary procedures are taken to ensure no harm is done to the fertilized ovum". Article 2/27 of Federal Law No. 28/2005, concerning personal status, mentions that: "In order to proceed with a valid marriage contract, it is conditional to submit a report from a competent medical committee formed by the Ministry of Health stating that the couples are free from diseases, prescribed by the same law according to which divorce may be requested".

### **Tunisia**

Tunisia has elaborated more on the matter of genetic testing. Even though regulations directly related to genetic testing have not yet been voted on in Tunisia, the country has stipulations concerning this issue in different existing laws indirectly related to genetic testing. Law No. 2001-93 (7 August 2001), concerning reproductive medicine, states that therapeutic actions on embryos, which may include genetic testing, require the consent of both parents and must be done strictly for medical purposes. The purpose of these actions is limited to detecting an abnormality and identifying a way to prevent and treat it.

According to Law No. 2002-54 (11 June 2002), concerning medical laboratories, genetic testing must be conducted in an authorized laboratory where confidentiality is respected. Results are delivered directly to the person concerned, to their legal representative, or to their attending physician. All references and results of research must be stored and kept confidential for at least five years. Law No. 2004-63 (27 July 2004), concerning the protection of personal data, states that the use and conservation of the results of genetic tests are strictly regulated with severe penalties in case of abuse.

Law No. 2003-51 (7 July 2003) modifies and complements Law No. 98-75 (28 October 1998), concerning the attribution of paternal name to abandoned children or children of unknown

lineage. The law states that DNA analysis can only be used to establish or to contest paternity if ordered by a judge.

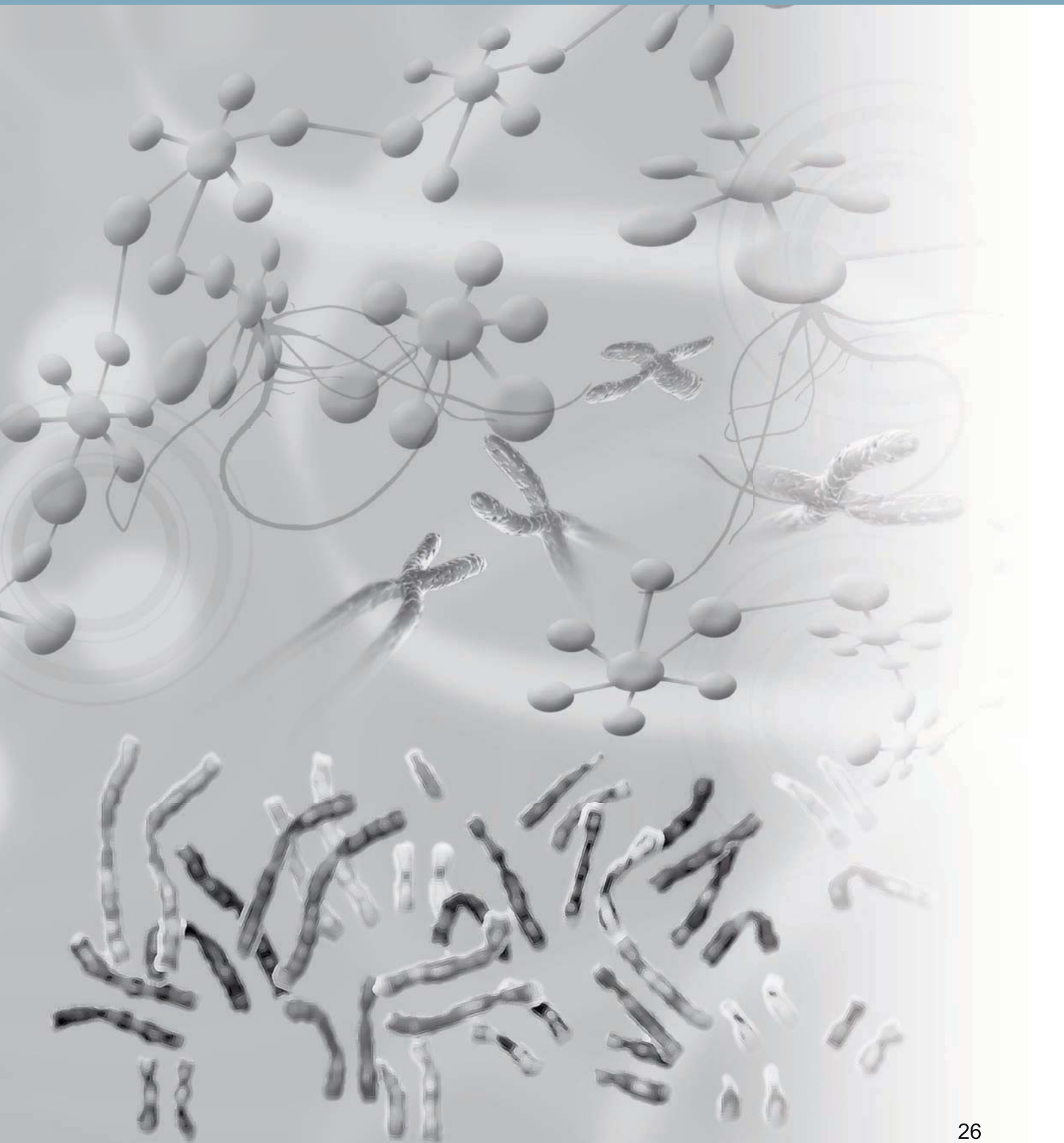
### **Lebanon**

During the last decade, many laboratories for genetic testing have been established in university hospitals and private clinics in Lebanon. These laboratories carry out the following tests:

- Genetic tests to diagnose mutations in monogenic or polygenic diseases
- Chromosome studies
- Genotyping, human leukocyte antigen (HLA) analysis
- Genetic tests for medical research
- Genetic tests for judicial purposes (legal medicine, DNA fingerprinting, etc.)

All abovementioned tests are regulated under Law No. 625 (2004) concerning human genetic tests. Articles 1-6 of this law address: genetic mutations, ethnic discrimination, genetic characteristics of the individual, prohibition of manipulations affecting human dignity, confidentiality of tests, and prohibition of every commercial practice in relation with genetics. Articles 7-20 concern genetic tests and their scientific or medical purposes, informed consent, delivery of results, paternity testing, the necessity of obtaining written consent from the guardians of minors and disabled persons, and the necessity of obtaining written consent from the Ministry of Health prior to testing groups or inhabitants of a particular region. Articles 21-26 concern the issue of DNA banks and medical confidentiality in relation to the conservation or destruction of results or specimens.

## 4. Human Genome and Gene Analysis



## 4. Human Genome and Gene Analysis

*The issue of the human genome and gene analysis and the issue of genetic testing proved confusing to most of the countries surveyed. Indeed, most of them could not distinguish between the two issues.*

*If we focus on informed consent, collection and storage of samples, release of results, intellectual property rights, confidentiality, and export and import of information related to the human genome and gene analysis we find that Syria, Yemen, Morocco, Libya, Palestine, Kuwait, the UAE, and Saudi Arabia have no regulations concerning this issue.*

### **Palestine**

Palestinian regulations are only relevant to genetic testing; the Draft Law on Forensic Medicine, which was presented in 2003 by the Council of Ministers, stipulates that part of the mission of the forensic doctor is to perform genetic tests (Art. 13).

### **UAE**

The UAE has a proposed Federal Law concerning the licensing of fertility treatment centres, which mentions in Art. 15: “Without prejudice to the provisions of Art. 14 of this Act, it is permitted upon the written consent of the couple, to perform pre-implantation genetic diagnosis for the purpose of identifying genetic diseases provided that all necessary procedures are taken to ensure no harm is done to the fertilized ovum”.

### **Kuwait**

Although Kuwait has no regulations on the human genome and gene analysis, it respects the IOMS recommendations and final statement in “Genetics, Genetic Engineering, the Human Genes, and Genetic Treatment: An Islamic perspective”. These recommendations state that genetic engineering is allowed for the prevention, treatment, or alleviation of diseases either in the form of genetic surgery or when genes are inserted into another body, but it is prohibited on germ cells due to some religious reservations. It also stipulates that genetic engineering is to be encouraged and provided to people lacking the financial means to undergo such costly practices, but that it must not be used to change the human genetic makeup, to tamper with the personality, or to interfere with competence or individual responsibility.

### **Saudi Arabia**

There are no regulations on the human genome and gene analysis in Saudi Arabia, but rather only draft guidelines such as the “Organizational System for Research Practices on Living Beings”, which were issued by NCBE. These draft guidelines are only partially respected and some institutes are bypassing them, especially the stipulation that a gene bank database should be established in King Abdelaziz City for Science and Technology, since some samples are being sent abroad.

Despite this fact, Art. 66-84 of these draft guidelines have some important stipulations concerning this issue. They stipulate that gene analysis is carried out for prenatal diagnosis and PGD and that genetic counselling is recommended, confidentiality is mandatory, all results are national property, and that international investigators may be invited to conduct research on stored

samples in Saudi Arabia after approval by the national committee.

## Libya

Libya has not established a legal framework for the human genome and gene analysis. It has merely issued recommendations in the Scientific Symposium on Gene Banks (2004) to preserve the confidentiality of the patients' hereditary data and highlighted the importance of scientific research in the field of genes and the need to draft legislation to regulate such research.

*Sudan, Qatar, Egypt, Algeria, Jordan, and Oman have either guidelines regulating this issue or national regulations, but most of these guidelines are not comprehensive.*

## Sudan

Among these countries, only Sudan has expanded on this issue under its effective Guidelines for Genetic Research on Sudanese Subjects (University of Khartoum, Institute of Endemic Diseases), which are based on the recommendations of the Human Genome Organization's ethical, legal, and social issues committee. The guidelines direct researchers to obtain either individual or family consent. They state that the storage of genetic material and information is restricted to authorized personnel and that the use of well-designed security procedures is required. The guidelines also cover two aspects regarding the release of research results and information. The first aspect affirms the right of the subjects to easy access to nominated members of the research groups for consultations about the results of their research, although the quantity of the information released is decided by the research team and not the research subjects. The second aspect deals with the release of information obtained from research to national or international collaborators, which should first be discussed and decided upon by the research group. Intellectual property rights are not described clearly in the guidelines. Confidentiality is implicitly expressed under the stipulation for the use of well-designed security codes and the restriction of access to the research team.

Concerning the export and import of information, the guidelines allow the research group to share genetic material with collaborating groups, and they regulate the shipment, usage of appropriate forms, and approval of the institutional and national ethical committee.

## Qatar

Qatar regulates issues related to the human genome and gene analysis through WHO's "Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services" under the title "Banked DNA", which are presented as an appendix to "Research Policies, Procedures, and Guidelines" by the Shafallah Genetics Medical Centre, (SGMC). According to these guidelines, existing stored specimens or samples, such as those in university or hospital departments or collections of blood spots, should not be subjected to new rules for consent or re-contact that may be established in the future. An informed consent that would permit the use of a sample for genetic research in general, including unspecified future projects, appears to be the most efficient approach, which avoids costly re-contact before each new research project. The consent should specify that family members may request and be given access to a sample to learn their own genetic status. While spouses may not have such a right of access, their concerns should be considered (i.e. if the couple is planning to have children, it is the moral obligation of the party whose DNA has been banked to provide the spouse with any relevant

information). All samples should be used with appropriate regard for confidentiality, except for forensic purposes.

Qualified researchers may have access if identifying characteristics are removed. Particularly between developing and developed countries, patenting has the potential to impede international collaboration to the detriment of service delivery to those with genetic disorders. Genetics differs from many areas of research in that important new knowledge can come from a family or an ethnic group with a particular genetic variant. If this leads to the development of a diagnostic test or new therapies, equity requires that the donors or the community in general, should receive some benefit.

### **Egypt**

Egypt only mentions that there are national regulations from the Medical Services Department, Gynaecology and Obstetrics Clinic Infertility and IVF Clinic of the National Research Centre in Dokki, Egypt, which regulates genetic testing and also claims to respect the opinions of the 15th IOMS Seminar (2004) on the Human Genome Project and its legal ramifications, without offering any further details.

### **Jordan**

Jordan mentions the Institutional Review Committee (IRC) regulations as well as the Jordanian intellectual properties Law No. 32 (1999).

The human genome and gene analysis is conducted in Jordan through collecting fluid samples (particularly blood) from human subjects and it is regulated by bioethics committees in each scientific institution. The committee specifies the amount of blood that needs to be obtained to conduct the study and the need for written informed consent to conduct any study, acknowledging the complete privacy of participants and maintaining the confidentiality of all disclosed information. It is prohibited to keep the excess samples, which must be completely destroyed. The party conducting the study on the samples should sign legally binding documents that prohibit transporting the samples outside the country, and all studies or research should be conducted in laboratories inside Jordan. The findings of the research can be published under the condition that written consent is obtained from participants beforehand.

If new scientific findings are made, the researcher has the right to obtain a patent under Art 1-40 of the above-mentioned Law No. 32.

### **Oman**

Oman has guidelines (“Guidelines for collection, transfer, and exchange of human genetic data, proteomic data and biological samples”), but they are not yet in practice. The release of the Human Genome Project data engendered great interest in genetic research in Oman. The high rates of consanguineous marriages, extended family structures, genetic diseases, congenital anomalies, and the relative isolation of some villages and communities have led to increased interest in developing genetic screening, diagnosis services, and research in Oman both on the part of local and international researchers. Both research and genetic services may potentially benefit from collaboration involving transfer and exchange of genetic data, proteomic data, and biological samples.

The Oman Genetic Material Task Force has examined the principles set out in the International Declaration on Human Genetic Data and recommends that they should serve as a basis for human genetic work in Oman. These general guidelines stipulate that prior, free, informed, and express consent without financial or other kinds of coercion or inducement should be obtained prior to the collection of genetic data, proteomic data, and biological samples and prior to their storage. The subject also has the right to withdraw his/her consent and the right to decide whether or not to be informed of research results. They also state that confidentiality must be respected.

All matters not covered in the prior consent are decided on by medical research ethics committees. These guidelines also encourage international cooperation and the sharing of benefits. Since said guidelines are not yet being implemented, the Oman Genetic Material Task Force also recommends that an independent committee be established to monitor and enforce the implementation of the recommended guidelines and the keeping of accurate records.

### Lebanon

Only Lebanon has directly and explicitly addressed this issue (Law No. 625 of 2004 on human genetic testing). Articles 1-6 of this law address: genetic mutations, ethnic discrimination, genetic characteristics of the individual, prohibition of manipulations affecting human dignity, confidentiality of tests, and prohibition of all commercial practices related to genetics. Articles 7-20 concern genetic tests and their scientific or medical purposes, informed consent, delivery of results, paternity testing, the necessity of obtaining written consent from the guardians of minors and disabled persons, and the necessity of obtaining written consent from the Ministry of Health prior to testing groups or inhabitants of a particular region.

Articles 21-26 concern the issue of DNA banks and medical confidentiality in relation to the conservation or destruction of results or specimens. A draft law is currently being prepared to create a national database for DNA profiles. This database will be under the control and supervision of the Ministries of Justice and the Interior. In addition, all major institutes and universities in Lebanon have their own institutional review boards to regulate all research related to the human genome and gene analysis in accordance with national and international guidelines on research bioethics.

### Tunisia

Tunisia has stipulations in a number of laws concerning the human genome and gene analysis. Law No. 2001-93 (7 August 2001), which concerns reproductive medicine, states that prior, informed, and written consent of research subjects is required before conducting research and that research on embryos for commercial, industrial, or eugenic purposes is forbidden.

Law No. 2002-54 (11 June 2002), which concerns medical laboratories, states that all references to and results of research must be confidentially stored for at least five years. Local ethics committees must approve all research procedures and protocols.

According to Law No. 2004-63 (27 July 2004), which concerns the protection of personal data, the use and conservation of genetic test results is strictly regulated with severe penalties in the case of abuse.

## **Bahrain**

The human genome and gene analysis in Bahrain is regulated by Law No. 11 (2004), which concerns premarital genetic screening for both genders. As part of the Ministry of Health's services offered to the public, it offers premarital genetic counselling and genetic tests for certain blood disorders based on biochemical analysis. However, since the lab facilities for prenatal tests involving karyotyping have not been optimized yet, the required tests are referred to specialized laboratories abroad. Furthermore, we note that this issue has been discussed as a limiting code of practice within the Bahraini Draft Guidelines for Regulations of Assisted Reproduction (p. 10), which mention that the "application of genetic engineering technologies on human gametes and embryos for the treatment of genetic hemoglobinopathies is only allowed in cases when an agreed consent is obtained from the committee in charge at the Ministry of Health".

## **Algeria**

The Algerian Executive Decree 05-438 (10 November 2005) provides the conditions to permit prenatal research.



## 5. Research Involving Human Subjects



## 5. Research Involving Human Subjects

*In most of the 17 Arab countries that participated in the UNESCO survey, research involving human subjects is addressed mainly through laws and guidelines. To date, Syria, Yemen, Morocco, and Saudi Arabia have no regulations or laws concerning this issue. However, Morocco and Saudi Arabia have, respectively, draft laws and draft guidelines that regulate this issue, but they have not yet come into effect.*

### Morocco

Research involving human subjects in Morocco is not yet legally regulated. However, a draft law for the protection of persons involved in biomedical research, which is very similar to the French law (Loi Huriet), is being prepared by the Ministry of Health. The draft of a new code of conduct for medical doctors states that “Medical doctors can participate in biomedical research involving human subjects according to the national law. They have the duty to check and confirm the relevance of the research as well as the objectivity of its hypothesis and conclusions. The physician who takes part in biomedical research as an investigator must take all necessary caution to make sure that the proposed research will neither deteriorate the relationship of mutual trust which binds him/her to the patient, nor affect the continuity of the care due to the patient” (Art. 15).

These draft laws are still under discussion and are not yet effective, but research ethics committees have been independently established in Moroccan medical schools (beginning in 1989 in Casablanca) and all research proposals are examined before obtaining the Ministry of Health’s authorization. These research ethics committees are working according to international guidelines to ensure the protection of participants in biomedical research.

### Saudi Arabia

The Saudi Arabian draft guidelines “Organizational system for research practices on living beings” issued by the National Committee on Biomedical Ethics (NCBE) states that the purpose of the research should be clear and that informed consent is mandatory (and can be withdrawn at any time) and should be submitted to the Institutional Ethics Committee for approval. It also provides for a monitoring system for bioethics and protocol review and approval. Benefit sharing is not clearly addressed in the guidelines and it is mentioned only that benefits should exceed the expected risks. NCBE is responsible for developing guidelines and its executive office is responsible for monitoring their implementation.

### Kuwait

The issue of research on human subjects is only briefly addressed in the Kuwaiti Ministry of Health’s regulation concerning the establishment of the Committee for Medical and Health-related Research Review (2006). It is silent on the purpose of research, informed consent, voluntary participation and withdrawal, and benefit sharing. It only addresses the research protocol review process and authorization of research. The regulation specifies that research authorization is granted by the Committee for Medical and Health-related Research Review, which is responsible for supervising the research, ensuring compliance with the Ministry of Health’s priorities, and reporting to said ministry. However, according to the survey results, most practicing doctors are unaware of these regulations, thus they are not effective. Kuwait

respects the IOMS guidelines, which state that the research purposes should seek to benefit the subject's health and benefit the overall wellbeing of humankind.

## UAE

Although the UAE has legal stipulations concerning research on human subjects, they are merely brief references to the issue and are by no means sufficient or comprehensive. This is evident when one examines the only law in the UAE that mentions this issue, Federal Law No. 7/1995 on practicing the human medicine profession. This law deals only with the responsibility of the physician conducting research on human subjects. Article 14 of proposed Federal Law, concerning the licensing of fertility centres, refers obliquely to this issue: "It is prohibited...to apply genetic modifications on the newborn features...".

## Algeria

As is the case in the UAE, Algeria has legal stipulations concerning research on human subjects, but they are merely brief references to the issue and are by no means sufficient or comprehensive. This is evident when one examines Law No. 90-17 (31 July 1990) on the protection and promotion of health, which modifies Law 85-05. It stipulates that experimentation on humans for scientific research purposes should respect moral and scientific principles that regulate the practice of medicine. The participant's consent or that of his legal representative is necessary.

## Palestine

In Palestine, the Amended Basic Law of 2003 considers medical or scientific experiments on any person without prior "legal consent" unlawful. It is worth mentioning that the Draft Palestinian Constitution (2003) has adopted a similar provision.

Concerning medical research, Art 60 of Public Health Law No. 20 (2004) stipulates that the patient must express his/her willingness to participate in medical research and training that take place in the public health institution. This right also extends to the respect of his/her privacy, dignity, and religious and cultural beliefs.

*Sudan, Qatar, Jordan, and Egypt have guidelines that stipulate the necessity of written and free informed consent to participate in research that has been approved by an ethics research committee. They also demand respect for the subject's right to withdraw from the study, with the exception of Jordan, which is silent on the withdrawal issue.*

## Sudan

Chapter 2 of the Sudanese Guidelines for Ethical Conduct of Research Involving Human Subjects emphasizes that autonomy, beneficence, non-maleficence, and justice are the core ethical principles for conducting research involving human subjects. This document also states that informed consent should be freely given by participants and must always be accompanied by the approval of an ethical research committee. The guidelines provide for the equitable distribution of burdens and benefits in the selection of subject groups in research and state that a subject who withdraws from research for reasons related to the study (e.g. side effects of a drug) or who withdraws on health grounds should be paid or recompensed as if s/he had completed the study, whereas a subject who withdraws for any other reason should be paid in

proportion to the amount of participation.

As for the Public Health Act Update (2006), it is mentioned in Chap. 2 Art. 4 that the public health council, in collaboration with other concerned bodies when relevant, is responsible for the supervision of research involving human subjects to guarantee the adherence to ethical practices that take into consideration the values, traditions, and cultural context of the Sudanese community. The act outlines the requirements of health services provided for the purpose of research, including obtaining informed consent and ethical clearance from the health research ethics committees.

### **Qatar**

In Qatar, the rules and regulations for research issued by Hamad Medical Corporation (HMC) and the research policies, procedures, and guidelines issued by Shafallah Genetics Medical Centre (SGMC), in addition to the recently adopted International Guidelines for Biomedical Research Involving Human Subjects written by the National Health Authority (NHA), regulate all research involving human subjects with nearly the same requirements and regulations. (The only difference is that NHA's adopted guidelines are more detailed.) Weill Cornell University in Doha operates under the ethical principles outlined in the Belmont Report and the Declaration of Helsinki, which are both encompassed in the SGMC guidelines, which regulate research involving human subjects in Qatar.

No research on human subjects can be initiated at SGMC or HMC without the approval of the SGMC Research Advisory Committee or the HMC Research Ethics Committee, respectively.

Obtaining the informed consent of every research subject is a requirement. The basic elements of the consent form are as follows: a statement that the study is for research purposes; the purpose of the research; the expected duration of the subject's participation; the number of participants in the study; a description of the expected risks and benefits to the subject; an explanation of the availability of compensation and medical treatment if injury occurs; and an assurance of confidentiality and the concealment of the subject's identity in any published research. Furthermore, participation is voluntary and refusal to participate or withdrawal will involve no penalty or loss of benefits to the subject. The subject must be informed that findings obtained during the research that may impact the subject's willingness to continue to participate.

NHA's adopted document adds extra requirements: the research subject must be told that, after the completion of the study, subjects will be informed of the findings of the research in general and individual subjects will be informed of any finding that relates to their particular health status. Additionally, subjects have the right to access their data on demand, even if the data lacks immediate clinical utility. Subjects must also be informed of the research sponsor, and whether or not biological specimens collected in the research will be destroyed at its conclusion. If not, the subjects must be provided with details about the specimens' storage and possible future use, and whether commercial products may be developed from biological specimens.

In addition to the informed consent requirement, the SGMC Research Advisory Committee requires that: risks to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits; and the selection of subjects is equitable. The HMC Research Ethics

Committee adds to the previous criteria that, in some cases, the committee may waive the informed consent requirement.

## Egypt

Article No. 43 of the Egyptian Constitution (1971) states: “No medical or scientific experiment may be performed on any person without his free consent”. Another important regulation addressing this matter is Decree No. 238/2003 (concerning professional ethics regulations), which was issued by the Ministry of Health and Population (MoHP) as an amendment to the 1974 regulations and pursuant to the resolutions of the Council of the Egyptian Medical Syndicate and the General Assembly of the Egyptian Physicians. Section 1 (Art. 52) of Chapter 4 of this resolution (entitled “Conducting Medical Research and Experiments on Human Beings”) requires that the physician observe all moral, ethical, and religious guidelines stipulated by the responsible authorities (MoHP and the Medical Syndicates) on conducting medical research on human beings. Article 53 deals with the review and authorization of research, as the physician must obtain permission from MoHP and the Medical Syndicates to experiment with new drugs or techniques.

Articles 54-57 of Section 2 (“Procedures that Must be Followed Prior to Conducting Research on Human Beings”) address the physician’s obligation to weigh the benefits and risks of the research and inform the subject of these benefits and risks, as well as of the source of funding for the research. These articles also address the need for written informed consent from the subject or his/her guardian (signed in the presence of a witness) and the subject’s right to withdraw from the research without facing serious consequences. The physician must justify his research and obtain the necessary approval to conduct research on human beings (Art. 57). Section 3 is concerned with the procedures that must be taken during and after conducting the research on human beings (Art. 58, 59, and 61).

These articles stress that the research must be terminated immediately if it becomes apparent that the risks of the research outweigh the benefits and insists that the physician monitor the welfare and safety of subjects throughout the research. It also requires that the physician keep all research results and subject’s data confidential. Article 61 asserts the necessity that the physician obtains a guarantee from the research funding body that if the treatment (e.g. a drug being tested) is effective it must be available free of charge to the subject throughout the research project. This can be considered temporary benefit sharing. Ministerial Decree No. 435/2006 (also tackles this issue through annexing thereto the WHO’s “National guidelines and regulations for good clinical practice (GCP)” and adopting this document as Egyptian guidelines. Section 2 of the guidelines clearly states that the sponsor and the researcher must obtain the approval of the relevant ethics committee regarding the protocol of the clinical trials and the materials and methods to be used in obtaining and documenting informed consent. These guidelines stipulate that the researcher must obtain written informed consent from the subject and ensure his/her safety and confidentiality during the research programme. It is also stated that any and all violators of these rules, laws, regulations, and codes of conduct will be penalized.

## Jordan

In Jordan, the Clinical Trial Law (for trials involving human subjects) No. 67 (2001) states that

clinical trials cannot be conducted on human subjects until written informed consent is obtained and the required medical tests are performed to ensure the safety of the human subjects. The party conducting the study is legally responsible for any injuries incurred by the human subjects. The law also requires an agreement with a Jordanian insurance company to cover the damages that may result from the study, especially injuries (adverse effects) to human subjects.

The law requires that human subjects' participation be voluntary, but does not mention the matter of participants' withdrawal after the initiation of the research and thus does not address the issue of the risk-benefit ratio for participants. The ethics board (IRB) must approve any and all research projects involving human subjects. The law mentions that violations of these regulations will result in penalization.

### Libya

This issue is tackled in Libya under Art 15 of Law No.17 (1986), which concerns medical liability. It forbids scientific testing on a living human subject without his/her consent. The subject must be guaranteed that the physician conducting the research is licensed and will carry out the tests in accordance with recognized scientific principles. Article 6 of Law No. 20/1991 (concerning the consolidation of freedom) stipulates that bodily safety is every person's right and that it is forbidden to carry out scientific tests on a living person unless s/he volunteers.

### Tunisia

Title VI of the Tunisian Code of Medical Ethics states its regulations related to experimentation and research involving human subjects. Permission for conducting research for therapeutic purposes is only granted after an evaluation of the potential benefits and risks. It stipulates that any human experimentation be conducted under the surveillance of a qualified doctor and great prudence must be exercised in experiments that could have potentially adverse effects on the patient. Article No. 106 states that, in the case of non-therapeutic research, the patient must be informed of the nature and objectives of the research and its effects on his life and health. Article No. 107 states that non-therapeutic research cannot be conducted without the subject's free and informed consent.

### Bahrain

In Bahrain, the Ethical Guidelines for Health Research emphasize the protection of human subjects by adhering to principles such as: protecting human rights and the autonomy of study subjects; weighing the benefits and risks of the study; obtaining informed consent; and submitting research proposals for institutional review.

Subject 27 of Decree Law No.7/1989 (on laws and ministerial decisions as to the regulation of the medical practice, private hospitals, dentistry, and the medical professions) states that physicians are not allowed to experiment on their patients or use them as subjects in research studies without first obtaining the approval of the relevant authorities in the Ministry of Health. Said authorities seek to prevent any adverse effects on patients participating in the research, which may result from research procedures or materials (e.g. drugs) used in the research.

## Lebanon

In Lebanon, this issue is well regulated under several laws and guidelines. Indeed, Law No. 574 (2004) pertaining to patient's rights and informed consent tackles in its first chapter the subject's right to access of information. Chapter 2 stipulates the necessity of obtaining the patient's consent. Chapter 3 requires respect for the patient's personal life and the confidentiality of his/her information. Chapter 4 ensures the patient's right to see his/her medical file.

Inspired by the Nuremberg Code (1947), the Helsinki Declaration (1964), which was reviewed by the General Assembly of the World Health Organization (1975), and the directives of WHO and Edinburgh (2000), and in recognition of the increasing number of medical faculties and university hospitals in Lebanon, the CCNLE found it necessary to propose a draft law on creating Institutional Review Boards at hospitals in which medical research or experimentation are conducted.

The draft law on establishing Institutional Review Boards in hospitals (submitted in 2002 and currently pending in parliament) was preceded by guidelines in 2001, which outlined general principles on drug testing on human beings. These guidelines were adopted by the Ministry of Health. They require:

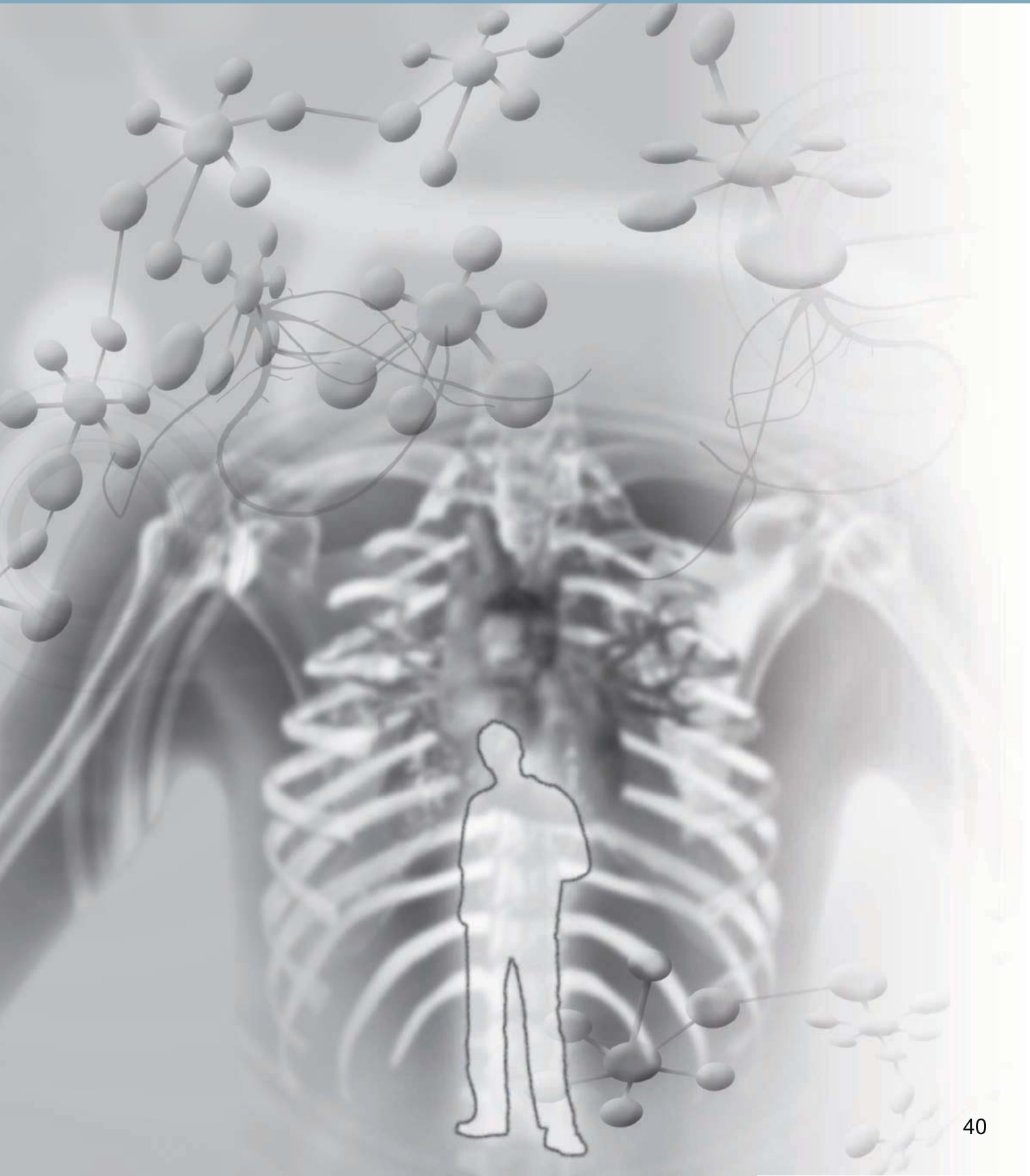
- Written and informed consent of the volunteering human subject
- Stated purpose of the research
- Assurance that the research should not present any danger whatsoever to the human subject
- Authorization of the Ministry of Health
- Special measures for research conducted on minors and subjects under guardianship.

## Oman

The Ministry of Health in Oman initiated the first national "Five Year Health Development Plan" in 1976. It established the Department of Research and Studies under the Directorate General of Planning in 1991. It has developed a plan for the prioritization of research, the development of a research culture, the implementation of ethical practices, and the development of the technical capabilities of potential researchers and research teams. The seventh "Five Year Health Development Plan, 2006-2010" addresses 30 topics in different priority areas, including research and experimentation. A specific "Health Research Policy" was created by a Ministerial Decision in 1999 and updated in the seventh plan.

The Omani authorities recognize that ethical committees and an ethical review system should be developed to ensure the broadest protection possible for potential research participants and to ensure the highest ethical quality of science and biomedical research. The purpose of ethical committees in reviewing biomedical research is to safeguard the subject's dignity, rights, safety, justice, benefits, and informed consent. Therefore, the Ministry of Health in Oman established the "Research and Clinical Studies Committee" in 1998 pursuant to a ministerial decision. The members of the committee developed the "Guidelines for Submission of Research Protocols for Review and Approval of the Research and Clinical Studies Committee". The committee relies mainly on the Helsinki Declaration to resolve any sort of ethical conflict in research involving human subjects.

## 6. Organ Transplantation





## 6. Organ Transplantation

*The issue of organ transplantation is one of the best regulated bioethics issues in the Arab world. Most of the 17 countries that took part in the survey have national regulations or at least some guidelines concerning this issue. Although they differ on some points related to organ transplantation, they agree on essential principles such as: the necessity of written consent from donors after both donors and recipients have been fully informed about the procedure and potential complications; the right of the donor to withdraw such consent at any time; and the principle of organ donation without financial compensation.*

### Sudan

The Sudanese Federal Ministry of Health established the Sudanese Programme for Organ Transplantation (SPOT) to ensure that all transplant programmes in Sudan follow best clinical practice as defined by evidence-based medicine. The current guidelines issued by SPOT set mainly managerial and technical standards for the transplant units and tissue typing laboratories across the country. The current guidelines focus on renal transplant practices. They state that a living non-related donor should only be considered when a living related donor is not available. The SPOT advisory board is responsible for ensuring that all transplant donations from living non-related donors are voluntary and that there is no financial remuneration apart from reasonable expenses (e.g. loss of employment earnings). An independent panel composed of a surgeon, a clinician, and a layperson considers every proposal including those involving living non-related donors.

The guidelines state that living related donors should be selected from the siblings or parents within the patient's family unit. Children (particularly females) should only be considered as a last resort. They also emphasize the importance of documenting measures taken to ensure that a donor being tested has not been coerced by other members of the family and that donation is truly voluntary. The Human Organs and Tissues Transplant legislation, endorsed as part of the Public Health Act in 1978, describes the conditions for the transplant of an organ or a part of an organ from a deceased person. The confirmation of the donor's death is a prerequisite for transplant. In addition, the legislation prohibits transplant from a deceased person without prior informed written or verbal consent in the presence of two witnesses. However, a close relative may give consent provided that the deceased had not expressed an objection to the donation of an organ or a tissue from his/her body when s/he was alive. A living donor must be made aware of the disabilities or risks that may possibly result from organ or tissue donation. The donor also has the right to withdraw consent at any time before the operation. These two last stipulations are mentioned in the legislation of most of the 17 countries.

It is to be noted that the survey in Sudan showed that the SPOT guidelines are in effect, whereas the legislation of 1978 is not.

### Qatar

In Qatar, this issue is addressed under Law No. 21 as to the Regulation of Human Organ Transplantation. According to this law, surgeons are permitted to transplant an organ from either a living donor between the ages of 18 and 70 or a brain dead donor in order to save a person's life or to treat the failure of a vital organ. Transplantation of reproductive organs that

bear genetic characteristics, whether taken from a living or a deceased person is prohibited. Transplantation from a deceased person requires a statement made by three physicians from different fields confirming death with the currently accepted reasonable medical standards and documentation (e.g. a will) written by a person expressing his/her willingness to donate his/her organs after death. In the absence of written consent from the deceased potential donor written in his lifetime, consent must be obtained from all first and second degree relatives of the deceased whether they are inside or outside Qatar. Donation is not permitted if the deceased had expressed (during his/her lifetime) in the form of a written will attested by two witnesses the desire not to donate his/her organs.

Violators of this law are punished by imprisonment and the payment of a fine.

### Libya

Organ transplantation is regulated in Libya under Art. 2, 3 and 9 of Law No. 4/1982 concerning the permissibility of dissecting cadavers and transplantation of deceased persons' organs. The law allows transplanting organs from deceased persons provided that they expressed their consent while they were alive or that consent is granted by one of their relatives (up until the fourth degree). Transplants must be performed in hospitals by specialized physicians. It is prohibited for a living person to donate an organ that is essential to sustain the donor's life; Art. 10 of the same law states that "it is forbidden for living persons who have reached 18 years and enjoy their full mental faculties to donate their single indivisible organs". The necessity of obtaining the donor's consent and the respect of the integrity and safety of the body is expressed in Art. 15 of Medical Liability Law No. 17/1986. Article 16 of this law permits implanting artificial organs, provided no harm is inflicted on the body and only after verifying their compatibility with the patient and preparing his/her body to accept them.

Furthermore, in 2006 the National Programme for Organ Transplant, under the sponsorship of the Ministry of Health and Environment, issued the basic principles of the processes, behaviours, and ethics of transferring and transplanting human organs. It provides for all of the aforementioned and restricts organ transplant operations to absolutely necessary cases. It also specifies that organs may be transferred from living relatives until the second degree, from milk siblings, or from those who have marital ties. This excludes the transplant of regenerated organs like bone marrow transplantation. Transplants may be carried out using the organs of deceased donors, unidentified deceased persons, or those with no living relatives following approval from the relevant authorities and provided there are no suspicions regarding the cause of death and that cause of death has been certified by physicians with no consanguine links to the recipient. This physician shall not participate in the organ removal and transplant. These guidelines also prohibit the use of organs from a minor or an adult under legal protection, including prisoners and those afflicted with mental disorders.

Both Law No. 4/1982, concerning permission to dissect cadavers and the transplant of deceased persons' organs, and the basic principles mentioned above affirm the right of the donor to withdraw his/her consent and prohibit the transplant of tissues or organs pertaining to reproduction. They also prohibit the sale and trade of human organs and the use of organs from fetuses except in specific cases and under strict rules. They also detail the accepted signs for death (cardiac death and brain death) and the necessity of carrying out tests on both the donor

and recipient before transplantation.

## Egypt

Egypt has no express stipulations regulating organ transplantation other than cornea transplantation, which is classified as an organ rather than a tissue in Egypt. Many articles in the Egyptian Penal and Civil Laws reference penalties for the wrongdoings of any person who causes harm to human organs. There are specific amendments to certain articles regarding physicians who act with the intent to cause harm (e.g. the amendment to Egyptian Penal Art. 240 by Law No. 95 of 2003). Law No. 103/1962 and Law No. 79/2003 regulate eye banks, eye grafting, and eye source. Decree No. 291/2000 and Decree No. 234/2003 from the Ministry of Health and Population also regulate the procedures and purposes of establishing eye banks, specifically those concerned with cornea removal and grafting and the sources for these corneas (e.g. brain dead donors).

As for Resolution No. 238/2003 of the Ministry of Health and Population on professional ethics regulations (which was issued as an amendment to the 1974 regulations and pursuant to the resolutions of the Council of the Egyptian Medical Syndicate and the General Assembly of Egyptian Physicians), it addresses medical interventions of a special nature, including human organ and tissue removal and transplantation. It also regulates under article 50 various aspects of dealing with human body parts in any way in general terms (such as informing the donor of the risks to which s/he may be exposed as a result of the organ transplant surgery, and the prohibition against trading in human organs). It also provides for the necessity of obtaining informed consent from the donor.

Concerning penalties, the Laws of Medical Syndicates deal with the violation of these rules by any physician (who by definition is a member of the Syndicate) through a disciplinary action or other forms of punishment, should the disciplinary council transfer the case to the criminal investigation authority. It should be noted that, although there are no regulations on organ transplantation (other than cornea transplantation), many debates have taken place between the religious authorities and the parliament on this issue.

## Algeria

In Algeria, Chapter III of Title IV of Law No. 85-05 (16 February 1985) is entirely devoted to organ transplantation. The religious basis of the text comes from fatwas issued between 1980 and 1985 by the Islamic Superior Council on dissection, organ transplantation, and blood transfusion. This law states that organs can be removed from living donors only if it does not endanger the life of the donor. It is prohibited to remove organs from minors, mentally disabled persons, and persons with diseases that will affect the health of the donor and the recipient. Art. 164 of Law No. 90-17 (31 July 1990) modifying Law No. 85-05 (16 February 1985) states that organs can be removed from a deceased person after medical and legal confirmation of death, provided there is written consent from the person during his/her lifetime signed in the presence of two witnesses. In the event that the donor did not express his/her wishes, consent must be given by one of the adult members of his/her family. However, the deceased person's cornea or kidneys may be removed without a family member's consent if the recipient's state of health so requires or if the required organ would deteriorate in the time between death and the granting of consent. Article 165 of this law also provides for the necessity of keeping the identities of the

donor and recipient confidential.

In addition to the abovementioned laws, there are many ministerial orders (from 1998 to 2006), fatwas (e.g. those issued by Sheikh Ahmed Hamani), and Islamic Committee Orders (e.g. No. 1, No. 5, No. 6) that regulate the issue of organ transplantation.

New legislation (Law No. 09-01 of 25 February 2009) addresses two types of trafficking: on the one hand, organs, tissues, and cells, and on the other hand, products of the human body. Organ trafficking leaves the buyer and the agent exposed to imprisonment of 3-10 years and to a heavy fine. However, the donor who has received remuneration, in cash or in kind, is not penalized. This law also specifies penalties (both imprisonment and heavy fines) for removing organs from someone or from a cadaver without consent, as well as the penalties for organ removal performed under aggravated circumstances (on a minor or a mentally disabled person) by groups carrying weapons or organized criminal groups. The penalties for trafficking tissues, cells, and other products of the human body are also delineated.

### Jordan

This issue is addressed in Jordan under Law No. 23 of 1977, which concerns benefiting from human organs, as well as under updates of the law in 1985 and 2000. These laws define organ transplantation as the removal, excision, or extraction of an organ from a living person or cadaver and the organs' modification or implantation into a living human beneficiary. They detail the conditions for organ donation from living, dead, and brain dead donors. For example, organ donation is allowed if it does not affect the living donor's health and organs cannot be removed from a cadaver donor before the donor is declared dead in a written medical report by a specialist who is not performing the organ transplant surgery. Organ transplants may be performed on among human subjects regardless of their age and written consent must be obtained from the donor or his/her legal guardians. Article 10 of this law details the penalties for violations of these laws.

It is important to highlight that all these laws stipulate that Jordan shall abide by fatwas issued by the Jordanian Fatwa Council concerning the issue of organ transplantation, particularly as it relates to brain death.

*It is to be noted that Jordan, Algeria, Qatar, Tunisia, Syria, Bahrain, the UAE, Kuwait, Lebanon, and Oman all mention in their respective surveys that organ donation is to be free of financial compensation.*

### Palestine

Palestine has no regulations on organ transplantation. Article 16 of the Basic Law (2003) makes reference to the transplantation of human organs and new scientific developments, but only generally addresses these issues, broadly stating that they should "serve legitimate humanitarian purposes". This same provision is also included in the Draft Constitution (Art. 27). Currently, there is a complete vacuum in the Palestinian legal system regarding transplantation and other issues related to new technologies, which may be harmful and may lead to serious violations of basic human rights. The only steps taken toward remedying the situation is a 2003 draft law on human organ transplantation, which remains in the general discussion phase.

It was drafted by Dewan al-Fatwa wa-Tashree' (the Palestinian Authority's governmental body responsible for legislative drafting within the Ministry of Justice), and previously prepared by the Islamic Fatwa and Research Centre and some specialist doctors.

### Tunisia

In Tunisia, Law No. 91-22 (25 March 1991) stipulates that living organ donors must be above 20 years of age and must enjoy their full mental faculties and legal capacities. Their consent must be given in the presence of the president of the tribunal. Concerning brain dead donors, diagnosis is based on clinical criteria and exams that are clearly laid out in a circular issued by the Ministry of Public Health (16 October 1998). Cadaver donors must be adults (or minors, provided that the consent of their legal representative has been granted), who did not oppose donating their organs during their lifetime and whose family members do not oppose such donation after their death. The law was updated in 1999 to provide for the possibility of choosing to write the term "donor" on national identity cards.

The National Centre for the Promotion of the Transplantation of Organs (CNPTO) manages the selection of recipients. It is also worth noting that only the anonymity of cadaver donors is guaranteed.

Tunisia bans the transplantation of reproductive organs that bear genetic characteristics, whether taken from a living or a deceased person.

### Syria

In Syria, this issue is regulated by Organ Transplant Law No. 30 (2003), which permits organ donation from living donors and cadavers. For living donors, the law does not require any kinship ties between the donor and the recipient. However, the donor must be an adult of 18 years or older. There is an exception permitting a minor to donate organs to his/her twin sibling, but this is conditional on the approval of both parents, if they are present, or one of them if they are not, or the children's legal guardian. Brain dead persons may be donors. The law also stipulates that the transplant beneficiary can be a minor. The law does not require preservation of anonymity. Breach of these stipulations is punishable by imprisonment and payment of a fine.

### Bahrain

Bahrain regulates organ transplantation under Decree Law No. 16 for year 1998 as to the transplant of human organs. The rules developed by the Ministry of Health, which are based on this law, state that organ donation can be performed with written consent from the donor and the recipient after both are proved fit for such a procedure. The donor can withdraw his/her consent at any time prior to the operation. As for donation by deceased persons, when the individual did not object to donating his/her organs while alive, written consent from his/her next of kin is sufficient. Death must also be confirmed and diagnosed by three physicians, including a neurologist and excluding the surgeon who will perform the transplant. This does not include donation from patients with brain death. Harvesting the organs of an unidentified cadaver is permitted with the approval of three physicians in the field. The law penalizes any violation of its provisions with imprisonment, payment of a fine, or both.

## Morocco

In Morocco, transplantation is regulated under Law No. 16-98, concerning the donation, removal, and transplantation of organs and human tissue. The law states that donation from living donors must be between related individuals (exclusively to/from parents, children, and spouses, provided that they have been married more than one year). Just as in Algeria, donation from minors and disabled persons is prohibited.

As is the case in the majority of the 17 countries participating in the survey, Morocco clearly requires free and informed consent that can be withdrawn at any time. Consent must be expressed and registered at the court of first instance in the presence of two medical doctors. As for brain-dead and cadaver donors, post mortem removal and transplant of organs are authorized if the individual expressed his/her consent while alive and this consent was registered at the court under the same conditions as living donors. Someone who is opposed to donating his/her organs after his/her death can express and register his/her refusal through a declaration to the President of the Primary Court. If there is no registered consent or refusal from the person during his/her lifetime, the principle of “presumed consent” is applied, unless there is opposition from close relatives (by decreasing order of importance: spouse, parents, or offspring).

Two decrees were adopted for the application of this law. The decree of 2 January 2003 created the Advisory Council for Human Organ Transplantation and put it in charge of monitoring the implementation of the law. The same decree listed the organs, tissues, and cells authorized for donation. The decree of 5 August 2004 institutionalized “registers” in the courts, reserved for declarations of consent or refusal to the donation of organs and human tissue.

The selection of recipients is addressed under the decree of 2 January 2003: “The Advisory Council for Human Organ Transplantation is consulted by the Ministry of Health on the national waiting list of transplantation candidates, which is held by the Ministry of Health”. There is no mention of xenotransplant in Moroccan law. As for financial compensation for donors, the decree of 2 January 2003 stipulates that it is prohibited and punishable by imprisonment and payment of a fine. It also stipulates that all expenses related to organ removal and transplant are to be covered by the recipient.

## UAE

This issue is regulated in the UAE under Federal Law No. 15/1993, concerning human organ transplantation, which stipulates that no donation shall be carried out from a living donor if it negatively affects his/her health. Furthermore, the donor must enjoy his/her full legal capacities and give his/her consent in writing in the presence of two witnesses. Organs may be transplanted from a deceased person provided that the consent of his/her closest relative (up to the second degree) is obtained. Where there is more than one first degree relative, the consent of the majority is required. In all cases, similar to many other countries in the survey, donation from a cadaver depends on the definitive verification of total death by a committee of three specialized, competent, and trusted physicians. A further requirement set by the UAE is the need to obtain a written declaration stating that the deceased person did not express to others his unwillingness to donate his/her organs.

## **Kuwait**

Kuwait regulates this issue under Organ Transplant Law No. 44/1989, which allows donation from living donors provided that they: are more than 21 years of age; are fully aware of the operation procedure and potential complications; and have signed a written consent in the presence of two witnesses; and that the consent has been approved by the Head of Unit or his/her deputy. Brain dead and deceased individuals must also have given written consent during their lifetime, otherwise their next of kin (first degree) must all give their written consent.

In cases where a patient is in need of organs and is in danger of dying, it is permitted to remove organs from cadavers after the consent of a committee of three physicians. In these circumstances, the transplant cannot take place until the Minister of Health or his/her undersecretary has approved. The law makes no mention of the selection of recipients, the anonymity of donors, or xenotransplant.

*It is worth mentioning that both Kuwait and Lebanon reported that there have been some cases of people advertising in newspapers for kidneys in return for monetary remuneration.*

## **Yemen**

Organ transplantation is regulated by Law No. 26 (2002) regarding the practice of the medical and pharmaceutical professions, which states that the donor should be selected from among the first or second-degree relatives, provided that the donor is more than 20 years of age. The recipient must be less than 60 years of age. Organ transplantation is allowed provided that both the donor and the recipient are informed about the procedure and the risks and that free, informed consent is obtained. The Yemeni National Organ Transplantation Centre performs kidney transplants and accepts donations from living related donors only. The centre is responsible for selecting the donor and the recipient.

Removing tissues or organs from cadavers is allowed, but not yet in practice because more legislation on the matter is required.

## **Saudi Arabia**

In Saudi Arabia, the Purport of Senior Scholars approved organ donation and transplantation from cadavers and living donors in 1982. This was followed by an Order in 1985 to establish the National Kidney Foundation, which later changed its name to “Saudi Centre for Organ Transplantation” by virtue of another Order in 1993. Organ transplantation is regulated under Saudi Regulations of Transplantation. It is allowed from both related and unrelated living donors and since 1994 it has been permitted to harvest organs from brain dead and cadaver donors, provided that they expressed their consent in their lifetime. Otherwise, consent from their next of kin should be obtained. Brain death must be declared by a committee of specialists. Financial compensation for donors (cadaver or living) is granted by the government. Donors and recipients should be no younger than 18 years and the minimum age for cadaver donors should be more than 6 months (5kg). The upper limit for donation and the anonymity of donors are in line with international law. Xenotransplant is not performed in this country. Saudi Arabia has a selection criteria and scoring system for every type of organ transplant. General selection

criteria include the exchange of organs with countries depending on agreements regulating this type of exchange.

### Lebanon

Kidney transplants are the most commonly practiced organ transplants in Lebanon. Other kinds of organ transplants are rarely performed. Cornea transplants are considered tissue transplants. Kidney transplants were first performed in 1985 and 611 transplants were carried out between 1985 and the end of 2001, of which 82 had deceased donors and 529 had living donors. In 2000, the rate of kidney transplant per one million inhabitants was 20.8 (3.7 from cadaver donors). Transplantation from related living or deceased donors is the most frequently performed transplantation, followed by transplantation using unrelated living donors.

Many factors hinder the growth of renal transplantation from cadavers. Firstly, a large part of the population is ignorant about encephalic death. This ignorance lies as much in a lack of proper education as in a lack of cooperation and coordination between hospitals. Furthermore, there is no powerful and efficient official agency that centralizes and distributes organs. A second hindrance is the small number of rural hospitals that have resuscitation departments capable of keeping patients alive, transforming potential donors into effective ones, harvesting organs, and transporting organs to hospitals that perform transplants. Thirdly, all drafted legislation must be in conformity with ethical ideals and religious beliefs and this time-consuming process forestalls transplants.

The positive attitude of the religious denominations caused the government to adopt Decree Law No. 109 (16 September 1983) concerning the organization of human tissue and organs, which was soon followed by Decree No. 1442 (20 January 1984) implementing Decree Law No. 109. Both stipulate the necessary conditions for organ transplantation using related and unrelated deceased and living donors. Only specialized hospitals certified by the Ministry of Health and supervised by multidisciplinary committees designated by the Ministry of Health in consultation with the hospital's administration are allowed to perform transplants. This legislation also addresses the signs of brain death, deceased and living donors' informed consent, and confidentiality.

A National Organization for Organ and Tissue Donation and Transplantation (NOOTDT) was established in 2002 by the Ministry of Health in order to coordinate the recruiting of donors and the counting of the recipients. A new law regulating the organ transplantations was drafted by CCNLE and submitted to the parliament for approval and it is still under discussion.

### Oman

In Oman, organ transplantation is regulated by Ministerial Decision No. 8 (1994), which was approved by the Grand Mufti of Oman. Organ donors may be living, deceased, or brain dead. Brain death must be diagnosed and certified by two separate examinations for brain stem function. Each examination must be undertaken by two clinical consultants and at least one of them must be specialized in neurology, neurosurgery, or anaesthesia. Donors must be more than 18 years old and enjoy their full mental faculties. Donors must give written consent and be informed about the consequences of donation, without pressure or inducement by financial, emotional, or other personal gain, and they can withdraw their consent without limitation or



condition. The donation must not negatively affect the donors' health and the recipients may be blood or non-blood relatives of the donor.

## 7. Assisted Reproductive Technologies (ART)



## 7. Assisted Reproductive Technologies (ART)

*On the subject of Assisted Reproductive Technologies (ART), the positions of the 17 countries surveyed overlap most of the time, whether they have current and effective regulations, guidelines, draft guidelines, or draft laws. All of these countries allow ART for married couples only (i.e. wife and husband). Most countries that have explicit stipulations on ART (Egypt, Algeria, Jordan, Bahrain, Saudi Arabia, Qatar, Lebanon, Oman, and Tunisia) prohibit surrogate motherhood, the donation of sperm, gametes, and embryos, and financial compensation.*

*Sudan, Palestine, Morocco, Jordan, Bahrain, Yemen, Syria, and the UAE have no regulations pertaining to ART, but they do have centres that provide in vitro fertilization (IVF) and other ART services.*

### **Sudan**

In the absence of national guidelines, the Sudanese centres providing ART services (e.g. Sudan Assisted Reproduction Centre and Sudan Centre for IVF) follow international guidelines.

### **Jordan**

Similarly, despite the fact that ART services are widely available in Jordan, there are no laws or regulations governing them. A proposal and recommendations for guidelines were submitted to the Ministry of Health for review and approval on 9 May 2002. These guidelines set standardized criteria for logistics, laboratories, and technicians that are licensed to conduct ART procedures. They prohibit sperm, ova, and embryo donation as well as financial incentives for donors, but permit preimplantation genetic diagnosis (PGD). Embryo gender selection is only available in the private sector and intracytoplasmic sperm injections (ICSI) are utilized for gender selection. Preserving embryos and gametes is allowed, but the deliberations and debates on the duration of preservation (ranging from five to ten years) are ongoing.

These draft guidelines are not fully in effect and there is a need to regulate the number of implanting embryos to reduce the incidence of multiple pregnancies, with its obstetrical and cost outcomes.

### **Bahrain**

In Bahrain ART is regulated under the Draft Guidelines for the Establishment and Regulation of Assisted Reproductive Units and Centres. These guidelines are currently in practice in accordance with the existing fatwas. (These fatwas on ART have been adopted by Saudi Arabia and Jordan as well.) The Ministry of Health is using the draft guidelines to control the registration, licensing, and accreditation of ART labs, personnel, and centres until the regulations are made law. The guidelines present a full description of the minimum requirements for the establishment of an ART centre in Bahrain. They also suggest methods for long term and continuous accreditation of embryo labs through the implementation of quality control and quality assurance systems. The guidelines allow embryo sex selection for medical purposes and prohibit surrogate motherhood and gamete and embryo donation.

The draft also dictates that the centres must present their data to the Ministry of Health for national registration, which requires periodic collection of information regarding cases,

techniques, outcomes, and other information. Each centre should have the means to update its facilities, present data to the public or the Ministry of Health when required, and resolve complaints submitted by patients and others. A committee from the Ministry of Health is in charge of periodic inspection and evaluation of centres offering ART services.

### **UAE**

The UAE has no regulations on ART, but there is a proposed Federal Law (2007) concerning the licensing of currently operating fertility centres. ART (i.e. IVF and ICSI) are carried out within legally married couples and surrogate motherhood is prohibited, as is the donation, import, and export of ova, sperm, and embryos. No financial compensations are allowed. The centres, upon receipt of the couple's written consent, may carry out pre-implantation genetic diagnosis (PGD) for the purpose of identifying genetic diseases, provided that the necessary precautions are taken to protect the fertilized ova from harm.

### **Yemen**

In Yemen, ART is practiced in three centres: two private centres in Taiz and Al-Hadaida and a third, which is both public and private, in Sanna. The only pertinent regulation concerning IVF for married couples requires a legal document testifying to the existence of an "Islamic marriage" and the procedure's accordance with the relevant fatwas issued by Sheikh Al-Zandany. In addition, there are allowances in the three IVF centres for cases of infertility that do not respond to classical drug or surgical treatments. IVF cannot be undertaken without the informed consent of the female patient and her spouse. Such consent must be in writing after the patient has been provided with sufficient information about the purpose, methods, risks, inconveniences, and possible failure of the procedure.

### **Morocco**

In Morocco, there is only a Draft Proposal for ART Regulation elaborated by the Moroccan Federation for Human Reproduction and the Moroccan Society of Fertility and Contraception. First submitted to the Ministry of Health in January 1999 and updated in December 2007, this draft is not in practice even though there is a strong need for national regulation because 13 ART centres are already practicing in the country. The draft defines and explains what is meant by ART, describes the situation in Morocco, discusses the current problems, and makes some suggestions that could solve the current problems of infertile couples in Morocco, while conforming to the cultural and religious context of Moroccan society.

The draft proposal suggests prohibiting the donation of ova, sperm, and embryos, as well as surrogate motherhood and the use of PGD for sex selection, and limits ART to legally married couples. It also calls for embryo cryopreservation and for an open discussion about national regulation concerning the use of supernumerary embryos in research.

### **Qatar**

There are no national laws regulating ART practices in Qatar, but Hamad Medical Corporation has issued guidelines that permit IVF for couples in a way that complies with Islamic principles and opinions. There is a consent form the couple must sign that details the procedure. In addition, there is a consent form for freezing embryos, in which the couple must state whether or not they agree to have their embryos frozen and, if they consent, they must specify the

precise number of embryos to be frozen. In the consent form, they acknowledge that they were informed about the reason for freezing embryos, which is to give the woman (in the event of problems occurring that prevent the initial transfer of the embryo to her uterus) a chance to have these frozen embryos transferred to her uterus in subsequent cycles. Defective embryos are to be destroyed. Sperm, ova, and embryo donation is not permissible and surrogate motherhood is also banned.

## Oman

In Oman, ART is regulated by the 2002 Code of Practice for Assisted Conception Unit (ACU) of Muscat Private Hospital (MPH). The regulations have been deemed in accordance with Islamic values. Sperm, ova, and embryo donation, surrogate motherhood, embryo selection based on sex, and embryo reduction are all prohibited. However, the regulations permit the preservation of sperm and embryos. PGD is not available because the requisite cytogenetic laboratories do not exist.

## Egypt

Egypt regulates ART through Decree No. 238/2003 of the Ministry of Health and Population on Professional Ethics Regulations, which was issued as an amendment to the 1974 regulations and pursuant to the resolutions of the Council of the Egyptian Medical Syndicate and the General Assembly of the Egyptian Physicians. Chapter 3 of the decree is concerned with medical interventions of a special nature and regulates assisted reproductive technologies. Article 44 is concerned with issues including IVF and ICSI. It permits medically assisted reproduction for legally married couples (who may resort to artificial fertilization *in vivo* or *in vitro*). The procedures, when allowed, must strictly follow the ethical guidelines and laws of the responsible authorities, which aim at preserving the purity of human lineages and treating infertility. Also, the decree prohibits the establishment of banks of gametes (ova and sperm) and embryos, but states that research may be conducted on gametes and embryos and the cryopreservation of the latter is allowed but the centres may not donate them. All assisted reproductive treatments must be carried out in the licensed centres, which must keep all data associated with each case, including the couple's consent form. The violation of these rules by any physician may result in penalization.

Although, there are no specific rules concerning the other main issues, such as embryo selection, human leukocyte antigen (HLA) typing and genetic diseases, financial compensation for donors, prenatal diagnosis, and selective abortion, some interesting opinions from various sources are being applied in some private medical sectors in Egypt. ART began being utilized in Egypt following the issuance of recommendations and proposals originating from the 1980 fatwa of the Fiqh Academy of Mecca. The Egyptian Medical Syndicate and the Ministry of Health and Population are currently seeking to develop guidelines for licensing IVF clinics and centres in Egypt and are examining: the guidelines of the first International Conference on Bioethics in Human Reproduction held by International Islamic Centre for Population Studies and Research of Al-Azhar University in 1991 (which now used by the Ministry of Health), the 1986-1990 fatwas of the Fiqh Academy (associated with the Organization of the Islamic Conference), the 1991 fatwa, the World Islamic Da'wa Association Seminar (held in Qatar) on the moral repercussions of research on genetics, and the 1994 fatwa of the Jordanian Islamic Fiqh Association for Medical Sciences.

## Libya

Artificial insemination is prohibited by virtue of the Libyan Penal Law; however, this prohibition does not apply to married couples who have given their consent (Art. 17 of Medical Liability Law No. 17/1986). It stipulates that it is prohibited to artificially impregnate a woman or to implant an embryo in her uterus unless the donor is her spouse and both spouses have given their consent.

Libya also addresses ART in Art. 403 Bis A and Art. 403 Bis B of the Libyan Penal Law appended to Law No. 75/1972. Surrogate motherhood and donation from anyone but the spouse are prohibited. Article 403 Bis A delineates the different penalties applied to whomever artificially impregnates a woman by force, threat, or deceit, as well as the penalties for the non-spouse donor who artificially impregnates a woman with her consent, and the penalties for the physician, pharmacist, midwife, or assistant who participates in the procedure. Article 403 Bis B delineates the penalties for a woman who consents to non-spousal artificial impregnation or who performs self-impregnation and the penalties for the husband who consents to his wife's artificial impregnation from a non-spousal donor.

Libya has also established the National Centre for Diagnosis and Treatment of Sterility by virtue of General People's Committee Decision No. 186/1993.

## Algeria

ART is regulated in Algeria by Ministerial Instruction No. 300 of 12 May 2001 outlining good clinical and biological practice in ART. ART was recently introduced in Algeria with the February 2003 birth of the first baby conceived by IVF (in a private hospital in Constantine). Currently IVF is practiced in five private centres and will soon be practiced in seven others in 2009, three of which are public.

It should be noted that this field is subject to certain rules stemming from religious dictates (e.g. all use of the embryos or preserved gametes is prohibited in the event of dissolution of the marriage, either by death or divorce). The ministerial instruction describes the relevant ethical principles, procedures, and practices to be applied to each case. IVF is reserved for married couples and it is recommended that the patient be a woman over 35 but less than 50 years of age who is having fertility problems. It also stresses the need for a classical infertility workup. The duration of cryogenic preservation of embryos should be three years and then they should be destroyed after informing the couple. Embryos and gametes should also be destroyed in the event of discovery of a spouse's disease.

## Tunisia

In Tunisia ART activities are governed by Tunisian National Committee on Medical Ethics Opinion No. 1 (12 December 1996) and Medically Assisted Procreation Decree No. 2003-1027 (28 April 2003) addressing reproductive medicine and practice. They prohibit: embryo selection based on sex; sperm, gamete, and embryo donation; and financial compensation for donors. HLA typing for genetic diseases, prenatal diagnosis, and selective abortion are authorized with both spouses' consent and must be performed for strictly therapeutic purposes. Embryos and gametes may only be preserved for reproductive purposes and the written consent of both spouses is required.

## **Kuwait**

In Kuwait, only IVF is practiced and it is regulated under Ministerial Decision No. 448 (2002) as to the licensing of IVF centres in the private sector. It forbids gamete and embryo preservation.

## **Saudi Arabia**

ART is addressed in Saudi Arabia under the Regulation of IVF Units, Embryos, and Infertility Management No. 2870/1/12. This regulation governs the licensing of IVF units (by the Ministry of Health) and details the supervision system and penalties for violations, which include imprisonment and/or payment of a fine. As for embryo selection based on sex, and HLA typing for genetic diseases, intervention is only allowed for gene therapy and must be approved by a committee. It is not allowed to preserve ova or sperm after fertilization, but storage of embryos is allowed for more than five years after obtaining the consent of the married couple. IVF units are required to adhere to Islamic fatwas.

## **Lebanon**

This issue is regulated in Lebanon by the Draft Law on Assisted Reproductive Technologies and the Code of Medical Ethics. Diverse ART activities began in Lebanon between 1980 and 1985. They include: artificial insemination by injecting sperm into a woman's uterus and fallopian tube, IVF, and introducing inseminated eggs to the uterus or fallopian tubes.

The draft law submitted by the CCNLE was immediately adopted by the Ministry of Health. However, it faced many obstacles from the Council of Ministers who wanted to consult the different Lebanese religious denominations on the subject, since some of those denominations prohibit ART except when practiced on married couples. The draft law prohibits donating sperm and ova, surrogate motherhood, embryo selection based on sex, and manipulations of the embryo. Prenatal diagnosis and selective abortion are only allowed to save the life of the mother. Violations of the draft law's provisions are penalized. Article 30 of the Code of Medical Ethics allows (Art. 30) the practice of assisted medical reproduction on legal married couples only.

## 8. Pharmaceutical research





## 8. Pharmaceutical research

*Pharmaceutical Research is regulated in roughly half of the 17 surveyed countries. Eight countries: Palestine, Syria, Morocco, Oman, Yemen, Saudi Arabia, Algeria, and the UAE have no regulations at all concerning this issue. Two countries have guidelines and six have laws. The countries that have regulations have adopted very similar positions on the key issues related to pharmaceutical research. Indeed, the regulations or guidelines in Sudan, Qatar, Egypt, Jordan, Tunisia, Bahrain, and Lebanon affirm the necessity of: obtaining written consent from the patient or participant in the research; providing the latter with financial compensation for his/her participation (with the exception of Bahrain, which does not address the compensation issue, and Tunisia, which forbids any financial compensation whatsoever); and obtaining a license for or approval of the research from the concerned authority before undertaking the research.*

### **Saudi Arabia**

The Saudi Food and Drug Authority has issued regulations, which are still being developed. They affirm the necessity of obtaining written informed consent and of ensuring the accuracy of data derived from source documents. They also affirm the right of the institutional review board or other regulatory authorities to access data for auditing. The guidelines permit the compensation of participants; however, the draft only discusses injuries or illnesses related to research trials (i.e. there are no explicit mentions of compensation for travel and time, for example).

### **Algeria**

In Algeria, there are no regulations concerning pharmaceutical research. A 1998 law promotes enhancing capability to innovate, including research in biotechnology in public and private enterprises, and Research Law 08-05 (23 February 2008), which completes the 1998 law, is related to the orientation and research programme for five years (2008-2012) but there is no specific mentioning concerning the pharmaceutical research. There is a brief reference in the Algerian Ministry of Health's Drug Policy to this issue: "Pharmaceutical research and development constitute an important component of the national research strategy in the field of health. Investment in this sector can bring benefits in the short and long term to develop new drugs and improve existing products. Pharmaceutical research and development include, among others, basic research in molecular biology, chemistry, immunology, and biotechnology."

### **Palestine**

In order to perform clinical research in Palestine for the purpose of developing new drugs, permission must be obtained, according to the head of the Pharmaceutical Control and Registration Department at the Ministry of Health. However, no clinical research is carried out in Palestine.

### **Morocco**

In Morocco there is no mention of pharmaceutical research or clinical trials. This research will be regulated by a law under preparation concerning research involving human subjects.

## Qatar

In Qatar, pharmaceutical research is regulated by the Rules and Regulations for Research of Hamad Medical Corporation (HMC), which also regulate research conducted on human subjects. These regulations state that all research proposals, including pharmaceutical research, must be submitted to and approved by HMC's Research Committee after the Research Ethics Committee (REC) evaluates the religious and ethical aspects of the proposal. The REC has the authority to approve, only by expedited review, research on drugs that are already registered at the Ministry of Public Health. Otherwise, a full review of the research is required (e.g. in the case of testing a new drug, increasing or decreasing medication dosage, and other actions which may increase the risks taken).

For research involving the administration of drugs, written informed consent signed by the patient or his/her guardian is required. In the consent, s/he authorizes a certain physician and his/her associates to administer the drugs; affirms his/her understanding that the drugs in question are being studied to determine the extent to which they may be of value in treating the patient's illness or condition; and expresses his/her understanding of the nature and purpose of the drugs used in the research. The consent also states that s/he will be reimbursed in the case of losses incurred as a result of participation in the study. The form he/she signs also states that the risks associated with the use of the drugs are voluntarily accepted and that s/he is free to withdraw consent or discontinue treatment at any time.

The National Health Academy's adopted International Guidelines for Biomedical Research Involving Human Subjects recommend that, as a general rule, research subjects in the control group of a diagnostic trial, therapeutic, or preventive intervention should receive an established effective intervention; however, it may be ethically acceptable in some circumstances to use an alternative comparator, such as placebo or "no treatment".

As for research conducted by a foreign-based company or researcher, the above-mentioned guidelines require that the external sponsor follow the research protocol for ethical and scientific review in their country, and the ethical standards should not be less stringent than they would be for research carried out in that country. External sponsors are also ethically obliged to ensure the availability of healthcare services essential to the safe conduct of the research and treatment for injuries participants sustain as a result of their participation in the research.

## Libya

There are no laws that regulate pharmaceutical research in Libya. There is only a draft law that organizes the pharmaceutical profession, which provides, for example, for the necessity to purchase drugs from licensed bodies and penalizes the pharmacist if s/he commits a professional error.

Based on Health Law No. 106/1973, the General People's Committee issued Decision No. 617/1983 for the reorganization of the Health and Drug Research Centre, which will undertake health and applied medicinal studies and research and apply them in treatment, as well as carry out scientific research on drugs and pharmaceutical formulations. The General People's Committee also issued Decision No. 642/1987 for setting up the National Medical Research Centre, which will: carry out tests for quality control on drugs, pharmaceutical preparations,

and locally manufactured or imported medical equipment; study and prepare the list and guide of drugs used in Libya in coordination with the relevant authorities; register medical pharmaceutical preparations and drug companies; verify the analytical materials and medical equipment and instruments; work towards manufacturing and testing new drugs; and invent new medical methods to detect diseases.

## **Kuwait**

Regulations regarding pharmaceutical research do not currently exist in Kuwait. However, the country respects the IOMS guidelines, which specify the phases of the research and the number of volunteers. As for the last phase (the sale of the product), the approval of the National Committee for Drug Registration is necessary. The sponsors are responsible for the treatment of participants if complications result from the research.

## **Sudan**

Pharmaceutical research is regulated in Sudan under the 2001 Pharmacy and Poisons Act, which mainly addresses technical standards and pays less attention to ethical aspects. This act permits conducting medical experiments for any drug or pharmaceutical preparation on human subjects provided that a license is obtained from the National Pharmacy and Poisons Council. In addition, the act describes the conditions to be fulfilled before the license is issued, which include meeting technical standards to ensure the safety of the subjects involved in the experiment and a provision that evidence must be provided to prove the experiment's safety (e.g. precedence set by experiments conducted in other countries). The act provides for the necessity of obtaining written informed consent from the participant or his/her guardian in case of minors. The act also lays full and direct responsibility on the body conducting the research for any injuries resulting from the experiment. This responsibility extends to financial compensation and all other legal obligations.

## **Egypt**

There are laws and regulations issued by the Egyptian legal authorities and the major bodies that regulate practices in pharmaceutical research, trading, and industries. These include the Egyptian Constitution (Art. 43), which addresses the issue in general terms and stresses the need for the full and uncompromised consent of the human subjects. Ministerial Decree No. 238/2003 is concerned with many issues including: the need for obtaining formal authorization to conduct drug experiments on human beings; the need for the physician to comply with all moral, ethical, and scientific standards for carrying out the research; the need to ensure that the drug being tested (if effective) will be freely available to the subjects during the research programme (which can be considered temporary benefit-sharing); and the need to inform the subjects of all aspects of the research (including the benefits and risks, sources of funding, and their right to freely withdraw from the study at any time). The guidelines of Ministerial Decree No. 435/2006 are concerned with issues such as informed consent, collection of data, financial compensation for participants in clinical studies, benefit sharing, and the responsibilities of the research sponsor. Other laws and ministerial decrees are concerned with regulating the process of manufacture, import, and export of drugs and cosmetics and the procedures for drug preparation, testing in licensed laboratories, and data recording. Many articles were formulated to penalize any infringement of the guidelines set by the concerned authorities.

## Jordan

Pharmaceutical research is regulated in Jordan under the Clinical Trial Law concerning human subjects and Drug Study Law No. 67 (2001), which states that drug studies cannot be conducted on human subjects until obtaining the approval of the Drug Study Committee and the written informed consent of the participants and performing the required medical tests to ensure the safety of the human subjects.

The party conducting the study is legally responsible for any injuries incurred by the human subjects. The law also requires the establishment of an insurance agreement with an insurance company working in Jordan to cover the damages that may result from the study, especially injuries to human subjects. It is to be noted also that any foreign-based company (researcher) can do clinical studies in Jordan provided it complies with all stipulations of this law.

## Tunisia

Pharmaceutical research involving human subjects is regulated in Tunisia under Decree No. 90-1401 (3 September 1990). This decree states that minors, mentally ill patients, and pregnant or breastfeeding women cannot participate in studies and that medical or scientific experiments cannot be carried out with financial compensation. All research protocols must be submitted to the Ministry of Public Health. This issue is also regulated by the Code of Medical Ethics and Law No. 2004-63 (17 July 2004) on the protection of personal data. According to these regulations, informed consent must be obtained in writing and the patient must be informed about the objectives of the investigations, the process, and the duration as well as about constraints and predicted side effects. Data collection must respect medical confidentiality and the law protecting personal data. Research conducted by foreign-based companies is authorized provided they comply with local regulations. The current practice obliges foreign pharmaceutical companies to sign legally binding agreements with the Ministry of Public Health so that any resulting conflicts must be settled in Tunisia.

## Bahrain

In Bahrain, the Royal Decree for Law No.7 (1989), regarding the practice of medicine and dentistry, indirectly regulates pharmaceutical research. There is a need to establish more explicit regulations on pharmaceutical research, as this regulation only states that physicians are not allowed to experiment on their patients or use them as subjects in research studies without the prior approval of the authorized body at the Ministry of Health. The committee's approval aims to prevent any deleterious effects resulting from research procedures or materials used (e.g. drugs) on patients participating in the study.

## Lebanon

This issue is regulated in Lebanon under several laws and guidelines. For example, Art. 11 of Law No. 574 (2004) on patients' rights and informed consent states that: "...a person under treatment may participate in clinical research with scientific benefit or in a medication test provided that s/he gives his/her written consent, that no mandatory obligation had influenced his/her decision....The consent to medical care applies also to the participation in clinical research. Therefore, in case the patient was not in a state that allows him to express his/her will, participation would require the consent of a trusted person". Law No. 367 of 1994 regulates the practice of pharmacy in Lebanon and the conditions for putting new medications

or treatments on the market.

The CCNLE recommends that researchers adhere to its guidelines outlining general principles of the experimentation of new medications on human subjects. They stipulate that the evaluation of any new medication should conform to the principles mentioned in these guidelines and provide for the establishment of special committees constituted of specialists and judges. Based on the expertise the members have acquired and the work of ethics committees around the world, these committees would evaluate any new medication and then determine a position and recommend that their position be adopted. Such decisions must be made on the basis of the following principles and criteria: the duty to test, sufficient pre-requisites, the scientific value of the project, adequate risk/benefit balance, free and informed consent, and the approval of an ethics committee.

This issue is also regulated by the (not yet adopted) draft law as to the establishment of ethics committees to monitor medical research and clinical experiments, which states that a central ethics committee should be established at the Ministry of Health, with representation from all universities with medical faculties, which would monitor the work of the Institutional Review Boards. This committee would be attached to the Minister of Public Health and would be established by a decision s/he issues.

## 9. Medical Practice



## 9. Medical Practice

*In general, the codes of ethics or conduct for physicians in most of the 17 countries surveyed share numerous similarities. They all emphasize as an essential rule the duty of medical professionals to respect human dignity, provide the best care available to patients and their families, treat patients with compassion, and protect their rights, safety, and confidentiality. These codes or regulations also regulate physicians' relations with their patients, colleagues, and the rest of the medical staff.*

### Sudan

The practice of medicine is regulated in Sudan under the Sudanese Medical Council Act of 1993, which is concerned with the council's responsibilities, duties, authorities, and membership, as well as other administrative and financial issues of the council. Chapter 3 of the act is concerned with the professional conduct oath that the physician takes prior to practicing the medical profession, which is meant to ensure ethical and professional competence. Chapter 7 is concerned with the complaints, offences, and penalties for malpractice. All of this is meant to ensure high-quality, professional, and ethical conduct within the medical practice. This issue is also regulated under the Medical Ethics and Medico-Moral Code of 1979, which details the duties and responsibilities of physicians to their patients, colleagues, and others. The ethical values and principles, including respect for patients, confidentiality and obtaining informed consent, are explicitly provided for in the code. Confidentiality for both adults and minors is provided for in the code, which also clearly describes the situations where the physician is not obliged to inform the court or the authority. The physician may deal ethically with similar situations, such as criminal abortion, illegitimate pregnancy, etc. The regulations of Sudan Paramedical Council of 1982 cover nursing ethics, which aim to preserve and promote health and prevent disabilities. They also state the conditions for registration, obtaining a license, and the nursing practice. The duties and responsibilities of the nurse to the community and the public are also described therein.

### Qatar

Qatar adheres to the Gulf Cooperation Council (GCC) Nursing Code of Ethics, a unified multinational code of ethics that regulates the nursing profession in all GCC countries based on their relevant laws, bylaws, rules, and regulations, on nursing codes of ethics existent in developed countries, and on all related documents issued by the WHO. This code sets forth three fundamental values that form the framework of the nursing profession in the GCC countries and that all stakeholders are supposed to adhere to. These values are: responsibility, dignity, and confidentiality.

Code of Conduct Policy No. OP 4009 (a professional code of conduct drafted for all HMC's staff) sets forth general rules and standards for business and personal ethics. All employees and those doing business with HMC are expected to abide by them, embodying the highest level of ethical conduct.

Although this is an institutional code, it complies with the applicable Qatar laws, rules, and regulations governing HMC. It focuses on the following points: treating patients, families, and employees with respect, dignity, and fairness; accurately maintaining records; exercising good

judgment in business and professional relations; avoiding actual or apparent conflicts of interest; delivering ethical and safe patient-centred care; protecting the rights and responsibilities of the patients and their families; conducting business activities with integrity; protecting the confidentiality and security of the patient and information; providing the highest quality of care with the utmost compassion; providing a safe, clean, and secure environment; and, finally, offering a truthful message to the community.

## Egypt

Professional medical practice in Egypt is controlled by the Egyptian constitution and a number of laws. Law No. 415/1954, Ministerial Decree No. 300/2000 of the Minister of Health and Population, No. 244/2001, No. 238/2003, and Decree No. 25/2002 regulate the scientific, professional, and ethical practices of physicians and nurses and their duties to each other and to their patients, and also detail the penalties for misconduct or malpractice. Guidelines are also present to regulate the practice of medicine and outline essential criteria for building hospitals and clinics. Islamic Opinions on Ethics of the Medical Profession are also effective for regulating the behaviour of Egyptian professionals.

## Algeria

In Algeria this issue is regulated under several laws and decrees, primarily Ordinance No. 76-79 (23 October 1976), a public health code that details and regulates the public health and medical professions (physicians, dentists, and pharmacists), as well as the terms and requirements for the practice of the medical profession. Chapter 2 of this ordinance regulates the paramedical profession. Executive Decree No. 96-122 (6 April 1966) addresses the composition, organization, and operation of the National Council of the Ethics of Sciences of Health. Executive Decree No. 92-276 (6 July 1992) includes a Professional Code of Conduct, which also delineates in detail the duties and obligations of physicians to their profession, patients, colleagues, etc. Law No. 85-05 (16 February 1985) specifies the penalties for violations of the rules concerning the medical practice. It is to be noted that there is a new law, not yet issued and still under discussion, related to the protection and promotion of health.

## Libya

Medical practice is regulated in Libya under Medical Liability Law No. 17/1986, which defines the purpose and ethics of the medical profession, which should be based on integrity, accuracy, vigilance, and care for human safety so as to serve the patients' interests and not the physicians' personal gain. It also details the tasks and duties of physicians to patients and their families, such as precisely diagnosing patients' illnesses, exerting efforts to reduce their pain, refusing to end their lives even if they have incurable diseases or are in a great deal of pain, and making sure they give informed consent to their treatment. It also regulates the physicians' relationships among themselves, which should be based on cooperation. This law also provides for the conditions for carrying out surgical operations and stipulates that physicians are responsible for any professional error they commit in the medical practice. The decision of the Minister of Health No. 654/1975 for issuing the executive regulation of Health Law for year 1973 regulates the nursing profession and its ethics, and defines the nurses' or assistants' duties and restrictions.

The 2006 Basic Code of the systems, behaviours, and ethics of transferring and implanting human organs sets the rules for the relationship between physicians and their patients and



states that the physician shall abide by the behaviours and ethics of the profession that have been in development from the ancient Greek era to the emergence of Islamic civilization to the modern era.

## Tunisia

Medical practice is regulated in Tunisia under the Medical Code of Ethics adopted in 1973, which tackles the general duties of physicians and their duties to their patients, colleagues, and the medical auxiliary. It also details specific rules for certain kinds of medical practice and experimentation and emphasizes basic principles such as the respect of life and dignity, respect of the patient's autonomy and privacy, professional independence, duty of assistance, and cooperation among physicians. Medical practice is also regulated under Law No. 91-21 (1991) as to the exercise and organization of the professions of physicians and dentists. To practice medicine or dentistry one must have Tunisian nationality, hold a degree of doctor of medicine, doctor of dentistry, or an equivalent diploma, and be listed on the roster of the National Order of Physicians. This law prohibits one person from practicing both medicine and dentistry or practicing pharmacy in addition to medicine or dentistry, and stipulates that the practice of the medical profession is incompatible with activities of a commercial nature.

It should be noted that the survey carried out in Tunisia mentions a need to amend the regulations in order to integrate developments related to new information technologies and scientific advances (e.g. those relating to medically assisted procreation).

## Jordan

Jordan regulates medical practice under the Jordan Medical Association Law (Medical Professional Law 1972), the Medical Constitution (National Medical Guidelines 1989), and the Penalty Law of 1960. These laws and guidelines address all aspects of good practice, medical and nursing ethics, and professional code of conduct. The focus of these guidelines is the patient-physician relationship, the nursing and medical oath, euthanasia (the act of ending the life of an individual suffering from a terminal illness or an incurable condition, by lethal injection or the suspension of extraordinary medical treatment), abortion, the physician's obligations to the patient, and professional confidentiality. Violations of these regulations will result in referring the violator to the Board of the Jordan Medical Association, which makes him/her liable for his/her conduct and subject to penalties.

## Palestine

In Palestine, this issue is regulated under the Law of Public Health No. 20 (2004), which describes the terms and requirements for practicing the medical profession and the rules and requirements regulating health institutions. According to the Law of the Palestinian Medical Council No. 1 (2006), the council is responsible for the preparation of curriculum development for all medical specializations. A number of laws and bylaws adopted during the Jordanian rule of the West Bank are still implemented in the West Bank. For example, the Dental Syndicate Bylaws (1960) and the Medical Doctors Syndicate Law No. 14 (1954) regulate the medical practice and provide for the necessity of obtaining authorization from the Ministry of Health and the requirement that physicians be members of the syndicate and take the oath in front of the syndicate. They also require physicians to respect the principles of honour and integrity in all circumstances, to maintain medical confidentiality, and to respect medical decency, traditions,

and exigencies related to their profession. Physicians are also barred from using advertisements or other methods to attract patients. Physicians' relationships with their colleagues should be characterized by equity and collaboration, thus they must avoid illegal competitions or defamation. In the Gaza Strip, many British mandate laws and regulations are still in force, such as Medical Practitioners Ordinance No. 58 (1947), which regulates the medical practice. It is interesting to note that the ordinance is not applicable to physicians coming from foreign countries to Palestine to perform surgery or provide medical consultation for a specific case.

## Syria

In Syria, the Law of Medical Practice Decree No. 12 (1970) sets the conditions for medical practice (medicine, dentistry, pharmacology, midwifery, and nursing). It also details the duties of those practicing medical professions and the penalties for violating these duties. The Physicians' Duties and Profession's Ethics Order sets the rules determining the general duties of medical physicians, their duties to their patients, medical confidentiality, and the relationships between medical professionals. Law No. 31 (1990-1991) regulates the medical syndicate. It is noteworthy that Art. 3 of this law stipulates that the decisions of the Syndicate of Physicians must conform to the recommendations of the Baath Party.

## Bahrain

Medical practice is regulated in Bahrain under the laws and ministerial orders for the regulation of the medical practice, private hospitals, dentistry, and medical professions. Regulations of medical practice were issued for the first time in 1971 and were updated from 1986 to 2003. The regulations concern the specifications of hospitals, licensing of medical staff, and inspection and evaluation of medical facilities in private hospitals. Best practice is described in detail with the essential requirements that should be present in every hospital department, logistics, job descriptions for medical staff, drugs, prescriptions, and safety measures in each area of medical practice. There is a special emphasis on paramedics and nursing and the minimum essential requirements for staff in these two fields.

## Morocco

Medical practice is regulated in Morocco under the Residential Decree relating to the Code of Conduct of the Medical Physicians (published on B.O. No. 2121 dated 19 June 1953, p. 828). The 1953 Code of Conduct that is still in practice was elaborated during the French protectorate and is inspired by the international and the French codes of conduct for medical physicians and by the Hippocratic Oath. It defines the general duties of medical physicians (including their right to refuse care to a patient for professional or personal reasons), their duties to their patients (duty to give care to patients, beneficence and nonmaleficence, honesty, medical confidentiality, respect for life, etc), and their duties to their colleagues. It is to be noted that there is a new code of conduct under preparation and discussion in the National Medical Doctors Council, which introduces some of the universally recognized concepts and principles in the field of bioethics and medical ethics (e.g. respect for human dignity, autonomy, freedom, privacy, consent, and human vulnerability). It also highlights the need for complementary national regulations concerning new topics such as: the beginning of life, assisted reproductive technologies, prenatal diagnosis, ending of life, intensive care, abortion, organ transplantation, biomedical research, the need for research ethics committees, etc.

## UAE

In the UAE, Federal Law No.7/75, which concerns the practice of human medicine, only sets the rules and requirements for obtaining a permit to practice medicine for both physicians who are UAE citizens and foreign physicians practicing in the UAE.

## Kuwait

Medical practice is regulated in Kuwait under the law concerning best practice of medicine and pharmacy in Kuwait (1965) and the law concerning best practice of medicine, dentistry, and related practices (1981). According to these laws, a physician may not practice medicine unless s/he is licensed to do so by the Medical Licensing Committee of the Ministry of Health. The license will not be granted unless the candidate is a registered member of the Kuwaiti Medical Association. Medical licenses can be permanent for Kuwaiti physicians and temporary for non-Kuwaiti physicians working in the private sector. Nurses must also be licensed to practice medicine by the Medical Licensing Committee of the Ministry of Health. It is to be noted that before licensed physicians travel to any foreign destination, they must notify the Ministry of Health of their intention and receive permission. It is also stipulated that physicians must inform the Ministry of Health if they suspect a patient of having a contagious disease and must follow the instructions given by the ministry.

## Yemen

Yemen regulates medical practice under Law No. 26 (2002), regarding the practice of the medical and pharmaceutical professions, which stresses that all health professionals must uphold the dignity and honour of their profession and demonstrate a high level of professional conduct by: being honest, just, factual, objective, and unbiased. They must be completely loyal to their patients and make available to them all the resources of their field. They must work with colleagues in a way that serves the patients' best interest, observe their professional ethical obligations, and give emergency care as a humanitarian duty, unless they are certain that others are willing and able to give such care. The abuse of professional privileges, self-advertising (unless permitted by the law), and the practice of euthanasia are deemed unacceptable and unethical conduct. It is to be noted that this law is not in effect, primarily because it is not supported by executive guidelines or bylaws and supplementary rules.

## Saudi Arabia

There is no law in Saudi Arabia concerning medical practice, but there are guidelines in effect—"Medical Ethics in Practice"—prepared by the Saudi Commission for Health Specialties. These guidelines are considered a manual to guide physicians with regard to medical ethics, determining their obligations to themselves, their profession, their patients, colleagues, and community. There is no mention of nursing ethics in the manual, as it is written only for physicians. National and local medico-legal committees are responsible for investigating cases of misconduct.

## Lebanon

Medical practice is regulated in Lebanon under several laws and decrees, the most important of which is Decree No. 1658. It defines medical practice, outlines the terms and qualifications necessary to practice medicine, and stipulates the required qualifications of Lebanese physicians, physicians who have acquired Lebanese nationality, non-Lebanese physicians from Arab countries, non-Lebanese physicians from non-Arab foreign countries, and non-Lebanese

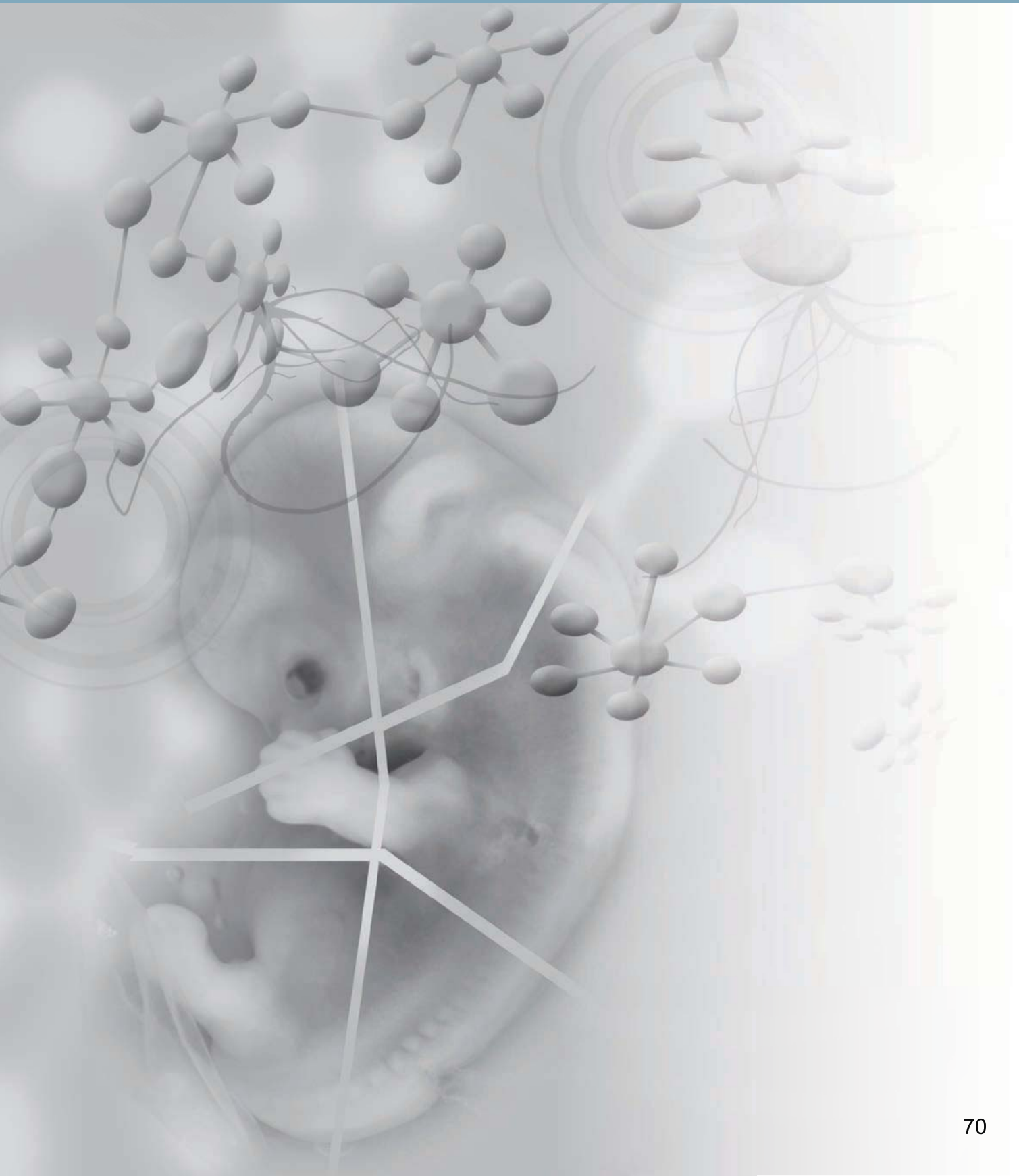
physicians who are professors at Lebanese medical faculties. This decree also addresses licensing physicians to practice the medical profession and determines the circumstances in which medical practice is prohibited.

Law No. 313 (2001) made amendments to a law concerning the establishment of two Orders of Physicians in Lebanon (7 December 1946) and addresses the conditions imposed on physicians and the organization of the two orders. In addition, the Code of Medical Ethics (1994) defines: the duties of the physician related to medical confidentiality, the patient-physician relationship, fees, professional independence, and professional liability. It also outlines the responsibilities of the physician with regard to maintaining patient records, research involving human beings, organ transplantation, medically assisted reproduction, abortion, etc. Finally, it describes the physician's responsibilities as they relate to preventive medicine, social medicine and hospitalization, and the relationship between medical professionals. It is worth mentioning that the Lebanese Order of Physicians has sent an update of this code to the parliament for approval.

### **Oman**

In Oman, the 2002 Code of Professional Conduct for Physicians (updated in 2007) lays out the core standards of conduct expected from all physicians working in the health sector in Oman. It is to be noted that patients who complain about the care or treatment they have received have the right to a prompt and appropriate response. A similar code for nurses and midwives was developed in 2005. The code also mentions the informed consent issue and provides for patients' confidentiality and privacy. Forty-eight manuals and guidelines have been published for different medical disciplines. Several Royal Decrees were issued regarding the practice of medicine and dentistry in 1996. Amendments were made to some articles regarding the licensing of private hospitals in 1998. Ministerial decisions were also issued setting the conditions and procedures for licensing the practice of medicine and dentistry in 1998 and for the investigation of complaints for alleged mismanagement of patients in 1999.

# 10. Abortion



## 10. Abortion

*In general, the abortion laws in the 17 countries surveyed were originally taken from the European colonial powers that governed them prior to their independence. Although different laws have subsequently been enacted, abortion on demand is still prohibited in all countries (with the exception of Tunisia) because of the influence of religious laws and attitudes toward the issue. In these countries abortion is allowed only to save the life of the pregnant woman. In some countries (Sudan, Qatar, Kuwait, Yemen, and Oman) this prohibition is extended to include cases of malformation of the foetus. In Algeria, Sudan and Libya there are some exceptions made for pregnancies that are the result of certain kinds of rape. If illegal abortions are performed for reasons related to "honour," the penalties are mitigated in Palestine, Syria, Lebanon, and Jordan. Only Tunisia and Oman allow abortion on demand (in Tunisia within the first three months of the pregnancy and in Oman within 40 days from gestation). Some of these 17 countries mentioned a need for study further of this issue with the objective of reforming abortion laws.*

### Sudan

Abortion is regulated in Sudan under the Medical Ethics and Medico-Moral Code of 1979, which prohibits voluntary abortion of all kinds unless the continuation of the pregnancy poses a risk to the woman's life or there is a great possibility that the foetus is malformed. The decision to perform an abortion should be made by two consulting physicians or by one experienced consultant, if two are not available. The consultants should write four copies of a report stating the reasons for the decision. Both consultants must sign the copies and each should retain a copy, while the third copy should be kept in the hospital where the abortion has been conducted or with the resident physician, and the fourth copy should be sent to the concerned authority. The abortion procedure should be conducted in a licensed hospital adequately equipped for the operation. The code also states that due consideration should be paid to the current laws and legislation, such as the Sudan Penal Code, in addition to the above protocol. The Sudanese Penal Code of 1991 defines abortion as a crime if carried out intentionally, but lists three exceptions: if the abortion is necessary to preserve the woman's life, if the pregnancy results from rape (in which case the duration of the pregnancy must not exceed 90 days and the mother must request the abortion), and if it is proved that the foetus is dead in the woman's womb.

The Penal Code describes the penalties for acts leading to abortion and those leading to an infant's death at or after birth. These penalties do not apply when the surgery is necessary to save the woman's life or to protect her from major harm.

### Qatar

In Qatar, the conditions for permitting abortion are regulated by Law No. 2/1983, which governs the practices of physicians, surgeons, and dentists. According to this law, it is prohibited to perform abortions; however, provided that the pregnancy duration is less than four months, abortion is authorized in the following cases: if the continuation of the pregnancy would cause certain and serious harm to the woman's health or if there is evidence that the foetus would be born suffering from serious and incurable physical malformation or mental deficiency and both spouses consent to the abortion.

Abortion must be performed in a government hospital upon the recommendation of a commission composed of three medical specialists, including a specialist in gynaecology and a specialist in obstetrics.

Violations of this law are regulated by Qatari Penal Law No. 11/ 2004. According to this law, the pregnant woman who does not meet the above criteria and seeks to and successfully terminates the pregnancy faces up to three years imprisonment. If the act is performed with her consent, the individual who performed the abortion faces up to seven years imprisonment. If performed without her consent, the individual who performed the abortion faces up to ten years imprisonment. Additionally, violent assault of a pregnant woman with prior knowledge of her pregnancy, which leads to miscarriage, exposes the assailant to up to ten years imprisonment.

## Egypt

In Egypt, Decree No. 238/2003, of the Ministry of Health and Population on Professional Ethics Regulations, prohibits physicians from carrying out abortion operations, except when the pregnancy might threaten the woman's health. This requires a written certificate confirming the risk from two specialists. In emergency cases, where the operation is carried out to save the woman's life, the responsible physician must write a detailed report on the case and attach it to the treatment file.

Penal Law No. 58/1937 (Art. 260-264) and Decree No. 238/2003 (Art. 29) of the Ministry of Health and Population on Profession Ethics Regulations, state that any physician who violates these rules will be subjected to disciplinary action by a Disciplinary Council. The penalties range from reprimand to expulsion from the Syndicate and withdrawal of his/her professional license, without which s/he cannot practice. The Disciplinary Council may also transfer the case to the Criminal Investigation Authority (Al-Niyaba Al-A'mma). It is to be noted that, although the decree addresses the various conditions under which illegal abortions may occur and provides for penalties (mainly imprisonment), there is a need to determine the resulting durations of prison sentences.

## Algeria

In Algeria, this issue is regulated under Ordinance No. 66-156 of the Algerian Penal Code (8 June 1966) and Public Health Code Ordinance No. 76-79 (23 October 1976). These regulations stipulate that abortion is permitted if it is necessary to save the life of the woman or to safeguard her from serious health risks. The Public Health Code also states that two physicians should make this decision after the woman has given her consent. Law No. 85-05 on the Protection and Promotion of Public Health (16 February 1985) also permits abortion when it is an essential measure to preserve a woman's mental health, when it is seriously jeopardized. Abortion is not permitted in cases of rape, unless the rape is committed in the context of terrorist violence, a condition that was stipulated in April 2004, after 1600 cases of sexual aggressions since 1993. This authorization was granted by virtue of a public authority decision and a fatwa.

The amended Art 310 of Penal Code Law No. 82-04 (13 February 1982) makes it a crime punishable by imprisonment and a fine to say or write anything in public or private, including in medical journals, that encourages abortion, whether or not an abortion is actually performed as a result.

Instruction No. 05 MSP/MIN/SP (5 May 1998) sets the conditions and methods of implementation of therapeutic abortion for victims of rape committed by one or more terrorists. Executive Decree No. 04-182 (24 June 2004) regulates the creation, organization, and operation of national refuge centres for girls and women who are the victims of violence. A reform of the Penal Code is in discussion and will take into consideration the issues of sexual violence and rape.

## Libya

In Libya, both Law No. 17/1986 (concerning medical liability) and Ministry of Health Decision No. 654/1975 (on issuing the executive regulation of Health Law of 1973) permit abortion only if it is necessary to save the woman's life. Ministry of Health Decision No. 654/1975 further details the conditions for this kind of abortion. Two physicians must agree on the need for abortion and express it in an official report indicating the name of the pregnant woman, her age, religion, and period of pregnancy. It must also include a statement about her previous pregnancies, her medical examination, the diagnosis of her situation, the factors confirming the potentially lethal risks of the pregnancy, and her consent or that of her guardian if she is a minor.

The Libyan Penal Law and the amendments of it set the different punishments and prison sentences for a woman who carries out a self-induced abortion or gives her consent to undergo an illegal abortion, for the person who performs it, whether or not s/he is a medical professional and whether s/he performed the abortion with or without the woman's consent. The Libyan Penal Law also specifies the penalties for the perpetrator of an abortion that is performed for reasons related to "honour".

## Jordan

Public Health Law No. 54/2002 and the National Medical Guidelines (1989) permit abortion if the pregnancy poses a threat to the woman's life or health. The threat must be confirmed by two physicians and the woman's consent must be obtained. (If she is unable to give consent, her husband or legal guardian may do so on her behalf.)

The Penal Law of 1960 describes the various conditions under which self-induced abortion and illegal abortion performed with or without the woman's consent may occur and lays out the penalties for such acts. Special consideration in penalties is mentioned if the abortion was conducted for the sake of the honour of the woman.

There is currently a demand in Jordan to update and modify these laws in accordance with that which relates to abortion in Islamic *Sharia*, which includes the permissibility of conducting an abortion on a woman whose pregnancy is less than 16 weeks in case of rape or if the prenatal diagnosis shows an anencephaly, and, in some cases, congenital deformity or chromosomal aberration, which would make it impossible for a baby to survive after birth.

## Palestine

Palestine has two criminal codes: Criminal Code Law No.16, 1960 (in force in the West Bank) and the Criminal Code Ordinance of 1936 (in force in Gaza Strip). The Criminal Code Law of 1960 only mentions abortion related to "honour": a woman who performs an abortion on herself, or a relative (up to the third degree) who performs an abortion on her shall enjoy extenuating circumstances if "honour" is a factor. The plurality of criminal codes in force is a real obstacle



towards unifying the Palestinian legal system. Indeed, the same “crime” is treated or punished differently in each part of Palestine. The Palestinian survey responses indicate that the draft criminal code needs to be improved because it contains ambiguities, even in comparison to the outdated Jordanian and British criminal codes in force.

## Syria

In Syria’s survey responses there is no mention of therapeutic abortion. Indeed, Criminal Law of 22 June 1949 updated in 1979 and Legislative Decree No. 12 of 7 January 1970 “Law of Medical Practice” prohibit abortion and provide for penalties for self-induced abortion or other cases of abortion. The Criminal Law also states that the pregnant woman who commits abortion for “honour” reasons or her relatives (up to the second degree) who abort her for the same reason benefit from extenuating circumstances.

## Tunisia

Unlike the other 16 countries surveyed, Tunisia expressly permits abortion when it is requested by a pregnant woman (Art. 214 of the penal code) provided it is carried out within the first three months by a physician in a hospital, sanitary establishment, or an authorized clinic. After three months, abortion is permitted when the continuation of the pregnancy presents a risk to the pregnant woman’s physical or mental health or when the foetus would be born suffering from a serious illness or infirmity.

## Bahrain

In Bahrain abortion is regulated under the Laws and Ministerial Orders for the Regulation of the Medical Professions, Private Hospitals, Dentistry, and Medical Practice, approved in 1987 and updated in 2003. Article 19 of Ministerial Order No.7 states that physicians are not allowed to prescribe medication for the purpose of aborting a pregnancy or to practice abortion except in situations where the continuation of the pregnancy is considered a threat to the mother’s life, including permanent illness (e.g. renal failure). Such a decision should be justified by three licensed physicians. In this case, the procedure should be conducted in a licensed hospital by a specialist physician and after obtaining a written consent from the pregnant woman or her next of kin.

## Morocco

Abortion is regulated in Morocco under Art. 32 of the Residential Decree as to the Code of Conduct of Medical Doctors (1953) and the Moroccan Penal Code, which allow the practice of abortion when the woman’s life is in danger and before the date of foetal viability, provided that the physician consults two other colleagues.

If the pregnant woman is a minor and she consents to undergo the therapeutic abortion, the physician must make all efforts, before undertaking the intervention, to obtain the consent of her husband or that of her legal representative from her family members. If the woman’s life is in danger and her spouse is either absent or unwilling to give his consent, the doctor can proceed with the abortion only after obtaining the written opinion of the chief consultant of the prefecture or the province specifying that there is no other way to save the woman’s life.

If for personal reasons the physician does not agree to perform the abortion, s/he can decline,

but must ensure the continuity of care by a qualified colleague. The laws also determine the penalties for illegal abortion.

## UAE

The UAE regulates this issue under Art 22 and 29 of Federal Law No.7/75, which allows therapeutic abortion when the woman's life is in danger, similar to most of the 17 countries undertaking the survey. The abortion procedure must be carried out by a gynaecologist and the approval of another specialist is necessary. A written report stating the reason for the abortion as identified by the concerned physicians is required and must be signed by the pregnant woman and her husband or guardian to the effect that the abortion is approved. Each concerned party retains a copy of the report.

A physician who violates these stipulations faces imprisonment, withdrawal of his/her license, and deletion of his/her name from the physicians' record. In all cases, the court confiscates the tools and equipment related to the profession present in the physician's clinic and closes the clinic for a period set by the court.

Advertising abortion services is prohibited by Ministerial Order No.774/2007 (amending Ministerial Order No. 430/2007). It is to be noted that there is a proposed 2007 Federal Law on medical liability that also regulates abortion but has not been adopted yet.

## Kuwait

The regulations in Kuwait are based on an interpretation of *Sharia* where only strict conditions permit the termination of pregnancy. The Abortion Law adopted in 1981 and updated in 1984 allows abortion only if the pregnancy presents a threat to the woman's life or if the foetus suffers from serious anomalies. The abortion may only be performed in governmental hospitals, except in emergency cases. Both husband and wife must consent to the termination (or the woman's legal guardian if the husband is absent). Furthermore, the decision of the physician requesting the abortion is examined and questioned by a medical committee of three Muslim physicians specialized in obstetrics and gynaecology, one of whom must hold at least the position of Head of Unit Consultant in OB/GYN. The hospital director's approval must be granted prior to surgery and s/he should inform the Under Minister via an urgent and highly confidential report. The case must be fully documented and the records kept at the hospital.

## Yemen

In Yemen, Law No. 26 (2002) sets the same conditions as Kuwait for allowing abortion (i.e. there must be a threat to the woman's life or anomalies in the foetus, and informed consent). The decision for the medical abortion should be delivered by a medical committee composed of two physicians from other specialties related to the patient's condition. Provided that the decision is in conformity with the Medical Council regulations and *Sharia* and that the termination is carried out in a medical institution (not necessarily a governmental hospital) that is equipped with all necessary facilities.

## Saudi Arabia

In Saudi Arabia, the Regulation for Practicing Medical Professions issued by the Royal Decree No. 5 and based on fatwa No. 140 (20-6-1407) abortion is allowed when the pregnancy

endangers the woman's life, provided such a decision is supported by a medical committee, which takes into consideration the fact that the pregnancy is less than four months. However, even if the pregnancy is more than four months, a medical committee can still decide to terminate the pregnancy to save the woman's life.

## Lebanon

Abortion is prohibited in Lebanon by virtue of the Lebanese Penal Code and the Code of Medical Ethics Law No. 288. These regulations prohibit proposing, selling, or using products that cause abortion, but give extenuating circumstances for women who self-induce abortion for reasons related to "honour," as is the case in Jordan, Syria, and Palestine. Abortion is only permitted in order to save the woman's life, in which case therapeutic abortion is allowed provided that religious beliefs are taken into consideration. The treating physician who recommends therapeutic abortion must consult two colleagues who confirm his/her diagnosis and sign a detailed medical report. The Order of Physicians Council must be informed and the patient must give informed consent. If the patient is in critical condition and is unable to give her consent, the physician may take the appropriate decision even if her family refuses. In the event that the personal beliefs of the treating physician prevent him/her from carrying out abortions, s/he may refer the patient to a colleague.

## Oman

In Oman, the regulations on abortion are based on the following fatwas: the fatwa of the Grand Mufti of Oman, the decision of the Islamic World Association regarding termination of pregnancy in cases of foetal congenital deformity (Mecca, 22-7-1410 H), and the fatwa issued by the Fatwa Committee in Kuwait (29 September 1984). Administrative Decision No. 30/99 (Director General of Royal Hospital) and the Criminal Procedures Law (Royal Decree No.7/74: For Abortion) state that abortion is prohibited for social reasons and physicians shall not terminate any pregnancy exceeding 120 days from the time of fertilization except to save the woman's life from pregnancy-related danger. The abortion can be performed with the husband and wife's consent if gestation is less than 40 days from the time of fertilization. If gestation exceeds 40 days and is less than 120 days, the abortion can only be conducted if it is done for strictly foetal-lethal malformations or maternal-underlying medical diseases, when pregnancy threatens the woman's life. A special consent form is used: both husband and wife must consent after being counselled by the treating physicians and two obstetricians' signatures are needed. In the case of foetal malformation, the signature of one paediatrician or neonatologist is requested and in case of maternal diseases that of a specialty physician is required. Two of the above three physicians should be of Muslim faith.

# General Conclusion and Recommendations

The following questions must be considered: Why should bioethical regulations and legislation in the Arab world be analyzed and addressed? What is the Arab contribution to the field of bioethics? How can we foster solidarity and assistance regarding bioethics in these countries, which differ in their political systems, cultures, ways of life, and beliefs and which are also affected by various conservative religious movements? We must also consider the obstacles and regional political conditions that prevent dialogue between societies and cultures. There are great obstacles to overcome and answers should be explored while keeping in mind the religious and political constraints. Finally, these issues should be addressed and these efforts made in a context of respect and tolerance.

There are a number of issues that must be kept in mind as new approaches to developing and reforming bioethics in the Arab world can be pursued:

- 1) Bioethics is a vast and growing field that cannot accommodate self-isolation or the ostracism of others. The exploration and development of bioethical practices and regulations encourage pluralistic debate since bioethics is in its nature interdisciplinary and is of such great concern and importance to all societies.
- 2) In some of the countries surveyed, there is a serious lack of legislation on bioethics. Legislation and regulations are often discordant and debate is tenuous. Over the last ten years, bioethics committees have increased in number in the Arab world, but they are disconnected and lack cohesion. Bringing together and introducing reforms to these committees poses a great challenge due to various countries' and authorities' resistance to engaging in pluralistic debate, which can be perceived as potentially causing problems for politicians and for religious leaders or communities.
- 3) Despite the many international exchanges currently taking place, the Arab countries' differences have made the problems and challenges regarding bioethical development and the creation of regulations and legislation increasingly complex. Nevertheless, through meetings and dialogue, bioethics is progressively becoming a means to founding a universal ethical culture. We must foster cooperation and exchange among Arab countries without compromising national and cultural identities. This is not an easy task because, as this study demonstrates, significant cultural and economic disparity exists, which results in different approaches to ethical and scientific issues. To achieve an acceptable degree of harmonization among the Arab countries, dialogue between the parties involved in bioethics is a necessity.
- 4) It should also be kept in mind that Islam is the state religion in the majority of the Arab countries surveyed and that Islamic bioethics are rooted in *Sharia* and *Fiqh*, which find their justification in the precepts of the Qur'an and Hadith. In some of the countries, universal principles are also embodied in legislation and are stipulated in their constitutions.

In countries that strictly adhere to Islam, it may be difficult to create independent bioethics committees that are pluralistic, multidisciplinary, and autonomous from political and religious authorities. However, thanks to fatwas issued by authorities who appear to be aware of the advances in modern science, most Muslim countries have not encountered major obstacles in passing legislation on problems resulting from the progress achieved by recent biological, medical, and therapeutic innovations. In addition, although existing Arab bioethics committees tend to work independently without coordinating their efforts, they often find points of commonality when their stances are guided by *Sharia*.

**5)** In contemporary societies, the state assumes the responsibility of regulating relationships between groups and between individuals to ensure that affairs affecting the public cannot be appropriated for the profit of particular interests. This is one of the bases of democracy and it is for this reason that political, religious, and scientific actors should not make decisions concerning bioethical problems independently. The various actors must work together and bring together the various bioethical trends of thought to reach consensus.

The isolation of the parties working to develop and advance bioethics in the Arab world presents many obstacles. We must encourage occasions for creating better harmony and mutual understanding, which will also serve to help moderate the radical positions adopted by certain countries. To facilitate collaboration between the countries and committees the following steps are suggested:

- 1)** The creation of a computerized Arab centre for documentation and information with a translation service to accommodate the documents collected from various national and regional committees
- 2)** The strengthening of the function of national bioethics committees as advisory bodies to the government for policy making
- 3)** The encouragement of direct communication between national bioethics committees and organization of annual meetings between the Arab bioethics committees
- 4)** The creation of a committee or an association to foster bioethical education in Arab faculties of medicine

For the observer or researcher who wishes to encourage bioethical development in the Arab world, there are two subjects of concern: exposing the challenges regarding bioethical issues and attempting to minimize the political and religious constraints that affect the creation and advancement of bioethics committees. These constraints inhibit debate and suppress opportunities for individual and collective initiatives to make progress in research and in practice.

Collaboration on bioethics can also constitute a step toward fostering conditions for peaceful coexistence in the Arab world. The willingness to come together and cooperate is essential for each individual and community. Bioethics can be a test for democracy.

It is absolutely essential that bioethics not merely become a discourse with to familiarize people with technical realities.

## References

- Tristan Engelhart:** *The foundations of bioethics*. New York 1986, p5
- Daniel Callahan:** *Why America accepted Bioethics*. Hasting Center report. Suppl23, dec 97.
- Lucien Seve:** *S'entendre en bioéthique*. Revue Projet.1998,
- Abd-al-Haqq Guiderdoni :** *Les principes fondamentaux de l'éthique en Islam*. Revue d'éthique et de théologie morale. 2001
- International Organization of Islamic Medicine:** *Islamic Code of Medical Ethics*. 1981
- Mohammed Arkoun:** *L'Islam hier-demain*. Buchet/Chastel 1978, p141
- Jean Ducruet, SJ:** *Les Contextes de la réflexion éthique*, Rencontres intercongregationnelles. Jbeil. Liban. 2005
- Emmanuel Kant:** *Critique de la raison pratique*. P.U.F 1971, p 30.
- Comité National Tunisien d'Ethique Médicale:** *Avis et activités*, 1996-2000.
- Pierre Gannagé:** *Le pluralisme des statuts personnels dans les Etats multicommunautaires*, Bruylant 2001
- Khalil Rfaa:** *Les apports de l'Islam dans l'éthique médicale*, *Revue du Conseil Supérieur Islamique*. Alger 1999.
- Hisham Nashabé:** *Points of convergence among Christians and Muslims*. CIB, ninth session, nov. 2002.
- Samuel Trigano:** *Le monothéisme est humanisme*. Odile Jacob, 2000, p32
- Henri Lammens:** *L'Islam, croyances et institutions*, Beyrouth, 1926, p 65





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EG/2011/SS/PI/01  
ISBN 978-92-3-104211-9