



شعبة الترجمة الرسمية  
Official Translation Department

## Law of Ethics of Research on Living Things

Royal Decree No. M/59  
August 24, 2010

Translation of Saudi Laws



**NOTE:**

The translation of Saudi laws takes the following into consideration:

- Words used in the singular form include the plural and vice versa.
- Words used in the masculine form include the feminine.
- Words used in the present tense include the present as well as the future.
- The word “person” or “persons” and their related pronouns (he, his, him, they, their, them) refer to a natural and legal person.



## Law of Ethics of Research on Living Things

### Article 1: Definitions

The following terms and phrases – wherever used in this Law – shall have the meanings assigned to them, unless otherwise required by context.

**Law:** Law of Ethics of Research on Living Things.

**Regulations:** Implementing Regulations of the Law of Ethics of Research on Living Things.

**KACST:** King Abdul Aziz City for Science and Technology.

**President of KACST:** President of King Abdul Aziz City for Science and Technology.

**National Committee:** National Committee of Biomedical Ethics.

**Monitoring Office:** Research Ethics Monitoring Office.

**Local Committee:** Committee for licensing research formed at an establishment in accordance with the provisions of this Law.

**Establishment:** A public or private corporate entity engaged in research activities on living things.

**Researcher:** A person academically qualified in a subject related to research and has completed a course on research ethics.

**Research:** A systematic experimental investigation aiming at improvement of biosciences or enrichment or development of general knowledge by using a living thing or parts thereof.

**Living Things:** Human beings, animals and plants.

**Genetic Material:** Chain of nitrogenous bases that exist within the cells or are extracted therefrom and are responsible for carrying traits and characteristics from the mother cell to the sub-cell and from one living thing to its offspring.

**Legal Capacity:** Reaching the age of eighteen, with mental ability to enter into legal relation on his own.

**Informed Consent:** A person giving his consent with his free will, without exploitation or coercion and upon full understanding of what is required from him and of the research objectives and potential risks as well as of rights and obligations arising out of his participation therein.

**Minor:** A person under eighteen years of age.

**Fetus:** Outcome of pregnancy from the beginning of nidation in the uterus to the time of its delivery or removal.

**Guardian:** A person having the right of legal authority over another person.

**Sperm:** The product of fertilization up to forty days.

**Zygotes:** An egg fertilized by a male sperm; from the time of fertilization until the time of division into eight cells.



**Gamete:** The product of fertilization; from the end of the zygote phase until the phase of nidation where the zygote is implanted in the uterus.

**Cloning:** The process of producing a complete individual genetically identical to another without sexual intercourse.

**Product of Pregnancy:** A fetus that comes out of or removed from the uterus.

**Experimental Animals:** Animals raised in cages or at certain places to be used in scientific experiments.

**Minimal Risk:** Minor harm not exceeding potential risk encountered in daily life, which cannot be avoided during ordinary clinical or psychological examination, including potential discomfort and inconvenience.

**Legally Incompetent:** A person lacking full legal capacity due to being a minor, lacking the ability of sound reasoning and judgment or being subject of a court ruling placing him under custody or continuation thereof which bars him from entering into a legal relation on his own.

**Disabled:** A person suffering from a permanent full or partial deficiency in his physical, sensory, communicative, educational or psychological abilities to an extent that affects the possibility of meeting his common needs compared to his non-disabled peers.

**Child:** A male or female not reaching the age of eighteen years which entails him to give an informed consent.

**Embryonic Stem Cells:** Cells removed from the fertilized egg in its early phases; before the differentiation phase.

**Adult Stem Cells:** Organically unspecialized cells that are removed from the cells of a fully developed living being.

## Article 2

This Law aims at setting the general principles and controls necessary for dealing with living things, parts thereof or their genetic material in research in light of applicable professional ethics not conflicting with Sharia.

## Article 3

No establishment may conduct research on a living thing except upon fulfilling procedures required under this Law. Research shall be subject to periodic inspection by the National Committee in accordance with the Regulations.

## Article 4

1. A national committee of bioethics shall be formed at KACST comprising specialists nominated by the competent minister or head of an agency for a renewable term of 3 years, as follows:
  - A representative of KACST, Chairman.
  - A representative of the National Guard, Member.
  - A representative of the Ministry of Defense and Aviation, Member.



- A representative of the Ministry of Interior, Member.
  - A representative of the General Presidency of Religious Research and *Iftha'*, Member.
  - Two representatives from the Ministry of Higher Education (Universities), Members.
  - A representative of the Ministry of Health, Member.
  - A representative of the Ministry of Education, Member.
  - A representative of the Ministry of Agriculture, Member.
  - A representative of the Saudi Wildlife Commission, Member.
  - A representative of the Food and Drug General Authority, Member.
  - A representative of King Faisal Specialist Hospital and Research Center, Member.
  - A representative of Human Rights Commission, Member.
  - The Director of Research Ethics Monitoring Office, Member.
  - A representative of the private sector selected by the Chairman of the Council of the Chambers of Commerce and Industry, Member.
  - A legal counselor selected by the President of KACST, Member.
2. The President of KACST shall issue the committee-formation decision, and said committee shall report to him.
  3. The President of KACST shall appoint a secretary for the committee.
  4. Committee members shall elect from among themselves a vice president.

#### **Article 5**

The National Committee shall convene periodically upon the Chairman's call or as necessary. The committee shall convene upon a call by its Chairman or upon a written request by one third of its members. Committee meetings shall not be valid unless attended by two thirds of its members. Committee resolutions shall pass by majority vote of attending members. In case of a tie, the Chairman shall have the casting vote. The Regulations shall determine committee work procedures and meetings as well as remuneration of members in accordance with applicable laws, resolutions and directives.

#### **Article 6**

The National Committee shall set standards for biological research ethics and oversee enforcement thereof. It shall be the authority regarding overseeing research ethics and monitoring implementation thereof. It shall particularly undertake the following:

1. Prepare bioethics research regulations and review them in accordance with recent developments.
2. Propose amendment to the Law and its Regulations.
3. Form specialized subcommittees for conducting detailed studies on research fields within the jurisdiction of the National Committee.
4. Set controls for sending biological samples to laboratories outside the Kingdom.
5. Oversee local committees and monitor compliance with Sharia and statutory rules when dealing with biological material.



6. Set ethical controls and monitor implementation thereof to safeguard rights of human subjects during research and ensure confidentiality and security of research information.
7. Establish a database for saving and retrieving national information on genetic material of Saudi society.
8. Coordinate between the Kingdom and other countries as well as Arab and international organizations with regard to its jurisdiction, in accordance with applicable legal procedures.
9. Set bylaws for the National Committee.
10. Propose annual budget of both the National Committee and the Research Ethics Monitoring Office.
11. Oversee and monitor the central information system for national genetic material banks and set controls for documentation and retrieval thereof.
12. Set rules and principles for ethical recognition of research laboratories working in biomedical fields.
13. Conduct periodic ethical evaluation and monitoring of national laboratories, and monitor medical research and experiments conducted on living things to ensure legitimacy.

The Committee may seek consultation from experts, associations, scientific centers or specialized agencies within the Kingdom and abroad.

#### **Article 7**

An annual financial allocation shall be set for the National Committee within the budget of KACST along with endowments allocated therefor.

#### **Article 8**

Pursuant to this Law, an office for monitoring research ethics shall be established, and it shall report to the National Committee. Said office shall be located at KACST in Riyadh, and it may establish branches in the Kingdom's provinces pursuant to a decision by KACST President upon recommendation by the National Committee. The office shall be headed by a specialist with experience in medical and scientific research and research ethics.

#### **Article 9**

The Monitoring Office shall be in charge of the following:

1. Register and oversee local committees in accordance with the provisions of this Law.
2. Monitor the implementation of research ethics subject to this Law through local committees.
3. Any other tasks assigned thereto by the National Committee.

The Regulations shall specify the office rules and procedures.

#### **Article 10**

Each establishment shall form a local committee consisting of at least five members. The Regulations shall determine the manner of forming said



committee as well as the provisions and rules governing its activities. The committee shall especially, but not exclusively, undertake the following:

1. Verify that the research conforms to applicable laws in the Kingdom.
2. Verify the validity of the informed consent procedures.
3. Issue approval to conduct research from an ethical aspect.
4. Monitor research implementation on a periodic basis.
5. Monitor the health condition of the human subject during the experiment.
6. Coordinate with the monitoring office as regards its relevant activities.

#### **Article 11**

No researcher may conduct research on any human subject prior to obtaining an informed consent from him or from his guardian in accordance with procedures specified by the Regulations.

#### **Article 12**

Upon obtaining the informed consent, the researcher shall clearly explain to the human subject or his guardian all potential outcomes of the research including harmful ones, if any, which result from withdrawal of the informed consent.

#### **Article 13**

The informed consent shall be documented in accordance with conditions and procedures specified by the Regulations.

#### **Article 14**

Subject to the provisions of Article 11 of this Law, the local committee may approve conducting the research without obtaining the informed consent if it is not possible to relate the information obtained by the researcher from the records or pathological samples to the source person or if the results related to individuals are available to the public.

#### **Article 15**

Research conducted on humans shall be for clear scientific objectives, and shall be preceded by sufficient laboratory experiments on animals if the nature of the research so requires.

#### **Article 16**

The expected benefit from the experiment or research to the human subject shall be greater than the possible harm.

#### **Article 17**

The researcher may not in any way exploit the conditions of the human subject and shall not expose him to any type of coercion or exploitation.



**Article 18**

Approval to conduct research on humans shall take into consideration their right to normal life and their safety from all types of harm in accordance with the provisions of *Sharia*.

**Article 19**

The researcher may not exploit the human subject for the purpose of trading in gametes, zygotes, organs, tissues, cells or any parts thereof or genetic data related to human derivatives or products.

**Article 20**

An organ removed for a purely medical purpose may be used in scientific research upon obtaining the informed consent.

**Article 21**

No research may be conducted on human zygotes, gametes or fetuses except under controls specified by the Regulations.

**Article 22**

No research may be conducted for the purpose of human cloning.

**Article 23**

Research may be conducted on tissues, living cells and separated parts, including stem cells extracted from the umbilical cord or adult stem cells, upon obtaining the informed consent.

**Article 24**

Prisoners, including those sentenced to death, shall be treated like other persons as regards conducting medical research on them. The Regulations shall specify ethical controls for conducting research on prisoners.

**Article 25**

Research may not be conducted on minors, incompetent or disabled persons unless the interest of these categories so requires. The Regulations shall specify ethical controls for conducting research on said categories.

**Article 26**

Pregnant women, fetuses and the product of pregnancy may not be used in research except in accordance with controls specified by the Regulations.

**Article 27**

Cells, tissues and derivatives of human sperms, gametes and zygotes may not





be transported or exploited for the purpose of research except in accordance with conditions and restrictions laid down by the National Committee.

**Article 28**

Fetuses may not be cloned for the purpose of obtaining embryonic stem cells, nor may male or female gametes taken from sperms or eggs be donated to produce fertilized eggs that can grow into a fetus for the purpose of generating stem cells therefrom and conducting research thereon.

**Article 29**

Banks for preserving reproductive male or female cells with the intent of conducting research thereon may not be established.

**Article 30**

Organs and tissues of fetuses aborted before reaching one hundred twenty days may be used in research and experiments in accordance with controls and conditions set forth in the Regulations.

**Article 31**

A central data bank shall be established within KACST for the purpose of maintaining information related to genetic material and regulating use thereof in accordance with procedures specified by the Regulations. Said bank shall provide information for research using genetic material in the Kingdom.

**Article 32**

When setting up local data banks for the preservation of genetic material, establishments conducting research on such genetic material shall comply with conditions and procedures specified by the Regulations.

**Article 33**

The same genetic sample may not be subject to multiple use in research projects of different purposes without obtaining an informed consent for each purpose except if such use is not related to the source person, provided this is approved by the local committee.

**Article 34**

The researcher shall observe the privacy and confidentiality of information related to those from whom the research samples have been collected.

**Article 35**

The local committee may restrict the researcher's use of research results on genetic material if said results harm public interest, provided the National Committee approves the same.



### **Article 36**

Research with negative impacts on society may not be conducted, especially research reinforcing racial discrimination.

### **Article 37**

The Regulations shall specify the ethical controls and criteria of genetic treatment research.

### **Article 38**

1. Animals may be used for research employing all experimental or scientific means not causing unusual pain to the animals.
2. Use of animals shall be restricted to research whose objectives cannot be realized without such use.
3. Endangered animal species may not be subject to negative use.

The Regulations shall specify ethical conditions and procedures for use of animals in research.

### **Article 39**

Plants may not be used in research that upsets environmental balance and distribution of vegetation. Endangered plant species may not be subject to negative use. The Regulations shall specify ethical terms and procedures of research on plants.

### **Article 40**

If research includes conducting genetic modification experiments on living things, the researcher shall take all necessary measures to prevent their escape from research laboratories.

### **Article 41**

KACST President shall designate employees in charge of detecting violations of the provisions of this Law and its Regulations in accordance with procedures specified by the Regulations.

### **Article 42**

A. A committee shall be formed pursuant to a decision by KACST president to review violations of the provisions of this Law and decide appropriate penalties, except for imprisonment, according to this Law. Said committee shall determine amount of damages for private claims. The committee shall comprise the following:

1. A *Sharia* counselor named by Minister of Justice, Chairman
2. A faculty member of a Saudi medical college, of a rank not lower than associate professor, named by the Minister of Higher Education, Member
3. A researcher specialized in genetic material, of a rank not lower than associate professor or equivalent, selected by KACST President, Member



4. A qualified and experienced researcher specialized in bioethics, selected by KACST President, Member
5. A legal counselor selected by KACST President, Member
6. A faculty member of a Saudi university specialized in zoology, of a rank not lower than associate professor, named by the Minister of Higher Education, Member
7. A faculty member of a Saudi university specialized in botany, of a rank not lower than associate professor, named by the Minister of Higher Education, Member

Said committee may seek the assistance of one or more experts as regards the issue in question.

- B. The committee seat shall be at KACST in the city of Riyadh. Similar committees may be established the Kingdom's provinces pursuant to a decision by KACST President.
- C. Remuneration of committee chairman and members shall be determined in the Regulations according to applicable laws, decisions and directives.
- D. The Regulations shall determine committee rules, procedures and meetings.
- E. Committee term of membership shall be three renewable years. If a member is unable to complete his term for any reason, a replacement shall be appointed in the same manner the replaced member was appointed.
- F. The committee shall convene if attended by two-thirds of its members upon a call by the Chairman as needed. Committee resolutions shall pass by majority vote of attending members. In case of a tie, the Chairman shall have the casting vote.

#### **Article 43**

Public prosecution before the committee shall be carried out by competent personnel designated by KACST President.

#### **Article 44**

Without prejudice to any severer penalty prescribed by other laws, a person violating any provision of this Law shall be subject to one or more of the following penalties:

1. Warning.
2. Suspension of research until the effects of the violation are rectified.
3. Barring the researcher from conducting the research subject of the violation.
4. A fine not exceeding two hundred thousand (200,000) riyals.
5. Imprisonment for a period not exceeding six months.

#### **Article 45**

If the committee decides to impose a penalty including imprisonment, a recommendation to this effect shall be submitted to KACST President for referral to the competent court.

#### **Article 46**

The committee may include in the final penalty decision publication of the



decision text at the expense of the violator in not more than three local newspapers, one of which at least is published in the region where he resides. If no such newspaper is published in the region, the decision shall be published in the newspaper published in the nearest region.

**Article 47**

An aggrieved party may appeal the penalty decision before the Board of Grievances within sixty days from date of notification.

**Article 48**

KACST President shall issue the Implementing Regulations of this Law within ninety days from date of publication of this Law.

**Article 49**

This law shall enter into force ninety days from the date of its publication in the Official Gazette.

**Article 50**

Existing establishments shall fulfill necessary conditions and requirements and adjust their status within ninety days from the effective date of this Law.

**Article 51**

This Law shall supersede all other provisions conflicting therewith.