SCRELC
Ethics. Guidance. Advice

STANDING COMMITTEE FOR RESEARCH ETHICS ON LIVING CREATURES (SCRELC)

جامعة الدمام
UNIVERSITY OF DAMMAM

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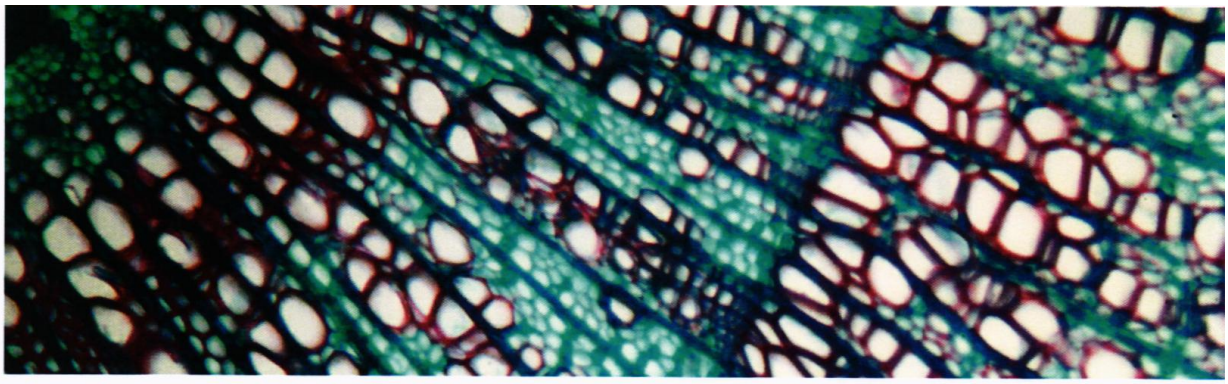
Implementing Regulations of the Law of Ethics of Research on Living Creatures



1435 H - 2014 G

Membership No: HAP-05-D-003, National Committee of Bio Ethics (NCBE), KSA.

Registration No: IORG0006803, Office for Human Research Protections (OHRP), USA.

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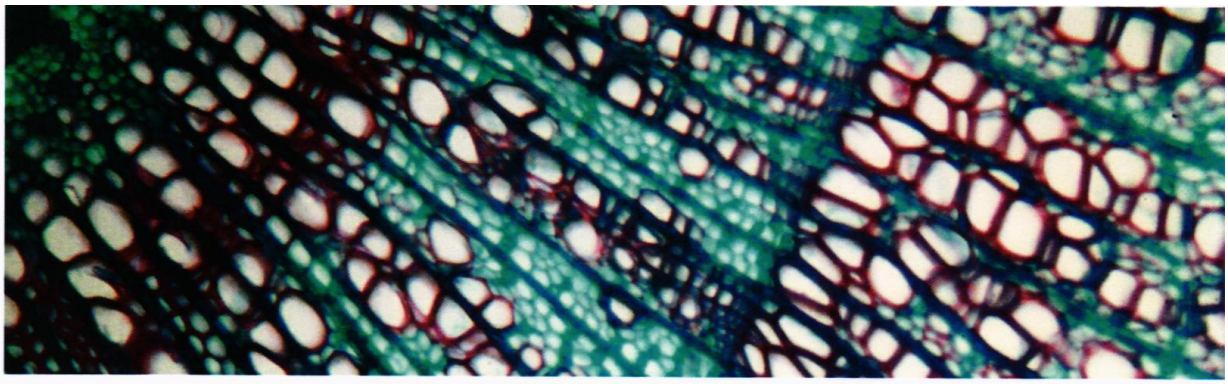

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MESSAGE FROM H.E. THE PRESIDENT

Scientific research is considered a strategic necessity and key economic pillar linked to the objectives of the development plans in the Kingdom of Saudi Arabia. This will enhance, by the grace of Almighty Allah, the achievement of the knowledge based economy through innovation, invention and entrepreneurship.

The Kingdom has spent and continues to spend relentless efforts and resources to achieve excellence among several national plans such as the National Plan for Science, Technology and Innovation and the AFAQ Project for High Education. This has underpinned the establishment of scientific research institutes and research centers of excellence in addition to practical and research chairs with specific projects that serve the community.

To achieve this goal research will have to observe ethics and values and ensure conservation of the basics and the glorious rights of the creature, the researcher and conserve the environment commensurate with local and global rules. The Royal Decree No. M / 59 dated 14/9/1431H has specified and legalized research ethics on living creatures to be strictly observed when conducting research. This was followed by the writing of the Implementing Regulations of the Law of Ethics of Research on Living Creatures. This is the first such law throughout the region and larger Middle East. The University of Dammam is keen to support scientific research and its results. To achieve this Standing Committee for Research Ethics on Living Creatures (SCRELC) was formed as per Resolution No. 42/1208 dated 10/01/1435 H.

Formation of SCRELC is a step in the right direction for the University to foster the culture of scientific research, innovation and entrepreneurship and be the prime incubator and hub for research both locally, nationally and internationally.

Professor Abdullah Mohammed Al-Rubaish
President of the University

Since the establishment of the Kingdom of Saudi Arabia (KSA) in 1902, the Leadership of the Kingdom have given Higher Education and Scientific Research a special high priority which culminated in the establishment of (35) universities, 27 of which are public, in addition to more than 19 centers of excellence in research. The government of the custodian of the two holy Mosques has also increased financial support for the scholarship program of the Custodian of the two holy Mosques. The budget for this program has now mounted to more than 9.9 billion Riyals supporting 150,000 student scholars studying abroad. This program has also implemented the national plan for science and technology and creativity to transform the Saudi national economy to a knowledge-based economy. With such ambitious expansion in scientific research arena the need has risen to regulate ethics in research in terms of local and a global vision.

Saudi Arabia has become the first regional country to have a special law that regulates ethics of research on living creatures as per the decision of the Council of Ministers No. 321 dated 13/09/1431 H.

The move to create the Standing Committee for Research Ethics on Living Creatures (SCRELC) at the University of Dammam is pursuant to Article 10 of the Law on Ethics of Research on Living Creatures as per the Royal Decree No. M / 59 dated 14/09/1431 H.

Professor. Abdulsalam Al-Sulaiman
Vice President for Scientific Research and Postgraduate Studies

Vision

University of Dammam (UOD) regards the use of humans and animals in research, and teaching to be an integral component of continued progress in education and science. The university expects all researchers to maintain the highest standards of ethics and professionalism when conducting research on living creatures and to be operated in accordance with applicable Shari'a provisions, Kingdom's Law and UOD regulations and guidelines.

Mission

University of Dammam Standing Committee for Research Ethics on Living Creatures (SCRELC) shall ensure the welfare, well-being and humane care and use of all Living Creatures used in research, and that research conducted at its premises is ethical, scientifically justified, and performed in accordance with Shari'a and the Kingdom's Law and regulations.

Objectives of UOD Local Committee

The University of Dammam is committed to the highest ethical standards of research involving humans, animals or plants. In addition to the objectives of Local Committees stated under "Article 10 of Chapter Six: Local Committee for Research Ethics" of the Law the University Standing Committee for Research Ethics on Living Creatures (SCRELC) will;

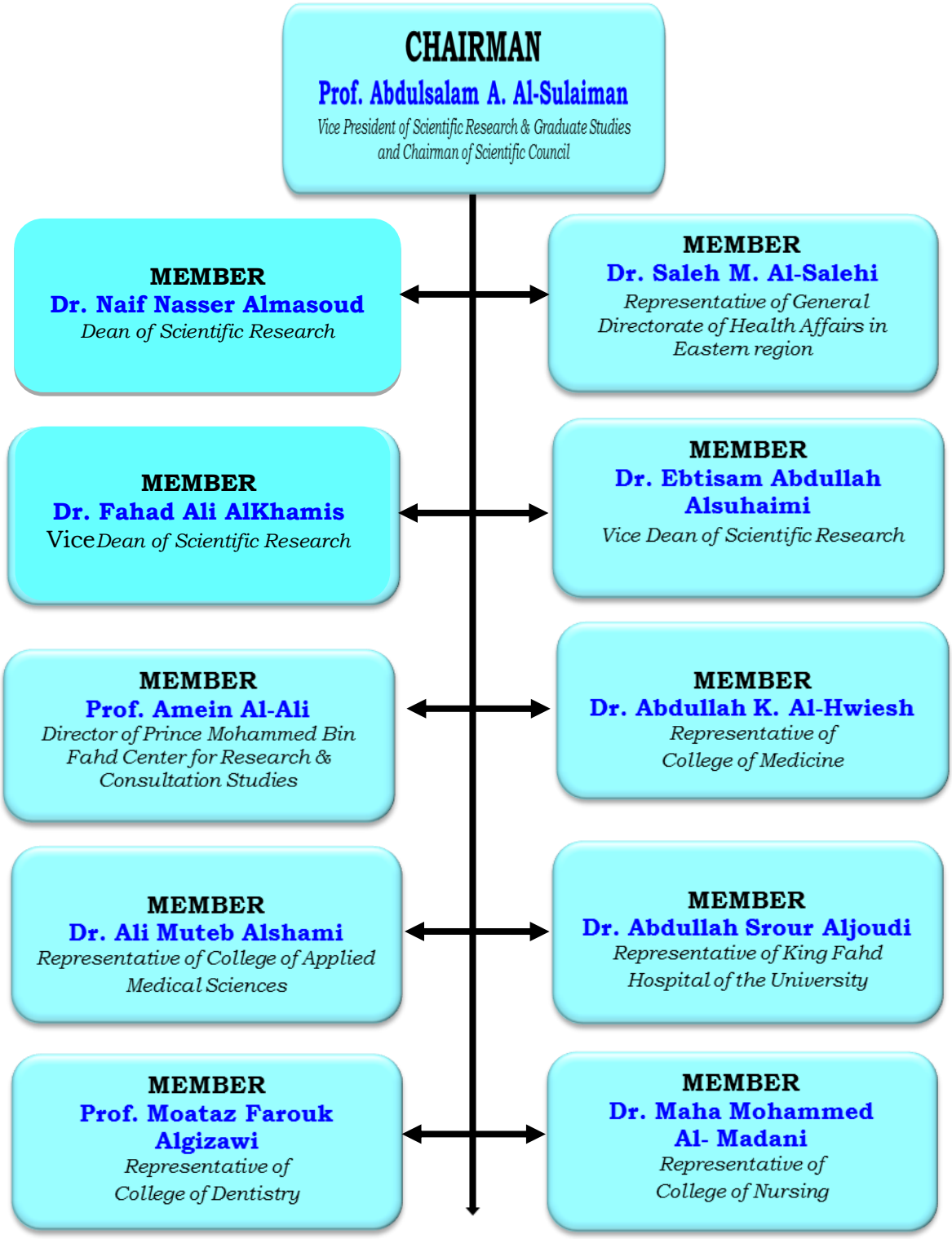
1. Collaborate With National Committee for Biomedical Ethics (NCBE) for establishment and implementation of standards in ethics in biotechnology and medical research and update the research committees in relevant colleges and centers.
2. Periodically evaluate and monitor various UOD research committees and research centers in the application of standards and regulations for ethics in biomedical research.

3. Periodically evaluate and control medical and pharmaceutical UOD laboratories that utilize organisms and insure its legitimacy.
4. Create a database for genetic material banks in the university and approve their inception.
5. Raise awareness of biomedical ethics and their importance for the workers in the field.
6. Coordinate with relevant authorities regarding strict compliance to ethics in biomedical research.

Applicability and Remuneration

1. This Law of Ethics of Research and Regulations on Living Creatures is applicable to all UOD conducted or supported research involving Living Creatures.
2. Remuneration of the Local Committee Chairman and members shall be determined in accordance with laws and procedures applicable at UOD.

STRUCTURE OF UOD'S STANDING COMMITTEE FOR RESEARCH ETHICS ON LIVING CREATURES (SCRELC)



CHAPTER ONE
DEFINITIONS AND GENERAL PROVISIONS

Article - 1 (of the law)

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 (LERLC)

UOD: University of Dammam

President of UOD: President of the University of Dammam

National Committee: National Committee of Biomedical Ethics, Riyadh

Monitoring Office: Research Ethics Monitoring Office, Riyadh

Local Committee: UOD Standing Committee for Research Ethics on Living Creatures (SCRELC)

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/her 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 this document, the following terms and phrases, wherever used, shall have the meanings assigned to them, unless otherwise required by context.
Human Subject: 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 new 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 for being minors, legally incompetent, or deprived of freedom of choice.

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 UOD Standing Committee for Research Ethics on Living Creatures (SCRELC) to evaluate research progress and conformity with the approved research plan.
Expedited Review: An evaluation carried out by SCRELC chairman, or by a member of the committee 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."

General Provisions

Article 1.2

Scope of Application
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.

1. 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 Shari'a 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 Shari'a.

Article 1.4

Banning Biological Research outside UOD

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

CHAPTER TWO
OBJECTIVES OF THE LAW

Article - 2 (of the law)
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 Shari'a.

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

Shari'a 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 (of the law)
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

UOD is responsible for any research conducted therein and will, through SCRELC, 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*

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 Shari'a 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
11. Monitoring Office 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.

** corresponds to Article 6 of the Law*

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 4.1

Sending biological samples

Upon sending biological samples to laboratories outside the Kingdom, the researcher or his/her designee at UOD shall comply with the following controls:

First: Samples sent abroad for research purposes;

1. Samples will be sent to international research agencies known for their research experience in the relevant research field(s).
2. An agreement will be signed in which rights of human subjects, researcher and national rights are guaranteed. Said agreement shall take the form of a joint research to be agreed upon by SCRELC.
3. If a researcher or institution in Saudi Arabia is found to have conducted or to be conducting the same research, the researcher will not send biological samples outside the Kingdom. In such case, it will be necessary to co-operate with the research conducted within the Kingdom unless there is a justification acceptable to SCRELC for non-feasibility of local co-operation.
4. Data sent with biological samples will not reveal the identity of sample provider; for instance, sending samples anonymously with coded numbers.
5. SCRELC shall notify the National Committee in writing of research content, objectives, sponsors, and participants upon approval of SCRELC. As per the Law the National Committee has the right to terminate or discontinue the research if it is found that

such research has no value for the Saudi society or is directly or indirectly detrimental thereto. This right of the National Committee will be stipulated in the agreement signed between UOD and any other foreign agency.

Second: Biological Samples sent abroad for diagnostic laboratory testing:

1. Ascertaining non-availability of said testing within the Kingdom of Saudi Arabia.
2. Sending samples to reference centers recognized in their countries such as diagnostic centers of the said disease in order to guarantee a reasonable level of quality control and ethical regulations.
3. Concluding an agreement between the sending and receiving agencies guaranteeing the rights of all parties, confidentiality of data, preventive measures for safeguarding the confidentiality of data of persons involved and manner of disposal of samples upon completion of testing.
4. The principle investigator when sending the data should not reveal the identity of sample provider. He can send these samples anonymously with coded numbers.

Samples sent will not exceed the normal quantity identity of sample provider; for instance, sending samples with coded numbers required for diagnosis and in accordance with controls set by the National Committee in this respect.

Third: In addition to controls stated in sections “1” and “2”, the researcher will, upon sending samples outside the Kingdom, observe the following:

1. Obtain Committee written approval from SCRELC for sending samples abroad by submitting an official letter indicating reasons for sending, quantity and type of samples as well as receiving agency, and notify the National Committee of this approval

2. Enclose a copy of the obtained National Committee approval with documents submitted to competent agencies such as customs and carriers.
3. Ensure safety of genetic samples during storage and transportation.
4. Dispose of excess genetic samples by standard scientific methods.
5. Genetic samples received from outside the Kingdom shall be subject to the same controls and provisions applicable to genetic samples taken within the Kingdom.

CHAPTER FOUR *
LOCAL COMMITTEE FOR RESEARCH ETHICS

Article – 5 **

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 5.1

In addition to the objectives previously stated the University Standing Committee for Research Ethics on Living Creatures (SCRELC) will seek to achieve the following;

1. Protect rights and ensure safety of the human subject;
2. Ensure that minors and legally incompetent and disabled persons are by no means abused.

SCRELC members, employees and all persons invited to attend its meetings shall keep as confidential all information they come by and shall not disclose any information included in research or research topics and proposals.

** corresponds to Chapter 6 and ** corresponds to Article 10 of the Law*

Article 5.2

If SCRELC member finds that any member of the committee 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 5.3

1. SCRELC may invite experts and consultants to attend its meetings without giving them the right to vote if a proposed item on the agenda so requires.
2. If the research subject proposed for discussion by SCRELC is related to any category of vulnerable group, SCRELC chairman will invite a specialist with experience in this field to take part in discussing said subject.

Said specialist will have the right to take part in discussion and in voting. If said specialist fails to attend the meeting, it will be required to obtain a specialist's written opinion of the matter.

Article 5.4

1. SCRELC resolutions will pass by simple majority vote of attending members. In case of a tie, the meeting chairman will have the casting vote.
2. SCRELC chairman will determine the voting method in committee meetings.
3. Issued resolution will be printed on SCRELC or establishment official stationary, and shall include a clear statement of resolution text. SCRELC chairman will notify the principal investigator of said resolution in writing.

4. In case the research application is rejected, the resolution will state the reasons for rejection.
5. SCRELC may issue non-binding recommendations, if necessary, and attach them to rejection resolution.
6. SCRELC may issue a conditional approval, and the resolution will determine the necessary procedure to reconsider the application and any requirements or suggestions for reassessment.
7. An aggrieved party may appeal SCRELC resolutions of rejection or provisional approval before the committee. If SCRELC dismisses the complaint as unconvincing, the aggrieved party may have recourse to the Monitoring Office to review the matter.

Article 5.5

The principal investigator, whether he belongs to the establishment or not, will submit the research approval to SCRELC, including the research proposal. Upon setting of research proposal, the researcher will observe the following:
1. Design of study will be appropriate to its objectives
2. Expected benefits and possible harms to which the human subject may be subject will be in balance
3. Research location shall be appropriate to the assistant group, including available potentials and emergency measures.

Article 5.6

The research proposal will comprise the following:
1. An abstract of the research within one page (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. Rationale for introducing any procedure, tool or device that has not been used before;

5. 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. Plan for dealing with risky cases;
7. Plan for disposal of extra biological samples;
8. A clear description of duties and responsibilities of research team;
9. Time schedule of research and criteria of research suspension or termination;
10. Case registration forms, daily cards, and questionnaires set for research subjects, in case of clinical research;
11. Research sample will be determined according to the following considerations:

11.1. Characteristics of sample from which the subjects will be selected;

11.2. Criteria for inclusion and exclusion of the human subject;

11.3. Methods through which initial contact and selection are carried out;

11.4. Means of providing complete information to potential participants in the research or their representatives.

12. In clinical research, the principal investigator will present a description of the individuals who will be given access to personal data of research subjects, including medical records and biological samples;
13. A list of expected results and ways to benefit therefrom;
14. A list of references

Article 5.7

The principal investigator will, if necessary, enclose the following documents with his/her research proposal:
1. Any plans to stop or prevent administration of standard treatments because of the research and justifications for preventing ordinary standard treatments for conducting the research;

2. Medical care offered to human subjects during and after the research;
3. A description of the efficacy of 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. Arrangements taken to provide compensation, if 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.

Article 5.8

To approve the research proposals submitted to SCRELC, the following procedures will be followed:
1. SCRELC shall prepare a special approval application form and publish it on its website, including the following:
    1.1. Name of local committee and its postal address, electronic mail address and contact numbers;
    1.2. Name of principal investigator and his ordinary and electronic mail address and contact numbers;
    1.3. Title, duration and objectives of research project;
    1.4. Date of submission of application.
2. The principal investigator will submit the application for approval according to the form referred to in the preceding paragraph 1 here above;
3. The principal investigator will fill in the approval form, and shall append with it the following documents:
    3.1. The research proposal;
    3.2. An updated, signed and dated CV of the principal investigator and co-investigators;
    3.3. Methods used for inviting human subjects, including advertisements;

d. "Informed Consent" forms;

e. Proof of passing a valid research ethics course;

4. SCRELC shall receive the application against a receipt given to the applicant indicating reception thereof and including number and date of submission.

5. SCRELC shall review the application in principle; if any requirements are missing, the committee will notify the applicant thereof within 10 work days of date of submission of application. The investigator will respond within 90 days of date of notification. The application will be deemed as rejected if the investigator fails to respond to committee's remarks and demands within the said period.

6. SCRELC 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 SCRELC shall evaluate the research proposal, provided it is complete and it satisfies applicable scientific conditions in the establishment.

SCRELC shall consider the researchers' ethical efficiency and ability to conduct the research, and will verify that the "Informed Consent" form contains all basic requirements.

8. The local committee will issue its decision indicating acceptance, rejection or amendment of research proposal within the period referred to in Paragraph 6 here above.

9. The committee resolution will include the following data:

9.1. Title of research project;

9.2. Date and number of research project;

9.3. Name of principal investigator and co- investigators;

9.4. Date of resolution.

9.5. 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 5.9

Before approval of research project, SCRELC shall verify the following:

1. No violation of Shari'a rules or applicable laws and legislations in the Kingdom;
2. Potential risk for the human subject is reduced to the minimum level through the following
    - 2.1. Adopting standard operating procedures and scientific methods for research design which do not expose research subjects to risks;
    - 2.2. Adopting standard and established procedures for therapeutic or diagnostic purposes as much as possible.
3. Evaluate benefits and risks that might ensue from the research;
4. Ensure that research subjects have been selected based on their understanding of research objectives, place, time and method of conducting, and pay a special extra attention in case of participation of individuals from vulnerable groups, such as special needs categories;
5. Ensure that the "Informed Consent" of the human subject contains all the required elements;
6. Ensure that the research plan includes a periodic monitoring of results to maintain safety of the human subject;
7. Ensure that the research plan includes management measures for protecting the human subject and his rights;
8. Ensure that appropriate measures are taken to protect privacy of the human subject and maintain confidentiality of data

Article 5.10

SCRELC 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:

3.1. 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;

3.2. 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 noninvasive 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:

5.1 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;

5.2. Weight taking or audiometry devices;

5.3 Magnetic resonance imaging (MRI) or ultrasonography imaging devices;

5.4. Electrography (ECG & EEG), Thermal Imaging, normal nuclear radiation rate measuring, infra-red imaging, blood flow measurement with ultrasound imaging (Doppler sonography), and echocardiography devices;

5.5. 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;

5.6. Search for information, records or samples that were previously collected or will be collected in the future for non-research purposes;

5.7. 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 5.11

1. Approval by expedited review will be issued by SCRELC chairman or by one or more members selected by committee chairman for their experience.
2. In case of expedited review, the research evaluator will have all the powers given to SCRELC except for rejection of research, which will be within the jurisdiction of the committee alone. If the evaluator decides to reject the research, he will 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, SCRELC chairman shall notify all committee members of the research projects that he has approved via whatever notification means he deems appropriate.

Article 5.12

SCRELC chairman has the power to approve any amendment of the research previously approved by using expedited review. Exceptions include interviews and surveys conducted on any of the special needs categories, amendment of research project or approval form, which shall be within the jurisdiction of the local committee.

Article 5.13

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 Law quoted in this document.

Article 5.14

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 5.15

1. If the Principal Investigator wishes to amend the research proposal approved by SCRELC, he should resubmit the matter to the Committee to obtain its approval prior to proceeding with the amendment.
2. The following may be exempted from review:
    - 2.1. Amendment of advertising material used for inviting human subjects, provided said amendment does not disrupt the content of such material;
    - 2.2. Amendments that only include providing administrative support to the study;
    - 2.3. Enrolling samples or cases brought from outside the establishment with the same terms.
3. In all cases, the Principal Investigator will furnish SCRELC with a detailed report on the amendment he has carried out.

Article 5.16

1. The Principal Investigator will obtain SCRELC 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:

2.3. Research title;

2.4. Research objective;

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

2.6. Indication of all facilities to be provided to human subject;

2.7. Number of research project in the Committee and expected date of completion;

2.8. Expected risks of the research, if any;

2.9. 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 5.17

If the Principal Investigator decides to transfer research supervision responsibility to a different investigator, he will take the following measures:

1. Submit a written application to this effect to SCRELC, including the following:

1.1. A written agreement for the replacement investigator to take responsibility for the research;

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

1.3. CV of the replacement investigator;

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

1.5. 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 SCRELC.

2. The Principal Investigator will proceed with his supervision of the research until SCRELC has reviewed the application;

3. SCRELC 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 5.18

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

2. SCRELC 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 5.19

SCRELC 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. SCRELC may assign specialists as it deems fit to perform this task on its behalf.

3. SCRELC 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 5.20

1. The principal investigator will provide SCRELC with a periodic report of the research every three months in case of conducting clinical research and every six months in case of conducting other types of research.
2. The periodic report will contain all the details of the research and its phases.
The investigator will attach to this report proof of his commitment to the procedures and controls set forth in this Law and its Regulations.

Article 5.21

If the principal investigator fails to submit the periodic report on time, SCRELC 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, SCRELC 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, SCRELC shall thoroughly review it and examine all required documents to ensure that no violations have been committed; otherwise, it will carry out whatever it deems fit;
4. If the principal investigator submits the periodic report during local committee review of research, SCRELC 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, SCRELC 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 5.22

1. The principal investigator will notify SCRELC immediately of any unexpected major harm that takes place during or after conducting the research, and should supply the committee with all information pertaining to the incident, indicating whether this incident is definitely, probably or by no means related to the research.
2. The principal investigator will include all expected minor harms in his periodic report submitted to the committee.
3. SCRELC shall notify the Monitoring Office of the incident of major harm and all related details either in writing within 24 hours in case of death or within no more than seven days in all other cases. Notification may also be done through phone calls depending on how serious the incident has been.

Article 5.23

1. If SCRELC 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 SCRELC finds that the investigator has not obtained required approvals, it will 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 SCRELC shall notify the president of any research that is suspended or referred to the Monitoring Office.

Article 5.24

SCRELC has the right to 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:

1.1. If the information is generally and publicly available;

1.2. 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:

2.1. If the information is recorded in a manner that reveals the identity of the source person.

2.2. 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 5.25

1. Subject to the provisions of paragraph 2 hereunder, SCRELC, 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 here above, SCRELC may exempt certain research projects that it has previously approved from periodic evaluation in either of the following cases:

2.1. 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

2.2. 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 will issue a decision including its approval or rejection of continuation of the said research.

Article 5.26

If, after the periodic assessment, the local committee disapproves of research continuation, it will 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 5.27

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 will consider said request in a meeting held for this purpose or in the nearest meeting.

Article 5.28

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

Article 5.29

SCRELC is keeping 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 its members, 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;
4. A statement of the reasons that led the 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 5.30

SCRELC 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. All scientific activities carried out by the committee, including scientific publications, workshops, colloquia and symposia;
4. All other information deemed by the Monitoring Office as necessary to be included in the report.

Article 5.31

1. Any member of the research team may file a complaint with the committee;
2. SCRELC shall consider said complaint in its next meeting or in a special meeting called for by the committee chairman.

Article 5.32

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

CHAPTER FIVE *
INFORMED CONSENT

Article – 6 **

No investigator will be allowed to conduct research on any human subject prior to obtaining an informed consent from him/her or from his/her guardian in accordance with procedures specified by the Regulations.

Article 6.1

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

Article 6.2

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;

** corresponds to Chapter 7 and ** corresponds to Article 11 of the Law*

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/she sustains any harm resulting from the research.

Article – 7 *

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 7.1

1. When obtaining the "Informed Consent", the investigator will in all cases observe the following:

   1.1. He shall, in a clear and simple language, explain in person the information stated in the "Informed Consent" form to the human subject (or his/her guardian if the subject is incompetent);
   1.2. The explanation shall be appropriate to the educational level, culture and understanding of the human subject (or guardian if the subject is incompetent);
   1.3. He shall, if required, explain any additional information not stated in the "Informed Consent" form;
   1.4. He shall answer any question raised by the human subject (or guardian if the subject is incompetent);
   1.5. He shall not obtain the consent in haste or use coercion or undue inducement to obtain it.
   1.6. 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;

** corresponds to Article 12 of the Law*

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

Article 7.2

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 – 8 *

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

Article 8.1

SCRELC shall 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 8.2

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

** Corresponds to Article 13 of the Law*

Article 8.3

1. The principal investigator will be responsible for obtaining the "Informed Consent" but he/she 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 committee to delegate another research team member or any other person fully aware of the research project to undertake such procedures. The committee may or may not approve this request based on the justifications provided by the principal investigator. In case of acceptance, the committee will 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 8.4

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, and the third for the committee.
2. If the human subject is a patient, a copy of the "Informed Consent" form shall be kept in his/her medical file.

Article – 9 *

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 9.1

SCRELC 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.

** Corresponds to Article 14 of the Law*

CHAPTER SIX *
RESEARCH ON HUMANS

Article – 10 **

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 10.1

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

Article 10.2

Prior to conducting clinical research on humans, the following will be observed:
1. The investigator will clearly and accurately specify his objectives and methodology;
2. The research will be preceded by sufficient experiments on animals if the nature of the research so requires.
3. Potential risks will not be greater than expected benefits.

** corresponds to Chapter 8 and ** corresponds to Article 15 of the Law*

Article 10.3

Unprecedented experimental surgeries and medical research will 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 10.4

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

Article – 11 *

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

Article 11.1

1. The investigator will 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 SCRELC finds that the potential risk to the human subject is greater than the expected benefit, it will deny permission to conduct the research.
3. SCRELC shall verify, through periodic reports submitted by the investigator, that the expected benefit is still greater than the potential risk.

** corresponds to Article 16 of the Law*

Article 11.2

1. Prior to approving research on humans, the 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 Shari'a and applicable laws. This will 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 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 11.3

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

Article – 12 *

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 12.1

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

** correspond to Articles 17*

Article – 13 *

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 Shari'a.

Article 13.1

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 – 14 **

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 14.1

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 14.2

In case the investigator is found guilty of violating Article (19.1) of the Regulations, he will 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 Shari'a.

** and **correspond to Articles 18,19 respectively*

Article – 15 *

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

Article 15.1

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

Article 15.2

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 15.3

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, SCRELC permission to conduct the research should be sufficient.

** correspond to Articles 20, respectively*

Article – 16 *

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

Article 16.1

UOD shall conduct research on human zygotes or gametes only under the following controls:

1. The practices indicated in the research proposal shall be consistent with the provisions of Shari'a and standard medical principles, and the research shall be justified in terms of its contribution to medical knowledge or technical applications;
2. The investigator will obtain the "Informed Consent" from the person donating zygotes or gametes in accordance with Article 11 of the Law.
3. The investigator will 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 16.2

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/she 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.

** correspond to Articles 21 of the Law, respectively.*

Article 16.3

No research will be conducted on human fetuses except for one of the following purposes:
1. Find a treatment for reproductive problems, in which case the research will be conducted in UOD reaching hospital;
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 16.4

The research proposal on human fetuses will 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 16.5

The investigator will use the minimum number of fetuses to achieve research purposes.

Article 16.6

In cases of research conducted to acquire new knowledge, the researcher will submit to the SCRELC proof that potential risk for the fetus is minimal.

Article 16.7

The investigator will prepare and keep records of the source of each fetus and the results of using said fetus in the research, and will submit periodic reports on the research to the committee.

Article 16.8

The investigator will abide by the controls and procedures set by the National Committee regarding research on stem cells, zygotes, gametes and fetuses.

Article – 17 *

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

Article 17.1

SCRELC will not permit research to be conducted on human cloning and any reproductive and research applications resulting therefrom due to constraints determined by shari'a, ethical principles and health-related harms, where harms and dangers to humanity outweigh the expected benefits.

Article – 18 **

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 18.1

Subject to provisions and controls set forth in the Law and Implementing Regulations and directives issued by UOD Standing Committee for Research Ethics on Living Creatures, 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:

** and ** correspond Article 22 and 23 of the Law, respectively*

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 performed for medical indications shall not be used for therapeutic purposes or 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 not be used whether in research or in scientific and laboratory experiments in accordance with applicable Shari'a 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. Research objectives will 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 SCRELC;
8. Assessing the expected benefit for the human subject and the extent to which it outweighs the possible harm shall be through a clear and thorough scientific assessment conducted by the investigator and submitted to the committee;
9. If the committee finds that the potential harm for the human subject outweighs the expected benefit, it shall not approve the research project;
10. The committee shall review periodic reports submitted by the investigator to ensure that the expected benefit continues to outweigh the possible harm;
11. The investigator or research team conducting the research shall be specialized and shall have sufficient scientific expertise and scientific competence;

12. 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;
13. The investigator will keep detailed records of the source of stem cells and results of their use in the research, and shall submit periodic research reports to the local committee.
14. UOD shall have its own bank to store stem cells for research purposes subject to the approval of the National Committee;
15. Stem cells stored in the stem cell banks will not be used for research purposes without the prior permission of SCRELC and the owner's consent, and upon obtaining the "Informed Consent" from the donor;
16. Each sample will be given a permanent label indicating to whom it belongs.
Information included in said label will be updated by the principal investigator under the supervision of the committee;
17. UOD shall set up a special record for research conducted on the sample under the supervision and monitoring of SCRELC;
18. UOD shall safeguard the sample and shall destroy it under the supervision of SCRELC when it is no longer needed or if the donor so requests;
19. UOD shall prepare a periodic report on research conducted on the sample for submission to SCRELC;
20. UOD shall submit, along with the research proposal, a description of the mechanism of safeguarding samples and records thereof;
21. All personal data resulting from the research conducted on the sample will be part of the rights of the donor, and they may not be used or published without his consent, taking confidentiality and privacy into consideration;
22. The National Committee may, when necessary, add or amend conditions for use of stem cells.

CHAPTER SEVEN *
RESEARCH ON INMATES

Article – 19 **

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 19.1

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

Article 19.2

SCRELC shall 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 will not be subject to clinical research whether by coercion or inducement or for any purposes other than those set forth in this Article.

** and ** correspond Chapter 9 and Article 24 of the Law, respectively*

CHAPTER EIGHT *
RESEARCH ON SPECIAL CASES

Article 20 **

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 20.1

1. UOD shall not conduct research 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 20.2

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

** and ** correspond Chapter 10 and Article 25, respectively*

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 will 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 will 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 20.3

If SCRELC 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 is within acceptable levels in accordance with medical
standards, if compared with expected benefits;
2. The ratio of the expected benefit exceeds that of other methods available outside the scope of the research;
3. The research will 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 20.4

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

1. If he/she had given the "Informed Consent" when he/she was competent or before the disability occurred, and his/her legal guardian later gave the "Informed Consent";
2. If precautionary measures taken for his/her 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 20.5

SCRELC 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 should 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 20.6

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

Article 21 *

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

Article 21.1

An investigator will not be granted permission to 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 the pregnant woman or her fetus does not exceed the minimum risk level;
3. The investigator will 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 will 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 will commit 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.

** corresponds Article 26 of the Law*

Article 21.2

No research on fetuses may be initiated unless the following conditions are satisfied:
1. The research will not harm or endanger the life of the fetus;
2. The research project will aim to provide health requirements for the fetus and to acquire information that cannot otherwise be obtained;

3. No research will 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 22 *
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 23 **
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 23.1

The UOD SCRELC shall see to it that fertilized eggs are produced in compliance with the provisions of the Law and Implementing Regulations and instructions issued by the National Committee.

** and ** correspond to Articles 27 , 28 of the Law, respectively*

Article 24 *

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

Article 25 **

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 25.1

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

Article 25.2

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

Article 25.3

1. Research will only be conducted on products of conception if the two following conditions are satisfied:
    - 1.1 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;
    - 1.2 The conditions set forth in the Law and Regulations regarding research on the minor, incompetent or mentally disabled person shall be applied.

** and ** correspond to Articles 29 and 30 of the Law, respectively*

2. Research will 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 25.4

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 will 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 NINE *
DEALING WITH GENETIC MATERIAL AND ITS BANKS

Article – 26 **

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 26.1

UOD gene bank in collaboration with the Central Gene Bank at KACST, Riyadh, and all relevant institutions will 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 26.2

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

Article 26.3

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

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

** and ** correspond to Chapter 11 and Article 31 of the Law, respectively*

Article 26.4

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

Article 26.5

UOD genetic material bio-bank will provide the Central Data Bank, KACST, Riyadh, with an annual report including the following data:
1. A classified list of genetic material available at the UOD bank, indicating date of acquisition and use;
2. A list of genetic materials withdrawn from the 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 – 27 *
When setting up local data banks for the preservation of genetic material, UOD shall comply with conditions and procedures specified by the Regulations.

Article 27.1

Prior to initiating research on genetic samples, the investigator or research team will 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 SCRELC;

** corresponds to Article 32 of the Law*

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 27.2

Prior to approval of the research on genetic material, SCRELC 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 27.3

1. In case of conducting therapeutic research on the genetic material of animals or humans, the research objective will 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 will 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 will be subject to controls and rules applied to clinical research as well as laws and controls issued by the National Committee.

Article – 28 *

The same genetic sample may not be subject to multiple uses 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 28.1

As per Article 33 of the Law and Regulations 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 SCRELC.

Article – 29 **

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

Article 29.1

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

** and ** correspond to the Article 33 and 34, respectively*

Article 29.2

If local or international researchers are invited to conduct joint research on genetic material, both UOD and the Principal Investigator will 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 – 30 *

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 30.1

SCRELC shall 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 30.2

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

Article – 31 **

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

Article 31.1

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.

** and ** correspond to Articles 35, 36 of the Law, respectively*

Article 31.2

SCRELC will insure that scientific results will not be leaked to the media if this could lead to promoting discrimination on the basis of race or family or tribal affiliation.

Article – 32 *

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

Article 32.1

The following ethical controls and criteria will be complied with when conducting genetic treatment research at UOD:

1. A written approval will be obtained from the National Committee in all matters related to gene therapy research;
2. Gene therapy research will be subject to controls and provisions set forth in the Law and Regulations and provisions set by the National Committee;
3. The research will be consistent with the provisions of Shari'a, and the research plan will include proof of taking such provisions into consideration;
4. The research will 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 will 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, SCRELC shall ascertain that all available treatment options have been exhausted;
7. SCRELC shall form a sub-committee of at least two persons with scientific competence on gene therapy research to evaluate this type of research. This sub-committee may invite experienced consultants to attend its meetings to help evaluate the research project;

** correspond to Articles 37 of the Law, respectively*

8. Gene therapy research will only be conducted in KFHU and/or at Prince Mohammed Bin Fahd Center of Research and Consultation Studies (PMFCRC) research laboratories under supervision of medically specialized and experienced personnel;
9. The research plan will include a detailed description of research objectives,
methodology, expected benefits, difficulties, risks and health complications for the human subject;
10. The research will be based on scientific principles, and preceded by sufficient laboratory experiments and animal testing;
11. SCRELC shall insure that the expected benefit(s) from the research will outweigh any potential risks;
12. SCRELC before approving the research shall review the experience of the investigator who will conduct the research to make sure he/she is qualified and specialized in genetic medicine and is assisted by a highly efficient medical team. Said investigator will be well versed in genetic and scientific material related to the subject of the research;
13. Gene therapy will 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. SCRELC shall handle genetic material in research, storage and disposal thereof, as well as collaborative research with centers abroad in accordance with the controls set forth in the Law and Regulations.

CHAPTER TEN *
USE OF ANIMALS AND PLANTS IN EXPERIMENTS

Article – 33 **

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 33.1

SCRELC shall only approve use of animals in scientific experiments where research objectives cannot be otherwise achieved.

Article 33.2

When conducting research on animals, the investigator will comply with the following:

1. Shari'a provisions related to humane treatment of animals;
2. Scientific principles and conventions governing experimental practices on animals;
3. Obtaining a license from SCRELC to conduct research on animals;
4. Obtaining approval from the committee to commence the research;
5. Using the minimum number of animals required to achieve research objectives and minimizing harm to and suffering of animals;

** and ** correspond to Chapter 12 and Article 38, respectively*

6. Observing that the expected results and desired benefits from the research outweigh any risks and harms to the animal subject of the research or the environment in general;
7. Practice shall be subject to appropriate and acceptable scientific and experimental principles.

Article 33.3

To obtain approval to conduct research on animals, any of the following shall be satisfied:
1. To prevent, diagnose or treat a disease or a deformity that must be rectified or whose effects must be removed;
2. To explore animal physiology;
3. Protection of the natural environment as well as general health of humans or animals;
4. Achievement of scientific advancement in biological sciences;
5. Contribution to forensic research;
6. Improvement of animal breeding methods and management;
7. Conduct preliminary research on pharmaceutical substances, toxins and radioactive effects.

Article 33.4

The research protocol will 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.

Article 33.5

SCRELC shall allow artificial hybridization to be conducted only 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 33.6

SCRELC shall only allow cloning of animals if medically proven safe as per a medical report approved by at least two specialists.

Article 33.7

SCRELC will adopt the policy that transplant of animal fetuses is subject to the same conditions governing the process of artificial insemination set forth in Article (33.5) above.

Article 33.8

UOD bank for preserving animal sperms or eggs for production or research purposes was established without prejudice to rules of artificial insemination.

Article 33.9

Research and experiments causing pain to animals will not be conducted unless the following two conditions are satisfied:
1. The investigator is well versed in physiology, and the research or experiment is useful to humans or animal species and shall seek to preserve and protect them or put an end to their pain and suffering;
2. The investigator should obtain committee approval.

Article 33.10

Pain-causing research and experiments on animals is allowed only when conducted under anesthesia unless this undermines research objectives, at the discretion of the investigator.

Article 33.11

In all cases, upon completion, the animal subject of research will be disposed of while under anesthesia, in accordance with the provisions of Shari'a.

Article 33.12

Animals earmarked for experimentation will 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 will be carried out in isolated places, and all procedures of epidemic quarantine will be enforced under the supervision of the veterinarian in charge. The disease and the measures taken for its control or treatment will be reported to the competent authorities.

Article 33.13

1. No research or experiment will 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 33.14

SCRELC shall not approve research or experiments involving endangered animal species unless the research or experiments are required for breeding or preservation of species. The approval of the Monitoring Office will be obtained before conducting the research.

Article 33.15

UOD shall not approve painful or harmful methods in hunting wild animals for the purpose of research.

Article 33.16

Captured animals will be subject to quarantine in their natural habitat before being moved to the research unit wherein they are to be quarantined once again before conducting the research.
The quarantine conditions and its duration will be as set by the National Committee.

Article 33.17

The Standing Committee for Research Ethics on Living Creatures will allow research on wild animals only in the following cases:
1. If it is impossible to achieve study objectives by using other alternatives;
2. The research will increase the number of animal subjects of the research and protect them from extinction without affecting their genetic nature;
3. To detect whether the animal subject carries any zoonotic or epidemic diseases or immunize said animal to prevent spread of such diseases.

Article 33.18

Upon completion of the research and ascertaining the well-being of the research animal, it will be released and returned to its original habitat, whenever possible.

Article 33.19

1. UOD prohibits the introduction of wild animals foreign to the Kingdom's wildlife for the purpose of research;

2. Genetically modified wild animals will not be returned to their habitat;
3. SCRELC shall not approve research conducted to increase the population of certain species of wild animals at the expense of other species unless said species is in danger of extinction.

Article 33.20

For capturing wild animals for the purposes of research, a permit from the National Committee indicating validity period and type of animal will be obtained, without prejudice to the hunting laws in the Kingdom.

Article 33.21

The principal investigator in collaboration with SCRELC and under veterinary supervision will see to it that animals or products thereof exposed to chemical, biological or genetic substances for the purposes of research will not be consumed, sold or given away. Said animals as well as wastes and products thereof will be disposed of through established scientific practices under veterinary supervision.

Article 33.22

UOD animal care facility is constructed in accord with the highest scientific, humane, and ethical principles. It comprises the following:
1. Enclosures for the care of experimental animals are constructed and appropriately equipped to meet the animals' needs therein
2. A qualified veterinary doctor to monitor animal safety and health and care for animals prior to commencement of research;
3. Fully equipped laboratories appropriate for conducting experiments and reaching sound scientific results.

Article 33.23

SCRELC through UOD shall submit an annual report to the Monitoring Office in the form designed for this purpose. The report will detail the 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 34 *

SCRELC neither allows research on plants that upsets environmental balance and distribution of vegetation nor approves negative use of endangered plant species.

Article 34.1

No research may be conducted on endangered plants unless it is necessary for reproduction or preservation of plants. The approval of the Monitoring Office shall be obtained prior to conducting the research.

Article – 35 **

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

Article 35.1

Genetic modification research on animals and plants will be conducted in laboratories designated for this purpose, and all measures will be taken to prevent escape of genetically modified creatures.

** and ** correspond to Articles 39 , 40 of the Law, respectively*

Article 35.2

Microorganisms subject to the research and their outcome will be disposed of through standard scientific procedures.

REFERENCES

1. King Abdul-Aziz City for Science and Technology. Implementing Regulations of the Law of Ethics of research on Living Creatures. The Implementing Regulations of the Law of Ethics for Research on Living Creatures for the Royal Decree No. M 95 Dated 14th of Ramadan 1431 (24th of August 2010) KACST, Riyadh 2013. http://www.ud.edu.sa/cs/groups/public/documents/document/mdaw/mdqx/~edisp/implementing.pdf

2. Professor Abdulsalam Al-Sulaiman. Standing Committee on Ethics of Research on Living Creatures. The second training session for members of the Committees for Research Ethics. University of Dammam. 10/6/1435 H (10th April 2014 G)

3. The Unified Regulations for Scientific Research at Saudi Universities 1431 H (2010)

4. Area 10: Scientific Research. National Commission for Assessment and Academic Accreditation (NCAAA) 2013

5. WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. 64th WMA General Assembly, Fortaleza, Brazil, October 2013. http://www.wma.net/en/30publications/10policies/b3/

6. United Nations. Ethics Office. http://www.un.org/en/ethic

7. WIPO, World Intellectual Property Organization. http://www.wipo.int/portal/en/index.html