National Committee of BioEthics

Implementing Regulations of the Law of Ethics of Research on Living Creatures

Version 3

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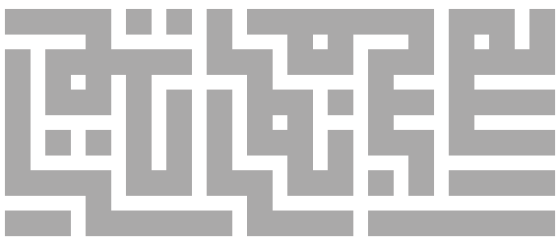

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Chapter One

Definitions and General Provisions

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 Creatures.

Regulations: Implementing Regulations of the Law of Ethics of Research on Living Creatures.

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 Creatures.

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 creature or parts thereof.

Living Creatures: 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 creature 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 (1.1)

Without prejudice to the meanings of the terms and phrases specified in Article 1 of the Law, the following terms and phrases – wherever used in the Law – shall have the meanings assigned to them, unless otherwise required by context.
Human Subject (Participant): A person who consents or whose guardian consents to conduct clinical, non-clinical or therapeutic research or experiments on him.
Principal Investigator: Lead researcher in charge of planning and conducting the research, collecting and analyzing data, and directing interventions stated in the research plan.
Clinical Research: Any research related to collecting and analyzing data for volunteers or patients for the purpose of obtaining general knowledge that can be applied to other individuals with regard to mechanism of disease, its incidence, prevalence, transmission or treatment of a disease.
Non-Clinical Research: Any research related to collecting and analyzing data not directly related to people for the purpose of obtaining general knowledge or facts.
Clinical Trial: Experiments conducted on human volunteers to examine safety and effectiveness of a medication or medical device.
Prisoner: A person deprived of liberty, whether serving a prison sentence, detained on trial, or is a correction facility inmate.
Vulnerable groups: Groups of individuals in need of additional protection due to their lack of legal capacity, their questionable or diminished capacity or their lack of freedom to choose.

Stillborn: A fetus delivered, came out of, or removed from the uterus with no signs of life such as heartbeat, natural breathing, movement, or pulsation of the umbilical cord if still connected.

Diagnostic Procedure: A test aiming at finding a certain disorder or disease in a living creature.

Medication: A chemical compound administered to a living creature to help diagnose, treat, prevent, cure or alleviate the effects of a disease or organic disorder.

Periodic Assessment: Observation of research progress by safety assessment and information monitoring committee to ascertain safety of the human subject on a continuous basis and to ensure nonexistence of any reason for discontinuation or modification of the research.

Periodic Follow-up: Review of the periodic report submitted by the principal investigator to the local committee to evaluate research progress and conformity with the approved research plan.

Expedited Review: An evaluation carried out by the local committee chairman, or by a committee member designated by him, of a new research project or modifications of a previously approved research where potential risk to the human subject does not exceed minimal risk.

Genetic Therapy Research: Any research which includes insertion or deletion of genetic material within body cells or targeting the same whether by modification or deactivation for finding a treatment for hereditary or other diseases.

Confidentiality: Non-disclosure or passing of any data, information or results related to the research or the human subject, to any third party not connected with the research.

Privacy: Observing common values, including traditions, thoughts and norms.

Safety Assessment and Information Monitoring Committee: A group of scientists, physicians, and statisticians independent from researchers, whose task is to review accumulated data during clinical experiments for prompt analysis and to observe any significant likelihood towards a certain trend in the results or unacceptable side effects requiring a recommendation for suspension of research or modification of its plan.

Genes: Molecular units of heredity data in all living organisms that encode the information required for building and preserving cells and performing all vital functions, and hence building bodies of Living Creatures and giving them their characteristic features.

Major Harm: Any harm leading to a participant›s death, jeopardy to his life, hospitalization beyond expectation, permanent disability, or deformation of fetus. This harm is deemed unexpected if not stated in the "informed consent".

Contract Research Organization (CRO): A public or private organization with which the beneficiary contracts to delegate to it the performance of one or more of the research tasks.

Beneficiary: An entity with a personal or corporate structure, public or private, authorizing the research organization (CRO) to carry out some or all of his responsibilities for research based on a contract between them, whether in his capacity as researcher, sponsor or financer of the research.

Contract: a signed contract between the beneficiary and the Contract Research Organization (CRO) that specifies the obligations and rights of each of either party.

Adverse events: unwanted event, expected or unexpected, or deterioration in a pre-existing condition, or any abnormal laboratory indicator during or after applying a treatment or procedure under investigation, whether related to the investigational procedure or not. Such event is considered unexpected if it is not listed in the informed consent.

Clinical Trial Agreement (CTA): it is a contract between the Contract Research Organization (CRO) and the principal investigator, detailing both parties' obligations and rights related to conducting the clinical trial.

Animal: all vertebrate and non-vertebrate animals recognized for use in experiments.

Pain in animals: a response to an internal or external stimulus that the specialist can recognize by observing the abnormal behavior of the animal.

Plant genetic resources: plant genetic resources for food and agriculture that contain any genetic resource of plant origin and are of actual or potential value for food and agriculture, including plant genetic material that contains functional units of heredity intended for sexual or vegetative propagation.

Traditional knowledge: traditional and heritage practices, which have accumulated over generations by the community and farmers for the use and preservation of plant genetic resources.

Plant variety: A group of plants within the range of one of the lowest known botanical classifications, defined by the ability of its distinctive and other genetic characteristics to reproduce.

Natural site: The natural environment in which plant genetic resources are located.

Unnatural site: The place where plant genetic resources are kept outside their natural environment.

Ecosystem: a natural space and its contents of living creatures plant, animal, and non-living components.

In-situ conservation: the maintenance of ecosystems and natural habitats, and the maintenance and restoration of populations of species that have viability constituents in their natural environments.

Natural habitats: The natural environment in which the living creature exists or the environment surrounding the species (which affects and is affected by this species).

Ex situ conservation: conservation of plant genetic resources outside their natural habitats.

Terminator seeds: seeds that produce sterile plants, used in some genetically modified crops, thus forcing farmers to buy seeds every year.

Microorganisms (Microbes): are minute living creatures that include bacteria, fungi, and viruses.

Dual-use research (microorganism): Research on uses that can benefit or harm humans or the environment.

Infectious microorganisms: are microscopic living creatures and include pathogenic bacteria, fungi and viruses.

General Provisions

Article (1.2)

Scope of Application

1- The provisions of the Law and its Regulations shall apply to any research establishment conducting research on living creatures in the Kingdom of Saudi Arabia.

2- Research conducted on samples taken from within the Kingdom shall be subject to the provisions of the Law and its Implementing Regulations as regards taking the informed consent and sending genetic samples abroad.

Article (1.3)

Principles Governing Provisions of the Law and its Regulations

In interpretation and application, the provisions of the Law and its Regulations shall be subject to Sharia provisions as adopted by official bodies in the Kingdom, laws and controls set by the National Committee, and principles of human rights, without prejudice to provisions of Sharia.

Article (1.4)

Banning Biological Research outside Licensed Establishments

Conducting biological research outside the premise and scope of supervision of licensed establishments shall be deemed a violation of the provisions of the Law and its Regulations.

Chapter Two

Objectives of the Law

Article 2

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

Article (2.1)

The Law aims to protect the rights of the human subject or part thereto, guarantee his safety and dignity, and not harm animals or plants when conducting research.

Article (2.2)

Sharia dictates and professional ethics enforced in official bodies in the Kingdom as well as rules and procedures set by the National Committee shall be observed in implementing the provisions of the Law and its Regulations.

Article 3

No establishment may conduct research on a living creature 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 (3.1)

No establishment may conduct research on Living Creatures except after registration of a local committee that grants licensing for conducting research and monitors research ethics in accordance with provisions of the Law and its Regulations.

Article (3.2)

The establishment shall be responsible for any research conducted therein and shall, through local committees, ensure that the researcher and research staff comply with controls, procedures and provisions set forth in the Law and its Regulations as well as decisions of the National Committee.

Chapter Three

National Committee of Bioethics

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 Ministry of National Guard	Member
A representative of the Ministry of Defense	Member
A representative of the Ministry of Interior	Member
A representative of the General Presidency of Religious Research and *Ifta'*	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 (4.1)

1- The President of KACST shall send a request for nomination to ministers and heads of relevant agencies as specified in Article 4 of the Law not less than three months before the formation or re-formation of the National Committee.

2- Each Minister or head of a relevant agency shall name a representative at the National Committee in ample time prior to the date set for formation of the committee, taking into consideration the following conditions:

a) Be a Saudi national.

b) Have academic qualification and experience necessary for contribution to committee work.

c) Be known for integrity and competency.

d) Not be previously convicted of a crime impinging on religion or honor.

3- If any member of the National Committee is unable to complete his term for any reason, or if he expresses his desire to discontinue his membership in the committee, or if he fails to attend three consecutive or seven non-consecutive meetings within the same year without an excuse acceptable to KACST President, a replacement shall be appointed in the same manner the replaced member was appointed to serve the remainder of his term.
4- Committee membership shall be a renewable term of three years, provided half the members are replaced upon committee re-formation for the third time. Membership may not be renewed for more than three consecutive terms.

Article (4.2)

1- The National Committee shall have a chairman in accordance with the Law. Said chairman shall have a deputy to be elected by members of the National Committee by secret ballot in the second committee meeting. The President of KACST shall be notified of the ballot result.
2- The Chairman of the National Committee shall oversee its activities and all its administrative, financial and technical matters, particularly the following:
    a) Call for National Committee meetings and approve meeting agendas.
    b) Preside over and manage National Committee meetings.
    c) Ensure that National Committee decisions and recommendations are properly reported and pursue implementation thereof.
    d) Submit National Committee budget to KACST President.
    e) Represent the National Committee before governmental, judicial and other bodies within the Kingdom and abroad.
3- The Deputy Chairman of the National Committee shall assume the tasks of the Committee Chairman in his absence or if so delegated.

Article (4.3)

A general secretariat for the National Committee shall be formed pursuant to a decision by KACST President upon recommendation of the Chairman of the National Committee to be in charge of the following:

1- Prepare for National Committee meetings, including preparing invitations and ensuring their delivery, as well as meeting minutes and agendas.
2- Provide documents, research and studies related to items on National Committee meeting agendas.
3- Prepare monthly reports on the activities of the National Committee.
4- Propose the annual budget of the National Committee and the Research Ethics Monitoring Office.
5- File and organize documents related to National Committee work.
6- Maintain, file and make available to the public regulations, rules, directives and controls issued by the National Committee in accordance with its jurisdiction as set forth by the Law.

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›s work procedures and meetings as well as remuneration of members in accordance with applicable laws, resolutions and directives.

Article (5.1)

1- The National Committee shall hold a monthly meeting upon a call by its Chairman or designee.
2- The National Committee may hold extraordinary meetings if its Chairman or designee deems it necessary. Said meetings shall only discuss items on the agenda without adding any other items unless the Committee Chairman or designee decides otherwise.
3- If one or more members deem it necessary to hold an extraordinary meeting and this is supported by at least one third of the members of the National Committee, they shall submit a request in writing or by e-mail to the Committee Chairman or his designee, naming the members in support of the meeting and the topic(s) to be discussed. In this case, the Chairman or his designee shall call the committee to convene within a period not exceeding ten days from the request submission date.
4- The National Committee shall convene at its headquarters or at any other place set by the Committee Chairman or his designee if necessary.
5- Invitations for the meeting shall be sent to Committee members at least ten working days prior to the meeting date. Invitations shall be delivered by hand or sent via ordinary mail or e-mail.
6- Invitations shall include venue, date and time of meeting. Papers and documents related to proposed items on the agenda shall be enclosed therein except for classified documents. Members may have access to all documents at the meeting place whether prior to or during the meeting.
7- The agenda of the National Committee meeting shall include the following items:
    a) Minutes of the previous meeting for approval.
    b) Topics proposed by the National Committee Chairman or members.
    c) Monthly reports prepared by National Committee Secretariat, if any, upon approval by Committee Chairman.

Article (5.2)

1- National Committee meetings shall not be valid unless attended by two-thirds of its members including the Chairman or his designee.
2- If the quorum provided for in Paragraph (1) above is not met within half an hour of the designated time of the meeting, the Chairman shall adjourn the meeting and set a new date within ten days. The call for said meeting shall be made at least five working days prior to the meeting date.

3- If the National Committee Chairman or his deputy fails to attend the meeting within half an hour of the meeting time, the Committee Secretary shall adjourn the meeting.
4- If the National Committee Chairman becomes aware that neither he nor his deputy can attend the meeting, and it is necessary to hold the meeting, he may delegate a Committee member to chair the meeting, and he shall have the powers of the Committee Chairman with regards to managing the meeting.
5- If any of the National Committee members has an interest in a proposed item for discussion that may affect his opinion or neutrality, he shall declare the same prior to the meeting. In such case, the Committee Chairman may ask him to leave the meeting or to remain without the right to participate in the discussion or voting. If the Chairman leaves for such reason, his designee shall chair the meeting.

Article (5.3)

1- Committee resolutions shall pass by simple majority vote of attending members. In case of a tie, the meeting Chairman shall have the casting vote.
2- Votes may be taken by a show of hands, secret ballot, electronically, or by any other means decided by the Chairman.
3- The National Committee may, if necessary, pass a resolution by circulation if approved by two-thirds of its members. Committee approval of said resolution shall be included in the subsequent meeting minutes.

Article (5.4)

The National Committee may, upon a call of its Chairman or his designee, invite persons with expertise in the item under discussion, whether from within or outside KACST, without such persons having the right to vote.

Article (5.5)

Remuneration of the National Committee Chairman and members shall be determined in accordance with laws and procedures applicable at KACST.

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 Creatures to ensure legitimacy.

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

Article (6.1)

The National Committee Chairman or any of its members may propose amendment to the Law or Regulations. Said proposal shall be submitted for review by the Committee in accordance with its work procedures, and shall then be referred to the President of KACST to address concerned authorities in this regard.

Article (6.2)

Approval of amendments to the Law or Regulations shall be by majority vote of National Committee members.

Article (6.3)

1- The National Committee may, if necessary, form subcommittees for conducting detailed studies on particular matters proposed for discussion.
2- In forming said subcommittees referred to in Paragraph (1) above, members shall be selected based on their academic qualification and competence in conducting research.
3- Remuneration of subcommittee members shall be determined according to applicable rules at KACST.
4- Remuneration of experts, associations, scientific centers or specialized agencies whose consultancy services are sought shall be determined according to applicable rules at KACST.

Article (6.4)

Upon sending biological samples to laboratories outside the Kingdom for research purposes, the researcher, his designee or the specialist involved shall comply with the following principles:

First: Samples sent abroad for research purposes

1- Samples transfer should be limited to international research agencies known for their research experience in the relevant research fields.
2- A Research Material Transfer Agreement shall be drafted to guarantee the rights of human subjects, the rights of the researcher and national rights. The said agreement shall take the form of a joint research to be agreed upon by the local committee in the institution to which the researcher belongs and approved by the official in charge of said institution.
3- If a different Saudi investigator or entity was/or is working on the same subject, samples should not be sent outside the Kingdom of Saudi Arabia. Collaboration should be made with the project running inside the Kingdom, unless such collaboration is rendered impossible for a valid reason that is accepted by the local ethics committee.
4- Data accompanying the submitted samples or material must not reveal the identity of the source person whose sample is submitted. Material may carry only coded numbers.
5- Notifying the National Committee of Bioethics in writing about the Local Ethics Committee decision including the project's purpose, sponsor/s and collaborator/s. The National Committee of Bioethics may decide to stop conducting or completing the project if it appears to carry no benefit to the Saudi society or if it poses a direct or indirect harm to the community. Such rights of the National Committee of Bioethics must be clearly stated in any agreement drawn between the local entity intending to send samples and any other institute outside the Kingdom of Saudi Arabia.

Second: In addition to the principles stated in sections "First", the researcher shall, before sending biological samples outside the Kingdom for research purposes, observe the following:

1- Obtain the Local Committee written authorization to send samples abroad, by

submitting an official letter indicating reasons for sending, quantity and type of samples as well as identifying receiving agency, and notify the National Committee of this authorization.

2- The researcher must enclose a copy of the obtained Local Committee approval with documents submitted to competent agencies such as customs and carriers.
3- Ensure security of genetic samples during storage and transportation.
4- Disposal of excess genetic samples must be performed according to standard scientific methods, and every precaution must be taken to ensure that the said samples are not stored in banks outside the Kingdom once these samples have been analyzed or studied.

Article (6.5)

1- The National Committee shall oversee local committees and monitor compliance with Sharia and statutory rules when handling biological material in accordance with the provisions of the Law and Regulations as well as guidelines set by the National Committee in this regard.
2- The rules and principles related to handling of genetic samples apply to all samples, whether the samples were taken in the Kingdom or imported from abroad.
3- Importing cells or other materials from commercial suppliers licensed in the country of origin for research purposes does not require obtaining an ethical approval.

Article (6.6)

A database shall be established at KACST for saving and retrieving national information on genetic material of the Saudi society. KACST shall supervise and monitor said database as follows:

1- Provide facilities, human resources and equipment required for setting up databases.
2- Receive data of genetic material from local genetic material banks available in research institutions.
3- Establish a central bank for saving and retrieving information on genetic material and provide said information for local genetic material banks.
4- Set controls and procedures for saving, retrieving and ensuring confidentiality of information on genetic material.
5- Set controls and procedures for requesting information on genetic material from the central genetic information bank.

The procedures for saving and retrieving data and information on genetic material shall be subject to provisions of the Law and Regulations.

Article (6.7)

Research laboratories operating in biomedical fields shall be ethically recognized upon satisfying the following conditions:

1- Laboratories are supervised by a governmental institution or a private agency licensed by competent authorities.
2- Laboratories are run by specialists qualified to perform their technical and administrative duties and responsibilities.

3- Laboratories, if not affiliated with a governmental institution, satisfy conditions set forth in the "Law of Private Laboratories".
4- The institution is able to meet legal liability arising from damage caused by practices conducted within its affiliated laboratories.
5- Laboratories meet safety conditions and preventive measures observed in establishing biomedical research laboratories.
6- Laboratories observe confidentiality and privacy with regard to Living Creatures or genetic material information available therein.

Article (6.8)

When coordinating between the Kingdom and other countries, or Arab or international organizations, the National Committee, in the context of exercising its jurisdiction, shall observe applicable legal procedures.

Chapter Four

Committee Revenues

Article 7

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

Article (7.1)

1- Committee revenues shall comprise the following:
   a) Financial allocations set for it within KACST's budget.
   b) Endowments allocated for the Committee.

2- Upon setting allocations referred to in Paragraph (a) above, the following procedures shall be observed:
   a) The National Committee Chairman shall submit the allocations set for the following fiscal year to be approved by the Committee 30 days before its submission to KACST President.
   b) Upon approval of allocations by the National Committee, the Committee Chairman shall submit said allocations to KACST President.
   c) The Committee Chairman shall coordinate with relevant departments at KACST to incorporate said allocations in KACST budget. Upon discussing such allocations, the Chairman may, if necessary, seek the assistance of any person either from relevant departments at KACST or from the Ministry of Finance, as he deems fit.
   d) Upon approval of the budget and setting the financial allocations for the National Committee, the Committee Chairman shall present to the Committee the allocations and the proposed spending plan.

3- Upon allocating endowments for the National Committee, the following procedures shall be observed:
   a) If the National Committee receives a request to endow any property for its activities, said request shall be presented to its members for discussion and decision thereon.
   b) Upon reviewing the endowment request, the National Committee shall observe all relevant laws, decisions and directives.
   c) If the endowment is accepted, the National Committee shall set necessary controls and procedures for dealing therewith.
   d) The National Committee Chairman shall submit annual reports to the Committee regarding the endowments allocated for its activities. The Committee may take any decision it deems necessary in this regard.
   e) The National Committee may, if required, form from among its members or others a subcommittee to manage endowments.

Chapter Five

Research Ethics Monitoring Office

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 (8.1)
The Monitoring Office shall report to the National Committee Chairman.

Article (8.2)
The President of KACST shall appoint, upon nomination by the National Committee Chairman, a full-time director for the Monitoring Office; said director shall be experienced in medical and scientific research and research ethics.

Article (8.3)
The Monitoring Office may establish branches in different areas of the Kingdom provided the following conditions are satisfied:

1- The need for opening a branch in the relevant area.
2- Financial allocations required for establishing and operating the branch.
3- Submission of a recommendation by the National Committee to KACST President stating the need for opening a branch.

The branch may be located in any governmental agency in the relevant area.

Article (8.4)
The Monitoring Office shall have an adequate share of the financial allocations set for the National Committee to pay for its activities.

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 (9.1)

The Monitoring Office shall register and oversee local committees and monitor their compliance with the provisions of the Law and its Regulations and the as well as controls and procedures set by the National Committee.

Article (9.2)

The following procedures shall apply upon registration of local committees:

1- The National committee shall prepare a registration form for the local committee to be published on its website, including the following:
    a) Name and address of establishment applying for registration.
    b) Date of application.
    c) Nature of research conducted therein.
    d) Names and CVs of local committee chairman and members.
2- The establishment applying for registration of a local committee shall complete the application form referred to in Paragraph (1) above, provide necessary data, and submit the form along with necessary attachments, including the decision of forming the local committee, to the Research Ethics Monitoring Office.
3- The Monitoring Office shall review each registration application submitted thereto by the establishment. If the application data is incomplete, the establishment shall be notified within 10 working days from the application submission date.
4- The Monitoring Office shall decide on the application within 15 working days from the date of receipt of the complete application, render a decision to this effect, and promptly notify the concerned establishment of said decision, provided the notification includes registration number and date.
5- The Monitoring Office may not reject any application for registration except on legal grounds. If the application is rejected, the Research Ethics Monitoring Office shall notify the establishment of the reasons for rejection.
6- The registration period for the committee shall be in accordance with the period specified in the decision to form it, and if a specific period is not specified in the formation decision, the registration period shall be three years, subject to renewal.
7- The monitoring office may cancel the registration of the local committee if it does not update its data or renew its registration.

Article (9.3)

In its supervision of registered local committees, the Monitoring Office may undertake the following:

1- Assign any person it deems fit to conduct field visits to the registered establishment at least once a year for examining committee documents and papers.
2- Assign any person it deems fit to attend local committee meetings, if required.
3- Ensure local committee compliance with relevant laws, regulations, rules and directives and coordinate therewith for this purpose.
4- Review complaints or grievances submitted by the principal investigator or by any member of the research team against local committee decisions.
5- 5- Review complaints submitted by the human subject in case he claims to have been harmed as a result of the research.

Article (9.4)

In its monitoring of local committee compliance with the provisions of the Law and its Regulations, the Monitoring Office may undertake the following:

1- Having access to all records and documents of research registered with the local committee.
2- Contact the participating human subject, if required.
3- Cancel, suspend, terminate or prevent prompt evaluation, if necessary.
4- Record any violation committed by the local committee and take necessary actions in accordance with the Law and Regulations.
5- The Monitoring Office shall conduct periodic ethical evaluation and monitoring of national laboratories, and shall monitor medical research and experiments conducted on Living Creatures to ensure legitimacy thereof.
6- Upon verification of occurrence of a violation or a reasonable possibility of a valid claim of harm, the Monitoring Office may refer the matter to the Violation Committee referred to in Article (42.1) of the Regulations to take appropriate action.

Article (9.5)

The Committee Chairman shall appoint office staff upon recommendation of the director of the Monitoring Office in accordance with applicable procedures including office secretariat to help carry out administrative and technical work.

Article (9.6)

The Office may, if necessary, seek the assistance of specialists, experts and consultants as it deems fit; remuneration of said persons shall be according to KACST applicable rules.

Chapter Six

Local Committee for Research Ethics

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 (10.1)

The local committee shall be formed of at least five members in accordance with the procedures set forth in Article (9.2) of the Regulations. Upon formation of said committee, the following shall be observed:

First: The Committee chairman or his deputy shall be of Saudi nationality with experience in the field of biological research.

Second: The number of members shall be determined according to volume and type of research expected to be reviewed.

Third: Members shall be of different specializations, and when named the following shall be observed:

1- One member at least shall have an interest in the main research field of the establishment.
2- One member at least shall be from outside the establishment, and shall fulfill the following conditions:
    a) He shall have no business relation nor direct or indirect interest with the establishment.
    b) He shall be of an acceptable level of education.
3- One member at least shall have an interest in biomedical ethics.
4- One member at least shall have adequate knowledge in research design and statistical analysis.
5- One member at least shall be adequately familiar with the customs, traditions and values of the Saudi Society.

Article (10.2)

1- The local committee shall be formed by decision of the president of the establishment or competent agency stating the names of committee members, chairman and his deputy. The chairman and his deputy shall have interest in biomedical ethics.
2- The relevant establishment or competent agency commits to providing the financial support needed for the local committee as well as committee members remunerations such as to ensure and preserve the independence of committee decisions and to ensure its continued operation.
3- Committee members, employees and all persons invited to attend committee meetings shall keep as confidential all information they come by and shall not disclose any information included in research or research ideas and proposals.

Article (10.3)

Local committee members shall be appointed for a renewable term of 3 years, provided half the members be replaced upon re-formation for the third time. Membership may not be renewed for more than three consecutive terms.

Article (10.4)

The head of the establishment shall appoint a secretary for the local committee upon the recommendation of its chairman, to undertake the following:

1- Receive applications submitted to the committee and verify that they meet all conditions, and include all components and documents, and present the same to the committee chairman.
2- Prepare agendas and minutes of committee meetings.
3- Coordinate local committee activities and communications with researchers and with the National Committee.
4- Archive copies of committee meeting minutes, including names of attending members, decisions issued, results of voting on such decisions, and a summary of the discussions taking place during every meeting.
5- Prepare letters of notification of committee decisions and recommendations to be signed by the committee chairman.
6- Any other work-related tasks assigned to him by the committee or its chairman.
7- Maintain confidentiality of information he is privy to and not disclose any information in the research or research ideas and proposals.

Article (10.5)

The local committee shall seek to achieve the following:

1- Protect the human subject of the research, as well as protect and ensure the human subject's rights and safety.
2- Verify compliance with all requested and documented procedures in the research project regarding the treatment of human subject participants and biological materials.
3- Ensure that the means by which advertisement, initial contact and selection, or information provided to the participant, do not lead to revealing his personal information or discovering his identity.

4- Ensure that necessary equipment and that such equipment is adequate for the safety of the human subject participants.
5- Ensure especially that minors, legally incompetent or disabled persons, or any other persons from (vulnerable groups) are never abused under any circumstance.

Article (10.6)
Committee membership shall be terminated for any of the following reasons:
1- Resignation.
2- Death.
3- Chronic illness that prevents a member from attending local committee meetings.
4- If any member fails to attend three consecutive or five non-consecutive meetings within the same year without an excuse acceptable to the local committee chairman.
5- Expiration and non-renewal of term of membership.
6- If a member is proved to have violated his commitment to keep information confidential and the committee chairman has issued a decision to this effect based on proven facts.

Article (10.7)
If the membership of any local committee member is terminated for any reason, committee chairman shall instantly address the concerned party to appoint a replacement to fill in the remainder of said member›s term, and shall notify the Monitoring Office thereof.

Article (10.8)
If the local committee chairman finds that one committee member does not effectively take part in committee activities or that he has not appropriately accomplished the duties assigned to him, he may notify the concerned party thereof and suggest whatever action he deems fit, including dismissal of said member and appointment of a replacement.

Article (10.9)
1- The local committee shall convene upon a call by its chairman whenever required.
2- Local committee meeting shall not be valid unless attended by the majority of its members including the chairman or his designee.
3- If the quorum is not reached within half an hour of the designated date of the meeting, the meeting chairman shall adjourn the meeting to be held within fifteen days thereafter.
4- Invitations for the meeting shall be delivered by hand or sent via ordinary mail or e-mail at least ten work days before convention date. The meeting agenda and all papers and documents related to topics proposed for discussion shall be attached to the invitations.
5- Local committee secretary shall record the meeting minutes, and attending members and committee secretary shall sign the minutes directly after the meeting or in the next meeting.

Article (10.10)

If a local committee member finds that he or any other member has any sort of direct or indirect interest related to any topic proposed for discussion by the committee, said member shall disclose such interest at the beginning of the meeting. In that case, the committee chairman shall ask the member who has declared such interest to withdraw from the meeting during discussion of related topic and shall record this action in the meeting minutes.

Article (10.11)

1- The local committee may invite experts and consultants to attend its meetings whenever a proposed item on the committee meeting agenda requires so. These expert guests do not have the right to vote.
2- If the research subject proposed for discussion by the local committee is related to any category of the (vulnerable groups), the committee chairman shall invite a specialist with experience in this field to take part in discussing said subject. Said specialist shall have the right to take part in discussion and in voting. If said specialist fails to attend the meeting, it shall be required to obtain a specialist›s written opinion of the matter.
3- If it deems it necessary, the local committee may invite the principal investigator to attend one of its meetings, provided he does not attend the meeting during which the final decision on the research project is made.

Article (10.12)

1- Local committee resolutions shall pass by simple majority vote of attending members. In case of a tie, the meeting chairman shall have the casting vote.
2- Local committee chairman shall determine the voting method in committee meetings.
3- Issued resolution shall be printed on local committee or establishment official stationary, and shall include a clear statement of resolution text. Committee chairman shall notify the principal investigator of said resolution in writing.
4- In case the research application is rejected, the resolution shall state the reasons for rejection.
5- Local committee may issue non-binding recommendations, if necessary, and attach them to rejection resolution.
6- Local committee may issue a conditional approval, and the resolution shall determine the necessary procedure to reconsider the application and any requirements or suggestions for reassessment.
7- An aggrieved party may appeal local committee resolutions of rejection or provisional approval before local committee. If the local committee dismisses the complaint as unconvincing, the aggrieved party may have recourse to the Monitoring Office to review the matter.

Article (10.13)

1- The local ethics committee reviews research project applications submitted by employees of the facility to which it belongs. It has the right to consider research applications submitted by investigators from nearby facilities after agreement with the investigator if there is no local ethics committee in the facility with which these investigators are affiliated.
2- If investigators from multiple establishments are collaborating on one common project - the principal investigator (PI) must obtain the approval of the local ethics committee in the establishment to which he/she affiliated with.
3- Collaborating investigators must submit the approval obtained by the principal investigator (PI) to the local ethics committees in their respective local committees to obtain their approval to conduct the research within the facility.
4- The local committee in the facility to which the collaborating investigator/s belong, may approve research by expedited review method based on the approval obtained by the principal investigator from his local committee.
5- The collaborating investigators shall submit periodic reports on the progress of the research to their establishment›s local, in accordance with the procedures set forth in Article (10/29) of these regulations.
6- The co-investigator/s shall inform the principal investigator and the local committee in the facility to which he/she is affiliated about every harm (adverse event) - serious or not - that occurs in the course of conducting the research project ,in accordance with the procedures set forth in Article (M 10/31) of this Regulations.

Article (10.14)

The principal investigator, whether he belongs to the establishment or not, shall submit the research approval to the local committee, including the research proposal. Upon setting of research proposal, the researcher shall observe the following:

1- Design of study shall be appropriate to its objectives.
2- Expected benefits and possible harms to which the human subject may be subject shall be in balance.
3- Research location shall be appropriate to the assistant group, including available potentials and emergency measures.

Article (10.15)

The research proposal shall comprise the following:

1- One page research abstract (size: A4).
2- Research objectives.
3- Statistical methodology, including sample size calculations, taking into account possibility of obtaining statistically significant results by using the minimum number of research subjects.
4- Justification and rationale for introducing any procedure, tool or device that has not been used before
5- Justification and rationale for using any substances that could be dangerous or

harmful to the human subject or his surroundings and methods of disposal of said substances after research is completed.

6- Ethical considerations in research and how to deal with them.
7- Plan for dealing with risky cases.
8- Plan for disposal of extra biological samples.
9- A clear description of duties and responsibilities of research team.
10- Time schedule of research and criteria of research suspension or termination.
11- Case registration forms, daily cards, and questionnaires set for research subjects, in case of clinical research.
12- Research sample shall be determined according to the following considerations:
    a) Characteristics of sample from which the subjects will be selected.
    b) Criteria for inclusion and exclusion of the human subject.
    c) Methods through which initial contact and selection are carried out.
    d) Means of providing complete information to potential participants in the research or their representatives.
13- In clinical research, the principal investigator shall present a description of the individuals who will be given access to personal data of research subjects, including medical records and biological samples.
14- A list of expected results and ways to benefit therefrom.
15- A list of references.

Article (10.16)

The principal investigator shall, as necessary, enclose the following documents with his research proposal:

1- Any plans and justifications to stop, prevent or alter administration of standard treatments because of the proposed research.
2- Medical care offered to human subjects during and after the research.
3- A description of proficient social, psychological and medical supervision for all human subjects.
4- A statement of the compensation or treatment that can be provided for human subjects in case of injury, disability or death as a result of the research.
5- Procedures taken to provide compensation, when required.
6- Indication of research funding methods and any research agreements related to the research. The human subject shall not incur any financial expenses for conducting the research on him.
7- Disclosure of potential conflict of interest that may occur in relation to conducting the project and how to address it.

Article (10.17)

To approve the research proposals submitted to the local committee, the following procedures shall be followed:

1- The local committee shall prepare a special approval application form and publish it on its website, including the following:
   a) Name of local committee and its postal address, electronic mail address and contact numbers.
   b) Name of principal investigator and his ordinary and electronic mail address and contact numbers.
   c) Title, duration and objectives of research project.
   d) Date of submission of application.
2- The principal investigator shall submit the application for approval according to the form referred to in the preceding paragraph 1 here above.
3- The principal investigator shall fill in the approval form, and shall append with it the following documents:
   a) The research proposal.
   b) An updated, signed and dated CV of the principal investigator and co-investigators.
   c) Methods used for inviting human subjects, including advertisements.
   d) "Informed Consent" form.
   e) Proof of passing a valid research ethics course.
4- The local committee shall receive the application against a receipt given to the applicant indicating reception thereof and including number and date of submission.
5- The local committee shall review the application in principle; if any requirements are missing, the committee shall notify the applicant thereof within 10 work days of date of submission of application. The investigator shall respond within 90 days of date of notification. The application shall be deemed as rejected if the investigator fails to respond to committee remarks and demands within the said period.
6- The local committee shall inform the applicant within 15 work days from completion of request of the expected time period to provide the final response to his request.
7- The local committee shall evaluate the research proposal, provided it is complete and it satisfies applicable scientific conditions in the establishment. The committee shall consider the researchers› ethical efficiency and ability to conduct the research, and shall verify that the "Informed Consent" form contains all basic requirements.
8- The local committee shall issue its decision indicating acceptance, rejection or amendment of research proposal within the period referred to in Paragraph 6 hereabove.
9- The committee resolution shall include the following data:
   a) Title of research project.
   b) Date and number of research project.
   c) Name of principal investigator and co- investigators.
   d) Date of resolution.
   e) Signature of local committee chairman or authorized person and date of signature.

10- The following documents shall be attached to the decision: Research forms with their appended documents including Informed Consent (the resolution number must be put on the Informed Consent form).

Article (10.18)

Before consenting to conduct a research project, the local committee shall confirm the following:

1- The research does not violate Sharia rules or laws or regulations observed in the Kingdom.
2- Potential risk for the human subject is reduced to the minimum level through the following:
    a) Adopting standard operating procedures and scientific methods for research design which do not expose research human subjects to risks.
    b) Adopting standard and established procedures for therapeutic or diagnostic purposes as much as possible.
3- Evaluating benefits and risks that might ensue from the research.
4- Ensuring that research subjects have been selected based on their understanding of research objectives, place, time and method of conducting research, with special additional attention in the cases in which the participation of persons requiring additional protection is requested, such as (vulnerable groups)
5- Ensuring that the "Informed Consent" of the human subject contains all the required elements.
6- Ensuring that the research plan includes a periodic monitoring of results to maintain safety of the human subject.
7- Ensuring that the research plan includes management measures to protect the human subject and the human subject's rights.
8- Ensuring that sufficient measures are taken to protect privacy of the human subject and maintain confidentiality of data.
9- In the case of clinical research involving testing drugs or equipment on humans, the authorization of the Saudi Food and Drug Authority must be obtained according to observed laws and regulations.
10- Every clinical research project must be registered first with the Saudi Food and Drug Authority before human subjects are invited to participate.
11- The Saudi Food and Drug Authority clinical studies database must be checked first to avoid conducting duplicate research.

Article (10.19)

The local committee may approve certain research by using the expedited review procedure in the following cases:

1- If the risk that the human subject may be exposed to does not exceed the minimal risk level.
2- If the research does not reveal the identity of the human subject.

3- If the research deals with clinical studies on drugs or medical equipment, provided:
   a) The drug is used in accordance with its licensing and dosages approved by the concerned party, and does not entail any increase in potential risk for the human subject.
   b) The medical equipment in use has originally been licensed by the concerned party and has already been utilized accordingly.
4- If taking biological samples for research purposes is carried out via non-invasive methods such as analysis of urine, saliva, nail or hair clippings, etc.
5- If research data is to be collected by using medical equipment approved by the concerned party, such as:
   a) Sensors which are directly applied on body surface or at a close distance thereto and which do not expose the body to a significant amount of energy and do not violate the privacy of the human subject.
   b) Weight taking or audiometry devices.
   c) Magnetic resonance imaging (MRI) or ultrasonography imaging devices.
   d) Electrography (ECG & EEG), Thermal Imaging, normal nuclear radiation rate measuring, infra-red imaging, blood flow measurement with ultrasound imaging (Doppler sonography), and echocardiography devices.
   e) Moderate exercise, muscle strength, body ratios (such as body fat ratio) and measurement of joint and muscle flexibility devices, provided these tests are deemed appropriate after taking age, weight and health condition into account.
   f) Search for information, records or samples that were previously collected or will be collected in the future for non-research purposes.
   g) Collect information via audio or video taping (static or moving) for the purpose of looking for the attributes or behavior of an individual or group without violation of privacy of the human subject.

However, excepted from these devices is the use of X-ray or electromagnetic microwave devices.

Article (10.20)

1- Approval by expedited review shall be issued by local committee chairman or by one or more members selected by committee chairman for their experience.
2- In case of expedited review, the research evaluator shall have all the powers given to the local committee except for rejection of research, which shall be within the jurisdiction of the local committee alone. If the evaluator decides to reject the research, he shall refer it to the committee for reviewing it according to the provisions of this Law and its Regulations.
3- In case approval of research is issued by using expedited review, the committee chairman shall notify all committee members of the research projects that he has approved via whatever notification means he deems appropriate.

Article (10.21)

The local committee chairman has the authority to approve any amendment of the research previously approved by using expedited review. Exceptions include interviews and surveys conducted on any of the (vulnerable groups), amendment of research project or approval form, which shall be within the jurisdiction of the local committee.

Article (10.22)

Applications for approval using the expedited review procedure shall observe the terms and requirements stipulated in the basic elements of the Informed Consent in accordance with the provisions set forth in Chapter 5 of the Regulations.

Article (10.23)

The expedited review procedure may not be used for approving research if the objectives of such research include the following:

1- Addition of a new medication.
2- Addition of new medical equipment.
3- Addition of a new invasive or interventional procedure.
4- Increase or decrease of a medication dose, which may lead to increased harms.
5- The research is conducted to identify new potential risks.

Article (10.24)

1- If the principal investigator wishes to amend the research proposal approved by the local committee, he shall submit the matter to the local committee to obtain its approval prior to proceeding with the amendment.
2- The following may be exempted from local committee review:
    a) Amendment of advertising material used for inviting human subjects, provided said amendment does not disrupt the content of such material.
    b) Amendments that only include providing administrative support to the study.
    c) Enrolling samples or cases brought from outside the establishment with the same terms.
3- In all cases, the principal investigator shall furnish the local committee with a detailed report on the amendment he has carried out.

Article (10.25)

1- The principal investigator shall obtain the local committee approval of all types of advertisements aiming to invite people to participate as volunteers in the research project such as newspaper ads, posters, folders, etc. prior to distribution or publication thereof.

2- Any advertisement proposed by the principal investigator to invite persons to participate as subjects of the research shall include the following data:

a) Research title.

b) Research objective.

c) Attributes qualifying persons targeted to be the research subjects (participants or volunteers).

d) Indication of all facilities to be provided to human subject.

e) Number of research project in the local committee and expected date of completion.

f) Expected risks of the research, if any.

g) Name and address of principal investigator or his representative, his contact numbers and his electronic mail address so that individuals aiming to join the research group may call him for further information.

Article (10.26)

If the principal investigator decides to transfer research supervision responsibility to a different investigator, he shall take the following measures:

1- Submit a written application to this effect to the local committee, including the following:

a) A written agreement for the replacement investigator to take responsibility for the research.

b) A written statement by the replacement investigator indicating his readiness to fulfill all commitments and obligations made by the principal investigator.

c) CV of the replacement investigator.

d) A statement indicating that all samples and medical information related to the research have been delivered to the replacement investigator.

e) A statement indicating that no part of research samples or results shall be used in any future research unless a new approval is obtained from the local committee.

2- The principal investigator shall proceed with his supervision of the research until the local committee has reviewed the application.

3- The local committee shall decide the application within a period not exceeding one month from date of submission thereof. In case of rejection, the decision shall be furnished with reasons for rejection.

Article (10.27)

1- The investigator may publish the results of the research he is conducting, provided he notifies and obtains approval of the local committee beforehand specifying the name of periodical in which he will publish said results.

2- The local committee may refuse to grant permission if the published material is inconsistent with the provisions of this Law and its Regulations or with the controls and directives issued by the national committee.

Article (10.28)

The local committee shall conduct the periodic monitoring of the research as follows:

1- Review research progress regularly based on the periodic reports submitted by the principal investigator, provided the periodic follow-up period does not exceed one year.
2- Examine research records to ensure their consistency with the approved research proposal and the submitted research reports or to guarantee documentation of "Informed Consent" procedures. The local committee may assign specialists as it deems fit to perform this task on its behalf.
3- The local committee shall set necessary procedures for carrying out the periodic follow-up process, and shall furnish the Monitoring office with a copy of said procedures.

Article (10.29)

1- The principal investigator shall provide the local committee with a periodic report of the research every three months in case of conducting clinical research and not more than 12 months in case of conducting other types of research.
2- The periodic report shall contain all the details of the research and its phases. The investigator shall attach to this report proof of his commitment to the procedures and controls set forth in this Law and its Regulations.

Article (10.30)

If the principal investigator fails to submit the periodic report on time, the local committee shall take the following measures:

1- Notify the researcher in writing that he must submit the periodic report within the period set by the committee.
2- If the principal investigator fails to submit the research within set period, the local committee may suspend the research project until the report is submitted and shall notify the principal investigator thereof.
3- In case the research project is suspended, the committee shall thoroughly review it and examine all required documents to ensure that no violations have been committed; otherwise, it shall carry out whatever it deems fit.
4- If the principal investigator submits the periodic report during local committee review of research, the local committee may end the suspension the research project, and notify the investigator not to be remiss in submitting reports in the future.
5- If the principal investigator persists in ignoring to submit the periodic report, the local committee shall refer the whole matter to the Monitoring Office to submit it to the Violations Committee to suspend the research project and decide appropriate penalties.

Article (10.31)

1- The principal investigator and the local committee shall immediately report any major harm (serious adverse event) occurring during or after conducting the research, according to the following procedures:

a) The principal investigator shall immediately notify the local committee as well as the research sponsor of any major harm (serious adverse event) occurring during or after conducting the research, provide the committee with all information pertaining to the harm related incident and indicate his assessment whether this incident is definitely, probably or unrelated to the research.

b) The local committee shall notify the Monitoring Office of the major harm incident (serious adverse event) and all related details as soon as possible either in writing or by telephone within a period not exceeding twenty-four hours from the time of the reported incident.

2- The principal investigator and the local committee shall report of any minor harm (adverse event) occurring during or after conducting the research, according to the following procedures:

a) The principal investigator shall notify the local committee of any minor harm (adverse event) occurring during or after conducting the research, within a period not exceeding seven days from the date of the incident, provide the committee with all information pertaining to the harm (adverse event) incident and indicate his assessment whether this incident is definitely, probably or unrelated to the research.

b) The local committee shall notify the Monitoring Office of the incident of minor harm (adverse event) and all related details either in writing or by telephone within a period not exceeding two weeks from the date of the incident, depending on the significance of the reported incident.

3- The principal investigator shall include all expected or unexpected harms (adverse events) in his periodic report submitted to the local committee.

Article (10.32)

1- If the local committee finds, through periodic monitoring of the research, that an unexpected harm has taken place as a direct result of the research but has not been referred to in the research proposal, it may take appropriate measures to stop the harm, including suspension of research project.

2- If the local committee finds that the investigator has not obtained required approvals, it shall suspend the research project and refer the matter to the Monitoring Office to submit it to the Violations Committee to decide appropriate penalties against the investigator.

3- The local committee shall notify head of the establishment of any research that is suspended or referred to the Monitoring Office.

Article (10.33)

The local committee may exempt the following research projects from the periodic follow-up:

1- Research involving study of information and data previously collected, provided one of the two following terms is fulfilled:
   a) If the information is generally and publicly available.
   b) If the information is recorded in a manner that does not reveal the identity of the source person.
2- Research including educational tests, surveys, interviews or public behavior monitoring, except in the two following cases:
   a) If the information is recorded in a manner that reveals the identity of the source person.
   b) If participation in the research should bring a person outside the scope of research to be subject to criminal or civil liability or jeopardize his financial position or career.
3- Research conducted for educational purposes.

Article (10.34)

1- Subject to the provisions of the following paragraph 2 hereunder, the local committee, following Standard procedures, shall conduct the periodic monitoring of research based on the periodic reports submitted by the principal investigator in accordance with the procedures it sets up in this regard.
2- As an exception from the provision of the preceding paragraph 1 hereabove, the local committee may exempt certain research projects that it has previously approved from periodic evaluation in either of the following cases:
   a) If the only objective of research continuation is a long-term monitoring of persons who took part in the research and no additional risk emerged in the research.
   b) If the research is nearly finished and only analysis of data and conclusion of results are remaining.
3- After the periodic assessment of the research is carried out, the local committee shall issue a decision including its approval or rejection of continuation of the said research.

Article (10.35)

If, after the periodic assessment, the local committee disapproves of research continuation, it shall suspend the research project without prejudice to its right of extending the treatment period in case its sudden suspension may cause harm to the human subject.

Article (10.36)

1- If the research project is suspended, the investigator may request the local committee to reconsider the suspension decision, by appending reasons for his request.
2- The local committee shall consider said request in a meeting held for this purpose or in the nearest meeting.

Article (10.37)
Upon completion of the research project, the principal investigator shall prepare his final report and shall deliver a copy thereof to the local committee along with related scientific publications, if any.

Article (10.38)
The local committee shall keep the records of its contributions in the field of research follow-up and evaluation, including the following:
1- A copy of all research proposals evaluated by the committee, along with evaluation results.
2- A copy of the "Informed Consent" form approved by the committee and periodic reports on research progress.
3- A copy of the reports detailing harm to the research subjects, if any.
4- A statement of the reasons that led the local committee to reject the proposal or request modification of research proposal.
5- Copies of periodic follow-up and evaluation proceedings.
6- Copies of all correspondences between the committee and the principal investigator.
7- A declaration of all new and important data provided to the human subject, including all necessary details of the method used to obtain his consent to take part in the research.

Article (10.39)
The local committee shall submit an annual report to the Monitoring Office, subsidiary to the National Committee, including:
1- Any changes in its formation.
2- A list of the research projects that it has studied and its decision in each case (rejection, approval or suspension), indicating reasons therefor.
3- Any scientific activities carried out by the committee, including scientific publications, workshops, colloquia and symposia.
4- Any other information deemed by the Monitoring Office as necessary to be included in the report.

Article (10.40)
1- Any member of the research team may file a complaint with the local committee.
2- The local committee shall consider said complaint in its next meeting or in a special meeting called for by the committee chairman.

Article (10.41)
In case of any disagreement with the local committee, the principal investigator may file a complaint with the Monitoring Office.

Article (10.42)

The research assignments carried out by the Contract Research Organization (CRO) for the beneficiary are subject to the stipulations of the law and regulations.

Article (10.43)

1- The beneficiary may authorize Contract Research Organization (CRO) to carry out some or all of his responsibilities for research based on the contract, such as developing the research project, selecting clinical auditors, following up on the course of the study, reviewing adverse events, or analyzing data. . This does not prejudice the responsibility of the principal investigator.
2- The beneficiary, when delegating some of his responsibilities for conducting the research to the Contract Research Organization (CRO), must specify in the contract what are the delegated responsibilities and obligations, the rights of each party and the details of the duties and responsibilities, and shall identify all the obligations that the Contract Research Organization (CRO) will bear.
3- It is permissible - by agreement of the beneficiary and the Contract Research Organization (CRO) to amend the contract by adding obligations or cancelling some previous obligations, provided that the amended contract indicates the status of the previous assignments that were not covered by the amendment. And, in all cases in which the assignments are transferred, suspended or amended, either by the beneficiary or the Contract Research Organization (CRO), the two parties must inform the principal investigator and the local ethics committee. In the event that the contract relates to performing assignments of a clinical trial, the Saudi Food and Drug Authority shall be notify of the changes as well.
4- Each party of the contract shall bear full responsibility for violations that may occur while performing his assignments.
5- In the event that the contract includes performing a clinical trial by an investigator unaffiliated with either party to the contract, the Contract Research Organization (CRO) shall sign with him a clinical trial agreement.
6- The quality and integrity of the final research data is the responsibility of the beneficiary.

Article (10.44)

1- The Contract Research Organization (CRO) conducting clinical trials must register a local ethics committee with the National Committee of Bioethics.
2- The Contract Research Organization (CRO) performing exclusively the roles of mediation and coordination – and in the absence of a local ethics committee at any of the contracting parties - must have an agreement with the nearest registered local ethics committee to carry out the tasks of reviewing the research proposal and following it up as stipulated in the law and regulations.

Article (10.45)
In addition to the conditions for the formation of local ethics committees stipulated in the law and regulations, when forming a local ethics committee in a Contract Research Organization (CRO) the chair of the ethics committee the absolute majority of the members or all of them must be from outside the (CRO).

Article (10.46)
Considering the provisions of Article (10/45) of the Regulations, the conditions for establishing and function of local ethics committees in Contract Research Organization (CRO) are subject to the same conditions stipulated in the law and regulation.

Article (10.47)
The Contract Research Organization (CRO) shall ensure that the beneficiary obtains ethical approval for his research; In accordance with the stipulations of the law and regulations.

Article (10.48)
In the event that the principal investigator delegates some of his research responsibilities to a Contract Research Organization (CRO), he must include a statement in his research proposal specifying the name of the (CRO), the type of tasks he delegated to it, attach a copy of the contract, the address of the institution and the means of contact with it.

Article (10.49)
The local ethics committee that granted approval for research project may request from the Contract Research Organization (CRO) any information or document related to the project, and may conduct field visits to the (CRO) to ensure that there are no violations in conducting research.

Article (10.50)
In the event that the Contract Research Organization (CRO) fails to provide the local committee with the requested information and documents related to research conducted within the (CRO) - the local ethics committee – may raise the matter to the Research Ethics Monitoring Office for presentation to the Violation Review Committee.

Article (10.51)
The Contract Research Organization (CRO) may, transfer all or some of its obligations to another (CRO), under two conditions:
1- To obtain the prior written consent of the beneficiary.
2- The transfer shall be in accordance with the provisions of Article (10/43).

Article (10.52)
If the Contract Research Organization (CRO) is unable to fulfill its obligations as stipulated in the contract it shall immediately inform the beneficiary, and it must deliver to him all the previous works that have been accomplish AS well.

Article (10.53)
It is not permissible for an institute to collect from the investigators employed by it any fees in exchange for reviewing their research to be conduct within that institute, unless the research sponsored by an outside body or for the benefit of that body.

Article (10.54)
The Results of the accomplished contract tasks considers confidential, and they are the right of the beneficiary. The Contract Research Organization (CRO) may not use them or dispose of them without consent of the beneficiary.

Article (10.55)
Both the beneficiary and the Contract Research Organization (CRO) shall abide by the relevant laws and regulations issued by the Saudi Food and Drug Authority in this regard.

Article (10.56)
Both the beneficiary and the Contract Research Organization (CRO) shall abide by the laws and regulations governing intellectual property rights, including the rights of investigators who carry out the obligations of both parties.

Article (10.57)
Specimens used in the research or left over after its completion shall be handle according to what stipulated in the law and regulation.

Article (10.58)
The beneficiary, the Contract Research Organization (CRO), the local Ethics Committee and all employees thereof, shall comply with the confidentiality of information, data and results related to the research, including the information pertaining to each party.

Article (10.59)
The Contract Research Organization (CRO) shall guarantee the security of personal information and data pertaining to the research that include those stored by electronic means, and shall take all necessary measures and means for electronic protection to prevent illegal access to the data or tampering with it by alteration or destruction.

Chapter Seven

Informed Consent

Article 11

No investigator 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 (11.1)

The local committee shall approve the "Informed Consent" form which will be appended to the research proposal submitted by the principal investigator to the local committee. The researcher may not use any other document or form other than the approved one to obtain the "Informed Consent". The researcher shall provide all research-related information to the human subject. Such information shall include research objective, potential risk and expected benefit, if any.

Article (11.2)

The "Informed Consent" form shall include the following:

1- A clear statement at the top of the first page that reads "You are invited by (Name of principal investigator) to participate in a scientific research".
2- Research title.
3- Name of institution approving the research.
4- Research objectives.
5- A description of any expected benefit for the human subject.
6- A description of any expected risk or harm that may affect the human subject or society.
7- A description of alternative treatments available outside the scope of the research, if any.
8- A statement of the level of respect accorded to the confidentiality of information that may reveal the identity of the subject, along with a commitment by the investigator to secure such confidentiality.
9- A description of all medical procedures and treatments related to the research or carried out only as a result of conducting the research, if any.
10- Duration of the research project.
11- A description of requirements to be fulfilled by the human subject.
12- A description of type, quantity and method of use of samples taken from the human subject, if any, with commitment to dispose with excess or leftover samples through recognized scientific methods.
13- A statement which explicitly reads as follows: "Participation in the research is voluntary. Refusal to participate shall not entail penalty or loss of benefits to which the

human subject would otherwise be entitled. The human subject may withdraw from the research at any phase without loss of benefits to which he is otherwise entitled".

14- Indication of risks or harms, if any, that might ensue due to withdrawal from research.

15- The investigator's pledge that the human subject (participant or volunteer) shall be notified of all information that may emerge during the research period, the knowledge of which may affect his decision for continued participation in the research, such as harms or complications not stated in the "Informed Consent".

16- Contact numbers and addresses to enable the human subject to obtain information related to the research or to his rights, or to report any harm sustained. Said numbers and addresses shall include the contact numbers and e-mail addresses of the local committee and researcher.

17- Signature of the human subject (male or female) or guardian, the researcher, and any other person whose signature on the form is required in accordance with the provisions of the Law and Regulations.

18- Date and place of the "Informed Consent".

19- Method of compensating of the human subject in case he sustains any harm resulting from the research.

Article 12

Upon obtaining the informed consent, the investigator 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 (12.1)

1- When obtaining the "Informed Consent", the investigator shall in all cases observe the following:

a) He shall, in a clear and simple manner, explain in person the information stated in the "Informed Consent" form to the human subject (or his guardian if the subject is incompetent).

b) The explanation shall be appropriate to the educational level, culture and understanding of the human subject (or guardian if the subject is incompetent).

c) He shall, if required, explain any additional information not stated in the "Informed Consent" form.

d) He shall answer any question raised by the human subject (or guardian if the subject is incompetent).

e) He shall not obtain the consent in haste or use coercion or undue inducement to obtain it.

f) He shall ensure via suitable methods that the human subject (or guardian if the subject is incompetent) has understood all the information provided to him prior to signing the "Informed Consent" form.

2- If the human subject is a patient, a person other than his attending physician shall obtain his "Informed Consent", provided said person is well-informed about the research and able to answer all the patient›s questions.

Article (12.2)

The "Informed Consent" form or the explanation presented by the investigator to obtain the consent may not include any statement absolving the investigator (or the institution) from liability against any unexpected error or harm that may occur during the research.

Article 13

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

Article (13.1)

The local committee may assign a qualified person to attend the interview in which the "Informed Consent" form is explained, if necessary, in order to verify compliance with the provisions of the Law and Regulations. In such case, said person shall cosign the consent form upon completion.

Article (13.2)

The local committee shall ensure the validity of the procedures used for obtaining the "Informed Consent" and shall assign a person to monitor the obtaining of such consent. It shall also ensure that the human subject is competent without prejudice to the provisions of research on minors and incompetent persons.

Article (13.3)

1- The principal investigator shall be responsible for obtaining the "Informed Consent" but he may delegate one of his assistants to obtain such consent provided said assistant is fully aware of the research project and able to answer questions raised by the human subject.
2- If the principal investigator or one of his assistants fails to carry out the procedures required for obtaining the "Informed Consent", the principal investigator may submit a request to the local committee to delegate another research team member or any other person fully aware of the research project to undertake such procedures. The local committee may or may not approve this request based on the justifications provided by the principal investigator. In case of acceptance, the committee shall ensure that the person assigned to obtain the consent is well-informed about all aspects of the research and the items of the "Informed Consent" form referred to in Article (11.2) of the Regulations.

Article (13.4)

1- The principal investigator or his duly appointed designee shall issue the "Informed Consent" form in three copies, one for the principal investigator, one for the human subject of the research to be conducted, and the third for the local committee or in the patient's file in the case of a clinical research.
2- If the human subject of the research is a patient, the researcher must document obtaining the "Informed Consent" in the patient's medical file.

Article (13.5)

1- The local Committee may waive the condition of documenting informed consent and accept a verbal consent in the following situations:
   a) If the risk of research does not exceed minimal risk.
   b) If the participant's signature on the (Informed Consent Form) ICF reveals the participant's identity and information.
2- The exemption from documentation does not apply to research that requires collecting biological samples, or research involving mentally incompetent participants.

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 (14.1)

The local committee may approve conducting the research project without obtaining the "Informed Consent" if the conditions set forth in Article (10.32) of the Regulations are satisfied.

Chapter Eight

Research on Humans

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 (15.1)

1- Each research proposal shall be subject to the approval of the local committee.
2- The local committee shall verify the scientific objectives of the research proposal.
3- The researcher shall obtain the "Informed Consent" from the human subject according to the provisions of the Law and Regulations.

Article (15.2)

Prior to conducting clinical research on humans, the following shall be observed:

1- The investigator shall clearly and accurately specify his objectives and methodology.
2- The research shall be preceded by sufficient experiments on animals if the nature of the research so requires.
3- Potential risks shall not be greater than expected benefits.

Article (15.3)

When conducting interventional human clinical trials that carry a risk to the participants - a data safety monitoring committee (DSMC/DSMB) should be appointed to monitor accumulating data and evaluate safety.

Article (15.4)

Unprecedented experimental surgeries and medical research shall be consistent with controls and criteria set forth in laws and regulations applicable in the Kingdom as well as the relevant agreements to which the Kingdom is party.

Article (15.5)

The investigator or research team conducting the experimental surgeries and medical research shall be specialized and shall have adequate scientific qualification, expertise and competence.

Article 16

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

Article (16.1)

1- The investigator shall evaluate the expected benefit to the human subject and the extent to which it is greater than the potential risk according to a scientific evaluation carried out by the researcher and submitted to the local committee.
2- If the local committee finds that the potential risk to the human subject is greater than the expected benefit, it must deny permission to conduct the research.
3- The local committee shall verify, through periodic reports submitted by the investigator, that the expected benefit is still greater than the potential risk.

Article (16.2)

1- Prior to approving research on humans, the local committee shall verify that the investigator takes into consideration the right of human subject to normal life and safety from all types of physical and psychological harm, and shall not affect him wholly or partially except with his consent and in accordance with the provisions of Sharia and applicable laws. This shall include all body organs and their components, such as living tissues and cells whether connected or otherwise.
2- The investigator or research team may not conduct any medical intervention on the human subject for research purposes that do not entail any expected benefit.
3- Approval of all competent government bodies shall be obtained in cases related thereto.
4- The local committee or the Research Ethics Monitoring Office may impose additional restrictions on any research on humans if conducting said research would endanger the human subject.

Article (16.3)

The human subject may seek indemnification for any harm resulting from conducting the research on him by filing a complaint with the local committee. If the local committee fails to respond, the human subject may submit the complaint directly to the Monitoring Office.

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 (17.1)

The provisions of Articles (24.1), (24.2), (25.1) and (25.2) of the Regulations shall be observed.

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 (18.1)

The provisions and controls of the "Informed Consent" referred to in Article 11 of the Law and Articles (10.17), (11.1), and (11.2) of the Regulations shall be observed.

Article 19

The investigator 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 (19.1)

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

Article (19.2)

In case the investigator is found guilty of violating Article (19.1) of the Regulations, he shall be subject to the appropriate penalties set forth in the Law and Regulations as well as laws prohibiting trade in human organs and not in conflict with Sharia.

Article 20

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

Article (20.1)

Subject to the provisions of the Law and Regulations regarding obtaining the "Informed Consent", human organs removed for medical purposes may be used in scientific research in a way not conflicting with the provisions of the Law and Regulations.

Article (20.2)

When conducting research on samples previously extracted for another research purpose or a purely medical purpose and it is still possible to relate said samples to their source, consent of the person from whom the samples have been collected is required prior to conducting research thereon.

Article (20.3)

When conducting research on samples previously extracted for another research or a purely medical purpose and it is no longer possible to relate said samples to their source, the local committee permission to conduct the research may be deemed sufficient.

Article 21

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

Article (21.1)
No research may be conducted on human zygotes or gametes except under the following controls:

1- The practices indicated in the research proposal shall be consistent with the provisions of Sharia and standard medical principles, and the research shall be justified in terms of its contribution to medical knowledge or technical applications.
2- The investigator shall obtain the "Informed Consent" from the person donating zygotes or gametes in accordance with Article 11 of the Law.
3- The investigator shall provide all research-related information to the persons donating zygotes or gametes, and their spouses, if any. Said information shall include a full explanation of the research potential risk and expected benefit.

Article (21.2)
When conducting research on human zygotes or gametes, the researcher shall accurately record all required data and information about the human subject and each person related to the zygotes or gametes under research, and all research findings. He shall keep records of the same for at least five years from date of research completion, and shall submit periodic reports on the research to the local committee.

Article (21.3)
No research may be conducted on human fetuses except for one of the following purposes:

1- Find a treatment for reproductive problems, in which case the research shall be conducted in an institution approved for treatment of such problems.
2- Conduct a new experiment expected to benefit human fetuses.
3- Acquire new knowledge about the condition of fetuses if it is not expected to achieve a direct benefit.

Article (21.4)
The research proposal on human fetuses shall include the indication that the expected benefit from the research would not be realized without using such fetuses, and that a similar benefit has been previously obtained through conducting research on animals, and that the research is justified in terms of its contribution to improvement of treatment techniques or knowledge of human diseases.

Article (21.5)
The investigator shall use the minimum number of fetuses to achieve research purposes.

Article (21.6)
In cases of research conducted to acquire new knowledge, the researcher shall submit to the local committee proof that potential risk for the fetus is minimal.

Article (21.7)
The investigator shall prepare and keep records of the source of each fetus and the results of using said fetus in the research, and shall submit periodic reports on the research to the local committee.

Article (21.8)
The investigator shall abide by the controls and procedures set by the National Committee regarding research on stem cells, zygotes, gametes and fetuses.

Article 22

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

Article (22.1)
No investigator shall be permitted to conduct research on human cloning and any reproductive and research applications resulting therefrom due to constraints determined by sharia, ethical principles and health-related harms, where harms and dangers to humanity outweigh the expected benefits.

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 (23.1)
Subject to the provisions and principles set forth in the Law and Implementing Regulations and directives issued by the National Committee, research may be conducted on tissues, living cells and separated parts, including stem cells extracted from the umbilical cord or adult stem cells, upon fulfilling the following conditions:

1- Fetuses may not be cloned for the purpose of obtaining and using stem cells in research.
2- Excess fertilized eggs from in vitro fertilization procedures or from insemination using donor ovum and sperm, shall neither be used for therapeutic purposes nor in stem cell research.
3- Male or female gametes taken from sperms or eggs may not be donated to produce fertilized eggs that can grow into a fetus for the purpose of generating stem cells therefrom.
4- Embryonic stem cells derived from aborted fetuses may be used for therapeutic purposes. Likewise, miscarried fetuses without any signs of life yet may be used in research or in scientific and laboratory experiments in accordance with observed Sharia rules in the Kingdom.
5- In case of stillborn fetuses, embryonic stem cells may be transferred and used in research.
6- Stem cells of an adult human may be used, provided said human is not subject to any harm, and such stem cells can be used to treat a patient, and the expected benefit outweighs the possible harm.

7- Induced pluripotent stem cells, in which adult stem cells are induced to obtain pluripotent cells which can be developed into other kinds of cells, such as nerve cells and others, can be used solely at an experimental and animal level, provided the following conditions are fulfilled:
    a) The research is conducted at a research center affiliated with a government agency, or with the participation of the said government agency.
    b) A written authorization is obtained from the local research ethics committee.
    c) It is pledged in writing not to use these induced pluripotent stem cells on humans.
8- Embryonic cells and derivatives can be imported only from the sources permitted by these regulations, once the authorization of the local committee is obtained. Commercially available induced pluripotent stem cells can also be imported from scientifically recognized sources.

Article (23.2)

It is prohibited to import the following stem cells:

1- Stem cells obtained from the insemination using a donor ovum and a donor sperm, performed to extract stem cells.
2- Stem cells obtained from deliberately aborted fetuses.

Article (23.3)

Cells can be used in clinical research (therapeutic research) under the following conditions:

1- A written authorization is obtained from the local research ethics committee.
2- A "Informed Consent" form is obtained from the human subject participant before the research project is initiated.
3- A written authorization is obtained from the Saudi Food and Drug Authority.
4- The expected benefit for the human subject and the extent to which it outweighs the possible harm shall be evaluated through a clear and thorough scientific assessment conducted by the investigator and submitted to the local committee.
5- The investigator or research team conducting the research shall be specialized and shall have sufficient scientific expertise and competence.
6- Research objectives shall be clearly and accurately defined, and the research is preceded by sufficient experiments on animals if the nature of the research so requires; subject to the discretion of the local committee.
7- If the local committee finds that the potential harm for the human subject outweighs the expected benefit, it must refrain from authorizing the research project.
8- The local committee shall review periodic reports submitted by the investigator to ensure that the expected benefit continues to outweigh the possible harm.
9- The "Informed Consent" shall be obtained from the human subject prior to conducting the research and the information provided shall contain a full explanation of expected benefits and potential risks of the research.
10- The investigator shall keep detailed records of the source of stem cells and the results of their use in the research, and shall submit periodic research reports to the local committee.

Article (23.4)

Stem Cell Banks may be established under the following conditions:

1- A written authorization from the National Committee is obtained.
2- The stem cell bank can only be established in a center affiliated with a government agency.
3- It is prohibited to send any stem cells to be stored outside the Kingdom.
4- Stem cells stored in stem cell banks for therapeutic purposes may not be used for research purposes without the permission of the local committee and the stem cells' owner's consent.
5- An accurate and strict mechanism shall be set up to safeguard all information and data with the utmost safety and confidentiality.
6- Each sample shall be given a permanent identification label specifying its ownership. Information included in said label shall be updated by the principal investigator under the supervision of the local committee.

Chapter Nine

Research on Inmates

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 (24.1)

When serving as subjects in medical research, inmates, even if sentenced to death, shall not be treated differently. Their confinement may not be exploited to compel them to consent to be research subjects.

Article (24.2)

The local committee may not approve research on inmates unless said research aims to achieve any of the following:

1- Study the criminal behavior of inmates, provided the research does not expose them to more than the minimal potential risk.
2- Study conditions of prisons and inmates as well as prevailing diseases and identify the circumstances leading to crime.
3- Study administrative rules and operational procedures applicable in prisons, so as to improve health and living conditions of inmates.
4- Inmates may not be subject to clinical research whether by coercion or inducement or for any purposes other than those set forth in this Article.

Chapter Ten

Research on Special Cases

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 (25.1)

1- Research may not be conducted on minors, incompetent or mentally disabled persons without obtaining the "Informed Consent" from parents or the legal guardians in accordance with conditions set forth in the Law and Regulations, provided they are informed of the level of risk and its probability as well as the person's assent.
2- Either parent or the legal guardian may grant the "Informed Consent" on behalf of minors, incompetent or mentally disabled persons provided his decision is based on the fact that the minor, incompetent or mentally disabled person is subject to no harm and may benefit from the research.
3- After granting the "Informed Consent", either parent or the guardian may withdraw the consent at any phase of the research if he finds that the research conflicts with the interests of the minor, incompetent or mentally disabled person or if the research deviates from the objectives upon which the consent was granted.

Article (25.2)

The local committee shall grant its approval for research on minors, incompetent or mentally disabled persons subject to the following conditions:

1- It is not possible to conduct the research on a competent person.
2- The interest of the minor, incompetent or mentally disabled person requires subjecting him to the research, provided he is not exposed to more than the minimal potential risk.
3- The research protocol includes clear and appropriate measures to minimize potential risk as much as possible.
4- Evaluation of potential risk and expected benefit from the research shall indicate type, nature, degree and possibility of risk as well as the direct benefit for the minor, incompetent or mentally disabled person subject of the research and for similar persons.
5- The research shall be conducted in a school, camp, hospital, or institution where the majority of occupants are incompetent or disabled, provided the research subject belongs to this category.

Article (25.3)

If the local committee finds that the research in whole or in part achieves a direct benefit for the minor, incompetent or mentally disabled person but that its risk exceeds the minimal expected level, it may grant its approval to conduct the research pursuant to the following conditions:

1- The potential risk shall be within acceptable levels in accordance with medical standards, if compared with expected benefits.
2- The ratio of the expected benefit shall exceed that of other methods available outside the scope of the research.
3- The research shall lead to a better understanding of an important problem that affects the minor, incompetent or mentally disabled person or his interest, help reduce such problem, or prevent some of its negative effects.
4- Obtaining the "Informed Consent" from either parent or from the legal guardian.

Article (25.4)

If the local committee finds that the research does not directly benefit the minor, incompetent or mentally disabled person but does not expose him to more than the minimal potential risk, it may approve the research in the following cases:

1- If he had given the "Informed Consent" when he was competent or before the disability occurred, and his legal guardian later gave the "Informed Consent".
2- If precautionary measures taken for his protection are adequate and acceptable.
3- If there are sufficient reasons that make it possible to obtain significant information through the research for understanding the case under study.

Article (25.5)

The local committee may, prior to giving its approval of conducting research on the minor, incompetent or mentally disabled person, require appointing a qualified lawyer experienced to handle such case. Said lawyer shall have no relation with the researcher or the institution supervising and funding the research and shall observe the interest of the minor subject of the research, in coordination with his parents or guardian.

Article (25.6)

The physically, but not mentally, disabled person shall be treated as a normal person, in terms of his responsibility for giving the "Informed Consent" and his understanding of research potential risks and expected benefits.

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 (26.1)

An investigator may not initiate any research on a pregnant woman unless the following conditions are satisfied:

1- Conduct appropriate studies, when possible, on animals and non-pregnant women that confirm the safety of methods and means of research, provided the results of such research are published in internationally recognized scientific journals in accordance with the provisions of the Law and Regulations.
2- The level of risk the research project poses to pregnant woman or her fetus does not exceed the minimum risk level.
3- The investigator shall not have any role in deciding how and when the pregnancy will be terminated or whether the fetus can survive after termination of pregnancy.
4- The research shall not lead to a change in pregnancy termination procedure if such change leads to more than the minimum level of risk to the pregnant woman or her fetus.
5- The research project aims to provide health requirements for the pregnant woman and her fetus and acquire information that cannot otherwise be obtained.
6- The principal investigator shall comit not to offer any type of reward in return for termination of pregnancy for research purposes.
7- Obtain the "Informed Consent" from both the pregnant woman and her husband.

Article (26.2)

No research on fetuses may be initiated unless the following conditions are satisfied:

1- The research shall not harm or endanger the life of the fetus.
2- The research project shall aim to provide health requirements for the fetus and to acquire information that cannot otherwise be obtained.
3- No research may be conducted on a living fetus unless it is nearly certain that its life is threatened or that the level of risk the fetus may face in case it remains in the uterus could be lessened, provided there is no safer means to achieve the same.

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 (27.1)

The National Committee shall set controls required for transfer and use of cells, tissues and derivatives constituents of human sperms, gametes and zygotes for research purposes. Said controls shall be reported to the Research Ethics Monitoring Office and local committees to abide by.

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 (28.1)

The National Committee shall monitor institutions where fertilized eggs are produced to ensure their compliance with the provisions of the Law and Implementing Regulations and instructions issued by the National Committee.

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 (30.1)

Research may be conducted on a pre-quickening stillborn fetus, if deemed necessary by the local committee, provided the research project is beneficial and contributes to the progress of applied sciences.

Article (30.2)

Samples may be taken from a stillborn fetus upon obtaining approval of the local committee, provided said samples are legally stored at approved gene banks.

Article (30.3)

1- Research may be conducted on products of conception if the two following conditions are satisfied:
   a) It is established through a medical report signed by two consultant physicians, upon medical examination of products of conception, that it has no chance for survival.
   b) The conditions set forth in the Law and Regulations regarding research on the minor, incompetent or mentally disabled person shall be applied.
2- Research may be conducted on products of conception if said research aims to improve fetus chances of survival and obtain important information that may not be otherwise obtained, unless there is additional risk to the products of pregnancy.

Article (30.4)

If the research is conducted on an aborted or miscarried fetus, the following controls shall be observed:

1- Obtain the "Informed Consent" from the woman and her husband in accordance with the provisions of the Law and Regulations as well as controls and procedures set by the National Committee in this regard.

2- The woman and her husband shall be informed of the methodology used in the research on the aborted or miscarried fetus and whether there is an intention to store tissues taken therefrom to be used later for research.

3- Only miscarried and lawfully aborted fetuses according to the Law of Practicing Healthcare Professions may be used in research.

Chapter Eleven

Dealing with Genetic Material and its Banks

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 (31.1)

The Central Data Bank and the local gene banks shall provide parties concerned with information available on different diseases affecting individuals, families or the community, subject to maintaining the privacy of the genetic material source and barring the possibility to identify the source of the sample.

Article (31.2)

The investigator shall maintain the confidentiality of research conclusions, and not identify their source.

Article (31.3)

When conducting research on genetic material, the following shall be observed:

1- Islamic values, local culture and environmental safety.
2- Applicable and internationally recognized practices relating to conducting research on genetic material.

Article (31.4)

Results of the research on genetic material shall be the property of the State. Neither the researcher nor the institution may provide said results to any internal or foreign body without permission from the National Committee, provided the material and scientific rights of the researcher or research team and the research subject are preserved.

Article (31.5)

The local genetic material biobank shall provide the Central Data Bank with an annual report including the following data:

1- A classified list of genetic material available at the local bank, indicating date of acquisition and use.
2- A list of genetic materials withdrawn from the local bank, indicating date of withdrawal and investigator or institution using it.
3- A summary of research conducted on samples withdrawn from the local bank and used.

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 (32.1)

Prior to initiating research on genetic samples, the investigator or research team shall observe the following procedures:

1- Set a detailed plan including, but not limited to, research objectives, study approach, expected results and risks, and submit the same to the local committee.
2- Explain to the donor, if known, the subject and nature of the research, expected results, and potential risks, particularly if the research has an unclear genetic therapeutic nature provided that the research plan is accompanied with proof thereof.
3- Obtain the "Informed Consent" according to the Law and Regulations.

Article (32.2)

The National Committee shall specify the data to be included in the "Informed Consent" form for research conducted on the sample of genetic material.

Article (32.3)

Prior to approval of the research on genetic material, the local committee shall take the following measures:

1- Carefully review and verify the research protocol and ensure that it contains appropriate laboratory tools and techniques as well as all prevention and sterilization measures required in such cases.
2- Ensure that the investigator or research team has the necessary expertise to conduct the research.
3- Ensure that the research project contributes to knowledge on genes relating to the community and adds new scientific contribution to previous research, and that it seeks to develop and improve scientific standards and health conditions of different categories of the community.
4- Verify that the investigator or research team applies adequate scientific methods and precautions to prevent escape of living organisms from research laboratories if research includes conducting experiments on microbes such as genetically modified bacteria or bacteria that will be genetically modified for the purpose of research.

Article (32.4)

1- In case of conducting therapeutic research on the genetic material of animals or humans, the research objective shall be limited to finding treatment for genetic defects or diseases, provided the research is conducted on somatic and stem cells only.
2- In all cases, no research may be conducted on reproductive cells for the purpose of modifying natural human characteristics.
3- Except for the provisions set forth in paragraphs 1 and 2 above, the genetic treatment research shall be subject to controls and rules applied to clinical research as well as laws and controls issued by the National Committee.

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 (33.1)

The same genetic sample may not be used in multiple research projects of different purposes without obtaining an "Informed Consent" for each purpose, unless the following two conditions are satisfied:

1- The sample was previously obtained for diagnostic purposes and was retained for a time sufficient to preclude identification of the source by the investigator.
2- Obtain the approval of 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 (34.1)

The principal investigator shall be responsible for maintaining the privacy and confidentiality of information related to donors and shall be liable for any damage sustained by the donors or the community.

Article (34.2)

If local or international researchers are invited to conduct joint research on genetic material, the institution and principal investigator shall emphasize the necessity of observing the privacy and confidentiality of information related to donors in accordance with the provisions of the Law and Regulations.

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 (35.1)

The local committee may restrict the principal investigator's use of research results on genetic material if publishing said results would harm public interest, subject to the approval of the National Committee.

Article (35.2)

If prevented from using results of his research, the investigator may claim indemnification for research expenses from the institution.

Article 36

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

Article (36.1)

Conducting research on diseases that are particular among a certain group for the purpose of treatment and understanding of mechanisms of transmission of said diseases may not be construed as promoting racial discrimination.

Article (36.2)

Scientific results shall not be leaked to the media if this could lead to promoting discrimination on the basis of race or family or tribal affiliation.

Article 37

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

Article (37.1)

The following ethical controls and criteria shall be complied with when conducting genetic treatment research:

1- A written approval shall be obtained from the National Committee in all matters related to gene therapy research.
2- Gene therapy research shall be subject to controls and provisions set forth in the Law and Regulations and provisions set by the National Committee.
3- The research shall be consistent with the provisions of Shari'a, and the research plan shall include proof of taking such provisions into consideration.
4- The research shall comply with the controls and criteria set forth in international agreements related to gene therapy and amendments thereto, without prejudice to Shari'a rules and provisions.
5- Said research shall be limited to incurable diseases affecting human life, which have not yet been successfully treated by conventional medical methods.
6- Prior to approval of research, it shall be ascertained that all available treatment options have been exhausted.
7- The local committee evaluating this type of research shall comprise at least two persons with scientific competence to evaluate gene therapy research. The local committee may invite experienced consultants to attend its meetings to help evaluate the research project.
8- Gene therapy research shall be conducted in qualified hospitals and research centers with required medical specializations, as well as experienced and qualified staff.
9- The research plan shall include a detailed description of research objectives, methodology, expected benefits, difficulties, risks and health complications for the human subject.
10- The research shall be based on scientific principles, and preceded by sufficient laboratory experiments and animal testing.
11- The expected benefit from the research shall outweigh any potential risks.
12- The research shall be conducted by a qualified investigator specialized in genetic medicine and assisted by a highly efficient medical team. Said investigator shall be well versed in genetic and scientific material related to the subject of the research.
13- Gene therapy may not be carried out for research purposes on gametes (sperms and ova) or experimental research on stem cells obtained from fertilized zygotes or related to reproductive cloning.
14- Handling of genetic material in research, storage and disposal thereof, as well as collaborative research with centers abroad shall be in accordance with the controls set forth in the Law and Regulations.

Chapter Twelve

Use of Animals and Plants in Experiments

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 (38.1)

Animals may be used in scientific experiments where research objectives cannot be otherwise realized.

Article (38.2)

When a research is conducted using animals, the investigator shall comply with the following:

1- Sharia rulings and regulations related to kindness to merciful treatment of animal (animal welfare).
2- Scientific principles and guidelines that govern sound practice of animal's experimentation.
3- Obtaining licenses from the relevant authorities as required.
4- Obtaining a license from the Local Committee that qualifies researcher to conduct animal research according to the procedures for granting licenses at the National Committee.
5- Obtaining approval of the local committee prior to commencing the research.
6- Provide scientific justifications for using animals and ensure, whenever necessary, that there are supporting data (e.g. in vitro experiments) previous before conducting research on animals.
7- Obtaining approval from the local committee before using any biological materials or any other dangerous materials on the health of human, fetus or animal.
8- Use minimal number of animals to achieve the research objectives.
9- Prevent or minimize harm or pain that might be inflicted on the animal as much as possible.
10- Considerations that the expected research results and benefits exceed the potential risks and harms to animals and/or the environment.
11- Ensure that the appropriate animal is selected to give credible research's data and results.

12- Experiments' execution is based on acceptable and sound scientific and experimental foundations.
13- Used animals shall be subjected to periodic and frequent monitoring of pain and health condition as outlined in the proposed research and/or surgical procedures based on veterinarian's assessment and local committee's approval.
14- Genetically altered animals shall be monitored for unexpected abnormal behavior, development and/or illness to prevent or minimize animal suffering.
15- Any observed or suspected animal health or pain issues shall be reported to the veterinary staff.
16- The animal must be anesthetized during pain causing experiments, unless this will negatively influence research objectives, such evaluation is entrusted to the veterinarian and approved by the local committee.
17- Implement scientific and ethical methods for the merciful disposal (euthanasia) of animals taking the species and age of the animal into consideration.

Article (38.3)

To obtain approval to conduct research on animals, any of the following applications shall be satisfied:

1- To Prevent, diagnose or treat a disease or a deformity.
2- To explore animal physiology, disease origin and progress.
3- To protect the natural environment and promote the overall health of humans, animals or the environment
4- To achieve progress in biological science.
5- To contribute to forensic and judicial research.
6- To improve animal breeding methods and management.
7- To conduct preliminary research on pharmaceuticals, chemical compounds, and vaccines safety.
8- To study radioactive compounds, its effects and protection.

Article (38.4)

Subject to the provisions of Article (10/14) of the regulations, the local committee - when reviewing research proposals involving animals experimentation - must verify that the proposal includes the following mandatory elements:

1- Principal investigator and research team credentials,
2- Scientific justification elaborating on the expected benefits if the research had been conducted before.
3- Experimental animals' species, source, number, age and gender.
4- Administration of anesthetic agents and methods, analgesics and antibiotics including doses and sites of injection.
5- The duration of water or feed deprivation or physical restraint of the animal and its justification.
6- Methods of monitoring and mitigating harm that may result from inducing a disease model or genetic modification in animal.

7- Criteria, timing and methods of disposal for eliminating animals under experiment with providing scientific justification when this is not applicable.
8- Any agreements with other parties related to the experiment, or to the experiment's results.
9- A detailed account of the sites where the experiment will be conducted.
10- Approval of the relevant authorities, when required.
11- The system of animals' identification used in the experiment, and the system used to save the information and data related to every animal in the experiment's records.
12- Emergency and hazards management plans.
13- Methods and mechanism for disposal of the experiment's components.
14- Mechanism used to save all data and information resulting from the experiment in dedicated databases
15- The Local Committee shall evaluate the health risks associated with the use of animals in research, including the possibility of exposure to allergens and biological, chemical and radiological risks.
16- The local committee – upon reviewing proposals including experiments that cause animals' pain and suffering -should evaluate the proposals to verify the following:
    a) Ensure that the experiment is not banned or restricted by the laws and regulations of the Kingdom, or by International or regional resolutions to which the Kingdom is a party or co-signatory.
    b) The lack of other alternatives that can meet the research objectives.
    c) Ensure the qualification and competence of the research team, the tools and materials used, and the laboratory environment in which the experiment will be conducted are optimal.

Article (38.5)
The research protocol shall take all measures necessary to prevent animal suffering, using the minimum number of research animals which have a low level of neurological or physiological sensation, while trying to avoid animal pain as much as possible.

Article (38.6)
Artificial hybridization may not be conducted except between animals of the same species, even if breeds are different, provided that the expected benefit outweighs the risks and that such risks can be prevented or controlled.

Article (38.7)
Animals may not be cloned unless medically proven safe as per a medical report approved by at least two specialists.

Article (38.8)
Transplant of animal fetuses shall be subject to the same conditions governing the process of artificial insemination set forth in Article (38.6).

Article (38.9)
Banks for preserving animal sperms or eggs for production or research purposes may be established, without prejudice to rules of artificial insemination.

Article (38.10)
Painful research and experiments on animals shall not be carried out unless the following conditions are met:
1- The investigator is fully cognizant of the functions of organs, and that the research or experiment is useful in the scientific field, such as discovering diseases or treatments in a way that contributes to the prevention of diseases and illnesses and preservation of health and the environment.
2- The availability of a veterinarian to monitor and evaluate pain in animals.
3- The investigator shall obtain the approval of the local committee

Article (38.11)
1- No research or experiment may be conducted on animals for the purpose of acquiring skills or practical training without using anesthetics except in cases where the animal is not subject to severe pain or torture.
2- Research and experiments may be conducted on animals for the purpose of demonstration and explanation to students, provided it is undertaken by a qualified person and the said research or experiment is necessary to explain theoretical information and furnish students with useful scientific knowledge.

Article (38.12)
Endangered animal species may not be used in research or experiments unless said research or experiments are required for breeding or preservation of species. The approval of the relevant wildlife protection authority shall be obtained before conducting the research.

Article (38.13)
Painful or harmful methods may not be used in hunting wild animals for the purpose of research.

Article (38.14)
Animals that captured from must be quarantined in their habitat before being transferred to the research unit; also, they must be quarantined again in the research unit before the research can begin. The National Committee determines the conditions for quarantine and the necessary period for it.

Article (38.15)
Wild animals may not be used in scientific research except in the following cases:
1- If it is impossible to achieve study objectives by using other alternatives.
2- Increase the number of animals subject of the research and protect them from extinction without affecting their genetic nature.

3- Detect whether the animal subject carries any zoonotic or epidemic diseases or immunize said animal to prevent spread of such diseases.

Article (38.16)

1- Animals earmarked for experimentation shall be disposed of if they contract an infectious disease other than the one under study. However, if it is possible to treat such animals, this shall be carried out in isolated places, and all procedures of epidemic quarantine shall be enforced under the supervision of the veterinarian in charge. The disease and the measures taken for its control or treatment shall be reported to the competent authorities.
2- Animals or products thereof exposed to chemical, biological or genetic substances for the purposes of research may not be consumed, sold or given away. Said animals as well as wastes and products thereof shall be disposed of through established scientific practices under veterinary supervision.
3- The disposal of animal subject of research shall be while under anesthesia and after the experiment immediately, in accordance with the provisions of Shari'a.
4- Upon completion of the research and ascertaining the well-being of the research animal, it shall be released and returned to its original habitat, whenever possible

Article (38.17)

1- Wild animals foreign to the Kingdom’s wildlife may not be introduced thereto for the purposes of research.
2- Wild animals may not be returned to their habitat after being genetically modified.

Article (38.18)

For capturing animals for the purposes of research, a permit from the relevant authority indicating the term of the license, and type of animal shall be obtained, without prejudice to the hunting laws in the Kingdom.

Article (38.19)

The institution licensed to conduct research on animals shall have facilities for the care of experimental animals, comprising the following:

1- Dedicated and equipped enclosures for the care of experimental animals that are appropriate for animals’ behavior and posture, nutritional and health requirements.
2- Periodic cleaning and sterilizing the enclosures as per recognized scientific standards.
3- Veterinary care.
4- Qualified team trained in providing animal care
5- Providing appropriate water and feed for the species and strains used.
6- Animal isolation according to species and health status

7- The research laboratories shall adhere to occupational health and safety standards, according to the following:

a) Use appropriate standards, means and biological agents to prevent harm to humans.

b) Providing safety training and appropriate protective equipment for research workers.

c) Providing preventive medical and emergency care.

Article (38.20)

The local committee in the institution licensed to conduct research on animals shall submit an annual report to the Monitoring Office, including: activities, experiments conducted, numbers, types and sources of animals used, results of each experiment, and destruction procedures, pursuant to forms prepared for this purpose.

Article (38.21)

Persons licensed to conduct experiments on animals as well as institutions, places and experiments shall be monitored by the Monitoring Office.

Article (38.22)

The National Committee shall set up rules and controls governing use of animals in research experiments in matters not provided for in these Regulations.

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 (39.1)

Plant research shall not be subject to the restrictions mentioned in this regulation unless it is in any of the following areas:

1- Research on plant genetic resources.
2- Research on endangered plant species.
3- Research that may violate the rights of traditional knowledge holders.
4- Research on plant genetic modifications.

Article (39.2)

When conducting research on plants, the investigator shall comply with the following:

1- Sharia provisions related to environment and agriculture protection.
2- Scientific principles and conventions governing experimental practices on plants.
3- Obtaining a license from the relevant authority when needed.
4- The approval of the local committee to commence the research must be obtained.
5- Restriction to the smallest number of seeds or plant specimens to achieve the research objectives when doing research on endangered plant species.

6- Observing that the expected results and desired benefits from the research outweigh any risks and harms to the plant subject of the research or the ecosystem and natural environment in general.
7- The appropriate plant must be selected to provide credible information and results.
8- Disposal of all waste related to biotechnology activities and manage them in a safe manner that does not harm human health or harm the environment.
9- Removal of all equipment, stickers, packages and other materials related to the research from the natural site after the completion of the study.
10- Reference to the country of the resource or the group providing the genetic resources in all publications emanating from their use.
11- Respect the desire of holders of traditional knowledge about plant genetic resources to maintain the confidentiality of certain parts of their knowledge.
12- Maintaining the confidentiality of the precise locations of the endangered plant genetic resources, their full documentation, geographical locations, and any other note related to their protection from extinction.

Article (39.3)

To obtain approval to conduct research on plants, any of the following shall be satisfied:

1- Conducting surveys and inventory of plant genetic resources, including those with potential uses, and assessing any risk they are exposed to.
2- Collecting plant genetic resources and information related to those resources that are under threat or have potential uses.
3- Monitoring the viability, the degree of diversity and the genetic integrity of the plant genetic resources in the non-natural site.
4- Conservation of plant genetic resources in-situ.
5- Genetic improvement of crops and production of varieties that withstand drought, salinity and heat, and resist diseases and pests.
6- Producing varieties that can adapt to unpredictable environmental changes and human needs in the future.
7- Conservation of plant genetic resources ex-situ.

Article (39.4)

Subject to the provisions of Article (10/14) of the regulations, the local ethic committee - when reviewing research proposals for experiments on plants - must verify that the proposal includes the following mandatory elements:

1- Principal investigator and research team credentials,
2- Plant species used for the experiment, source and quantity.
3- Any agreements with other parties related to the experiment, or to the experiment's results.
4- A detailed account of the locations where the experiment will be carried out.
5- System used to save all data and information resulting from the experiment in dedicated databases.
6- Emergency and hazards management plans.

7- Means and mechanism for the disposal of the experiment's components.
8- Approval of the relevant authorities, when required.
9- The local ethics committee – upon reviewing proposals that include experiments on plant genetic resources - should study the proposals to verify the following:

a) Verify that the experiment is not prohibited and that it has no restrictions in the laws and regulations in force in the Kingdom, or within international or regional agreements or decisions. The Kingdom is a party to it or signed to it.

b) Verify that the investigator will obtain plant genetic resources in accordance with the laws and regulations in force in the Kingdom and the conditions set by the relevant authority.

c) Verify that there is no prohibition on the collection, circulation, entry, exit, or modification of plant genetic resources that will be used in research, either permanently or temporarily, according to the lists drawn up by the relevant authority.

Article (39.5)

A permit must be obtained from the relevant authority when importing or exporting plant genetic resources from the Kingdom in accordance with the provisions of the relevant laws and regulations.

Article (39.6)

It is permissible to import plants, plant products, or beneficial organisms for the purposes of scientific research in accordance with the provisions of the relevant laws and regulations and in accordance with the conditions laid down by the relevant authority.

Article (39.7)

Endangered plant species may not be used in a negative manner. It is not permissible to do research on endangered plant species unless the said research is required for reproduction or preservation of species. The approval of the Monitoring Office shall be obtained before conducting the research.

Article (39.8)

When reviewing research proposals on endangered plant species the local committee must thoroughly assess the proposal, and confirm that:

1- Endangered plant species are not used in research in scientific research except when there are no other alternatives that achieve necessary and important scientific hypotheses.
2- Obtaining a license to conduct research on endangered plant species from the relevant authorities.
3- Ensure that experiments with endangered plants will not cause any harm to their survival or ecological distribution.

Article (39.9)
The investigator licensed to conduct experiments on plants, as well as facilities, places and experiments shall be subject to monitoring by the Monitoring Office. In a manner that does not conflict with the applicable regulations related to food, medicine, agriculture, the laws of wildlife reservations, the laws for hunting, utilizing and protection of living aquatic wealth in regional waters, and all relevant laws and regulations in the Kingdom.

Article (39.10)
Penalties set forth in the Law and Regulations shall be imposed on any person violating regulations and provisions therein.

Article 40

If research includes conducting genetic modification experiments on Living Creatures, the investigator shall take all necessary measures to prevent their escape from research laboratories.

Article (40.1)
Genetic modification research on plants shall be conducted in laboratories designated for this purpose, including suitable growth rooms in buildings and green houses, provided all measures are taken to prevent escape of genetically modified creatures.

Article (40.2)
When the research includes experiments to modify creatures genetically, the investigator must ensure that the plants - genetically modified to resist insects - will not lead to extinction of beneficial insects.

Article (40.3)
When the research includes experiments to modify creatures genetically, the investigator must ensure that the plants - genetically modified for weed resistance - will not induce non-cultivated plants to become herbicide resistant.

Article (40.4)
The investigator must ensure that the new genetically modified plants cannot pose an environmental risk to the related wild crop and other species.

Article (40.5)
The investigator should properly assess the potential risks of introducing a new genetically modified plant.

Article (40.6)
Research for production of genetically modified seeds known as terminator seeds is prohibited.

Article (40.7)
Microorganisms subject to the research and their outcome shall be disposed of through standard scientific procedures.

Article (40.8)
To grant approval for conducting research on micro-organisms, any of the following shall be satisfied:
1- Protecting the natural environment and promoting the overall health of humans, animals or the environment.
2- Optimal progress in the biological sciences.
3- Reducing biological risks.

Article (40.9)
When conducting research on micro-organisms, the investigator shall comply with the following:
1- Principles and controls that govern experimental practices on micro-organisms.
2- Pledge not to misuse pathogens, knowledge and technologies - in dual use of microorganisms – and not to pass them on to those who may misuse them.
3- Obtaining the approval of the relevant authority when required.
4- Obtaining the approval of the local ethics committee before starting research.
5- Not to release into the environment micro-organisms that are resistant to any of the antimicrobials, even if they are not pathogenic.
6- Not to release micro-organisms that prove to be harmful to the environment, and he must dispose of them in a safe scientific manner.

Article (40.10)
Subject to the provisions of Article (10/13) of this regulations, the local committee - when reviewing research proposals for experiments on micro-organisms - must verify that the proposal includes the following mandatory elements:
1- Principal investigator and research team credentials.
2- Any agreements with other parties related to the experiment or what results from it.
3- An accurate description of the locations of the experiment sites.

Article (40.11)

The local committee - when reviewing research proposals for experiments on micro-organisms must verify:

1- Principal investigator and research team credentials and their ability to deal with different strains of micro-organisms, especially research on micro-organisms with a dual-use potential.
2- Conducting research on infectious micro-organisms in special laboratories equipped for such research.
3- The adequacy of the laboratories in which the research is conducted, in accordance with the conditions stipulated in Article (M6 / 7) of the Regulations.

The local committee, when reviewing research projects on micro-organisms that may entail risk, may require the participation of a person specialized in the field of research and its risks among the research work team.

Article (40.12)

A local committee may refuse permission to publish information on dual-use micro-organisms if it deems that its publication could lead to its use in a way harmful to humans or the environment.

Chapter Thirteen

Violation Review Committee

Article 41

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

Article (41.1)
Inspection employees, named pursuant to a decision by KACST President, shall be in charge of detecting violations of the provisions of the Law and Regulations, without prejudice to the authority of the Monitoring Office and the local committee with regard to detection of such violations.

Article (41.2)
For the purpose of detecting violations of the provisions of the Law and Regulations, the inspection employees may enter and inspect institutions licensed under the Law, examine records and documents, request necessary data, and question employees therein. Institution owners and officials shall facilitate the work of the inspection employees.

Article (41.3)
Inspection employees shall record every violation in an official report including name of violator or violating institution as the case may be, a description of the violation, time of detection, recording of any relevant sample, paper, or document seized therein. The report shall be signed by the relevant inspection employee and the violator. If the violator refuses to sign, such incident shall be recorded in the report.

Article (41.4)
The violator shall be notified of the detected violation in writing.

Article 42

1- 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:
   a) A Sharia counselor named by Minister of Justice — Chairman
   b) A faculty member of a Saudi medical college, of a rank not lower than associate professor, named by the Minister of Higher Education — Member
   c) A researcher specialized in genetic material, of a rank not lower than associate professor or equivalent, selected by KACST President — Member
   d) A qualified and experienced researcher specialized in bioethics, selected by KACST President — Member
   e) A legal counselor selected by KACST President — Member
   f) 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
   g) 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.
2- 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.
3- Remuneration of committee chairman and members shall be determined in the Regulations according to applicable laws, decisions and directives.
4- The Regulations shall determine committee rules, procedures and meetings.
5- 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.
6- 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 (42.1)

One or more committees shall be formed pursuant to a decision by KACST President to review violations of the provisions of the Law and Regulations, upon nomination of members of said committee(s) by competent bodies in accordance with Article 42 of the Law.

Article (42.2)

Violation Review Committee term of membership shall be three renewable years. If any member is unable to complete his term for any reason, or if he declares his wish to discontinue his committee membership, or if he fails to attend three consecutive or seven non-consecutive meetings within the same year without an excuse acceptable to KACST President, a replacement shall be appointed in the same manner the replaced member was appointed to fill out the remainder of his term.

Article (42.3)
The Violation Review Committee chairman shall manage its affairs and head its meetings, and committee members shall deliberate in camera.

Article (42.4)
The Violation Review Committee shall particularly perform the following tasks:
1- Review claims submitted thereto by KACST representative of public prosecution against violators of the provisions of the Law and Regulations.
2- Decide appropriate penalty from among the penalties set forth in Article 44 of the Law, except for imprisonment, against the violator after hearing his statements and reviewing his defense.
3- Submit a recommendation to KACST President for referral of violators to the competent court if the committee finds that the violation detected requires a penalty including imprisonment. KACST President shall refer the case to the Bureau of Investigation and Prosecution to submit it to the competent court.
4- Review compensation claims filed therewith by civil suit claimants and estimate the appropriate compensation if deemed justifiable, after hearing the defendant.
5- Compel the violator to publish the decision text at his expense in at least 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 (42.5)
The Violation Review Committee shall hold its meetings at KACST upon a call by its Chairman as needed, and may, if necessary, hold its meetings at any other place with the approval of KACST President. Committee meetings shall not be valid unless attended by two thirds of its members, including the chairman. Committee resolutions shall pass by majority vote of attending members. In case of a tie, the Chairman shall have the casting vote.

Article (42.6)
Violation Review Committee members shall be notified of each meeting date at least ten days prior to the meeting, and meeting proceedings shall be recorded in special minutes set for such purpose.

Article (42.7)
The Violation Review Committee may seek technical assistance from specialists or experts with regard to an issue before it, provided the letter sent to said specialists or experts specifies the remuneration.

Article (42.8)
In a compensation claim, if the claimant requests technical assistance from any agency with experience, the Violation Review Committee may, at its discretion, approve his request and refer the claim papers to said agency.

Article (42.9)
The Violation Review Committee may summon any of KACST personnel whose presence it deems necessary to seek advice on matters filed therewith.

Article (42.10)
The Violation Review Committee may, if necessary, approach public and private agencies as regards any of its affairs.

Article (42.11)
The Violation Review Committee may take any measures necessary to proceed with claims filed with it. It may itself conduct the inspection or delegate a member for this purpose, provided said member submits an inspection report.

Article (42.12)
The Violation Review Committee shall have a secretary appointed pursuant to a decision by KACST President.

Article (42.13)
The secretary shall manage the technical and administrative affairs of the Violation Review Committee, and shall particularly undertake the following duties:

1- Prepare committee minutes and arrange its meetings.
2- Coordinate between the committee and parties concerned from within and outside KACST, including meeting dates and notification of notices and decisions.
3- Perform typing, copying, and archiving tasks and save and retrieve files.
4- Keep a file for violations which includes the following:
    a) Violations with serial numbers.
    b) Name of violator.
    c) Date of receipt of violation report.
    d) Description of violation.
    e) Penalty imposed by the committee, and penalty decision and date thereof.
    f) Decision of the Board of Grievances with regard to the violation in case of an appeal.

Article (42.14)

1- The Violation Review Committee shall consider public suits and notify the violator of the date of hearing at least ten days in advance. The notification shall include a description of the violation; date, time and place of scheduled hearing, summoning the violator or his representative to appear before the committee and present his defense.
2- The Violation Review Committee may not consider public suits for a violation after the elapse of more than one year after detection without taking any action.

Article (42.15)
The Violation Review Committee shall consider civil suits and notify the defendant of the date of hearing at least ten days in advance. The notification shall include a copy of the petition and any other documents submitted by the claimant; date, time and place of the hearing, summoning the defendant or his representative to appear before the committee and present his defense.

Article (42.16)
If the defendant or his legal representative fails to attend the first hearing, the Violation Review Committee shall adjourn the hearing and notify the defendant of the new hearing date. If the defendant fails to attend a second time, though properly notified, the Violation Review Committee may proceed with the consideration of the case as if he was present. The defendant shall be deemed present if he attends one hearing and fails to attend the rest of the hearings.

Article (42.17)
The secretary of the Violation Review Committee shall draft the hearing minutes under the supervision of the hearing chairman, provided the minutes include names of attending members, place and time of the hearing, names of attending parties to the suit or their representatives, all hearing proceedings, as well as statements and defenses of parties. The minutes shall be signed by the committee chairman, members, secretary and parties to the suit or their representatives.

Article (42.18)
If the Violation Review Committee finds that the violation considered includes a crime punishable by other laws, it shall refer the criminal case to the competent agencies to take legal action, in accordance with said laws, and shall decide the violation under consideration unless it finds that either violation cannot be decided separately from the other.

Article (42.19)
Decisions of the Violation Review Committee shall be reasoned and shall include a rebuttal of all defenses raised by parties to the suit. A committee member (or the chairman) adopting a different opinion shall include said opinion in the minutes with the reasons thereof.

Article (42.20)
The Violation Review Committee secretariat shall notify the parties concerned of committee resolutions by official letters delivered to them or their legal representatives, provided that the notification letter includes the following text: "A party against whom a committee decision has been issued may appeal before the Board of Grievances within sixty days from date of notification."

Article (42.21)
Procedures of the Board of Grievances shall apply to matters not provided for in the Violation Review Committee Procedures.

Article (42.22)
An aggrieved party may appeal Violation Review Committee decision before the Board of Grievances within sixty days from date of notification thereof.

Article (42.23)
Remuneration of Violation Review Committee's chairman and members shall be determined according to Regulations of Joint Governmental Committees and their Work Procedures issued pursuant to Civil Service Council Decision No. (1/1270) dated 21/11/1428 H approved by wired High Order under No. (3759/MB) dated 12/6/1432 H.

Article 43

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

Article (43.1)
One or more public prosecution representatives shall be appointed pursuant to a decision by KACST President to file suit and litigate before the Violation Review Committee against violators of the Law and Regulations.

Article (43.2)
Based upon the contents of the violation detection report, the public prosecution representative shall file the public suit before the Violation Review Committee.

Article (43.3)
The Violation Review Committee shall consider the suit without delay, and if it is necessary to consider the suit in more than one hearing, the committee shall notify the parties concerned of the date, time and location of each hearing.

Chapter Fourteen

Penalties

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 (44.1)

The National Committee may warn the researcher, the institution, or both if it finds that the violation committed does not require a severer penalty, taking into consideration that repeating the violation may require additional penalties at the discretion of the committee.

Article (44.2)

If the penalty is a suspension of research, the suspension period shall not exceed two years. If the violation is not rectified, the research shall be cancelled.

Article (44.3)

The National Committee may bar the principal investigator from conducting the research subject of the violation, or from practicing any other activity that may affect the research.

Article (44.4)

The National Committee may impose a fine not exceeding two hundred thousand (200,000) riyals on the researcher, the institution, or both if violation is established.

Article (44.5)

If the National Committee finds that the violation committed requires imprisonment, it shall take Article (45.1) into consideration.

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 (45.1)

The Committee shall recommend an imprisonment term appropriate to the violation committed and state reasons for not imposing a lesser penalty.

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 (46.1)

A copy of the decision shall be delivered in person or through registered mail to the person against whom the penalty decision was issued.

Article (46.2)

If it is decided to publish the violation text in newspapers, it shall be noted that the researcher deliberately committed the violation or insisted on committing it.

Article 47

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

Article (47.1)

Provisions of Article (42.22) of these Regulations shall be taken into consideration.

Chapter Fifteen

Concluding Provisions

Article 48

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

Article (48.1)

These Regulations shall be published in the Official Gazette, and shall enter into force as of its publication date.

Article (48.2)

No amendments to these Regulations may be made except in the same manner they were issued.

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 (50.1)

If the institution fails to rectify its status in accordance with the conditions and requirements stipulated in the Law and Regulations within the ninety-day period set forth in Article 50 of this Law, it shall be barred from conducting research.

Article 51

This Law shall supersede all other provisions conflicting therewith.

DEAR COLLEAGUES

Your opinions and suggestions are welcome. So please do not hesitate contacting us if you have any notes about it.

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