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وثيقة إجراءات العمل القياسية باللغة الإنجليزية

English Standard Operating Procedures Document

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This document covers the procedures for the Medical Research Ethics Committee of the National Research Center

- **Purpose:** To cover all the activities of the committee and the way the committee acts in response to these events, including its vision, mission, values, goals, and objectives, as well as how to recruit a chair person, members, and independent advisors, conflicts of interest, maintaining confidentiality, non-disclosure of information, periodicity of meetings, quorum requirements, and procedures. Also evaluation, standards and procedures for reviewing research, how to vote and make decisions, and minutes of committee meetings, communicating decisions and responsibilities of researchers during the conduct of the study, deviation from the study, and procedures for retaining paper and digital documents.

- **Application field:**

1. National Research Center
2. Medical Research Ethics Committee
3. Researchers applying to the committee from outside the National Research Center
4. Research, projects, and scientific theses

- **Definitions:**

Medical Research Ethics Committee: It is a committee formed by a decision of the head of the National Research Center concerned with caring for the rights, safety, and health of the subjects, as well as the care and welfare of animals and preserving medicinal plants from extinction by reviewing the research plans submitted to it and ensuring that they fulfill all the documents and requirements. It also reviews the necessary documents based on the formation decision and assigned tasks. The committee is composed of a group of people with medical and non-medical specializations, including some members from outside the National Research Center.

Clinical medical research: studies or experiments conducted on human volunteers to evaluate the safety and efficiency of any therapeutic, medicinal, surgical, nutritional, preventive, or diagnostic interventions to arrive at scientific discoveries for diseases. As well as studies conducted to explore the medical data of volunteers for a retrospective questionnaire to evaluate the effect of a medication, behavior, or surgical intervention by internationally accepted research ethical standards.

Good Medical Practice: A set of internationally and locally recognized principles and standards that are applied in planning, managing, implementing, monitoring, auditing, recording, analyzing and reporting medical research with the aim of providing confidence that the data and announced results of the research are credible and accurate in order to maintain its integrity and volunteer participants, their rights, and the confidentiality of their data from any harm

Research: These are studies or experiments conducted on human volunteers or laboratory animals, or include medicinal or food plants, which include medicines, therapeutic or diagnostic interventions by methods previously known or registered internationally or locally, or on which previous research has been published with the aim of making comparisons between those methods by different ways to find the best methods

Projects: These are researches funded by internal, local or international bodies and may include research aspects only or clinical medical research.

Scientific dissertations: These are the research studies that are conducted to obtain an academic degree, including a diplomat, master's degree, doctorate, etc.

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Responsibilities:

1. Head of the National Research Center
2. Vice President of the National Center for Scientific Research and International Relations
3. Chairman and members of the Medical Research Ethics Committee
4. Researchers submitting their studies to the committee

Forms:

- Checklist for documents submitted to the committee
- Arabic Declaration of Helsinki
- English Declaration of Helsinki
- Definition of serious adverse effects
- An administrative statement about the committee's conflict of interest
- A document on maintaining the confidentiality of information and avoiding conflicts of interest for committee members
- Conflict of interest document for researchers
- Requesting an amendment to the research plan, deleting or adding members
- Model of progress in human research
- Informed consent form in Arabic
- A form of pledge to preserve the rights of researchers participating in the research
- Research evaluation form form for reviewers
- Informed consent evaluation form
- Initial approval form in English
- Periodic follow-up form
- Final approval form in English
- A model for publishing research from a project
- Meeting minutes template

References:

1. Law No. 214 of 2020 regulating clinical medical research
2. Executive regulations of Law No. 927 of 2022
3. Guide for the Supreme Council for Review of Clinical Medical Research Ethics for the year 2024
4. Good medical and laboratory practices
5. Helsinki Declaration of 2013 and its amendments
6. International ethical guidelines for health-related research conducted on human subjects
7. International Ethical Guidelines on Research of the Council of International Organizations for Medical Sciences in cooperation with the World Health Organization
8. Institutional Animal Care and Use Committee
9. Guidelines for medicinal plants

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1. Introduction

The National Research Center's Medical Research Ethics Committee (MREC) is committed to review research to preserve all aspects of the health and safety of participants and researchers, animal welfare, and the preservation of plants and the environment.

While the primary goal of research is to enhance the well-being of society, an important objective of research involving human subjects is protection of the rights and welfare of subjects who participate in research. Accordingly, research should be guided by the ethical principles embraced by the Declaration of Helsinki, Belmont Report and The International Guiding Principles for Biomedical Research Involving Animals developed by the Council for International Organizations of Medical Sciences (CIOMS) as well as Good Medical and Laboratory Practices (GCP and GLP) guidelines, and the Institutional Animal Care and Use Committee (IACUC) and medicinal plants guidelines and recommendations, and World Health Organization (WHO) rules regarding the ethics of scientific research.

These principles in human subject research include autonomy (respect for persons), beneficence (protecting subject welfare), non-maleficence (minimizing potential harms of research) and justice (avoidance of exploitation). Justice also requires that the benefits and burdens of research be distributed fairly among all groups and classes in a society, as well as between the different countries who are participating in the research. In animal subject research the principles are the 3Rs,

1. Replacement: methods which avoid or replace the use of animals in research
2. Reduction: use of methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals.
3. Refinement: use of methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals used.

2. Assurances

The president and vice president of NRC for research and international affairs will oversee the research practices in the NRC and assures that these practices will conform to the principles of research ethics. Part of this assurance includes the establishment of an appropriated constituted Medical Research Ethics Committee which shall have the responsibility to review and monitor research involving human or animal subjects and also researches that involve medicinal plants.

3. Vision, Mission, Values, and Goals for the MREC of the NRC

- **Vision**

MREC vision is to be one of the leaders and model in the Middle East Region, Africa and to be recognized internationally in reviewing and evaluating the ethical conduct of researches and offering professional services.

- **Mission**
  - Ensures that research involving *human participants or* animal subjects abides by all ethical responsibility for safeguarding their rights and welfare
  - Monitoring the conduct of the research to guarantee safety and standing to the approved protocol
  - Empowers the MREC members partnering with sponsors, investigators, volunteer subjects, institution, community to promote the highest level of human and animal subject protection through scientifically and ethically sound research.
  - Continuously evolving our processes to match *the international standards* while complying with regulatory, legal, and ethical requirements.

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- Advocating, with peers, regulators and the public in the interest of improving the research atmosphere
- Dedicated to educate young MRECs and investigators while creating, applying and sharing research education that has significance for our organization and society.

- **Values**

MREC believes in working in a team approach, independence, confidentiality, fairness, integrity, justice, non-prejudice, impartiality, equality, and transparency. In response to protecting human participants and preserving animal rights Medicinal plants and the environment.

- **Goals**

We strive to achieve our mission and vision through the following organizational goals:

1. Protection of human subjects involved in research clinical trials and animal subjects involved in pre-clinical trials and medicinal plants.
2. Providing ongoing lifelong refresher training of the MREC members to keep their standards competent and expert.
3. Raise awareness of the community about research and human rights in participating in clinical trials and animal welfare in pre-clinical trials.
4. Orientation of young investigators about the standards of writing, conducting, and ethical review of the protocols
5. Serving as a facilitator and resource to researchers
6. Valuing different types of research, including experiential and clinical trials.
7. Promote collaborations with international research agencies
8. The committee works to preserve the environment, and for this purpose, it will be a paper-free committee.

- **Objectives:**

i. Protection of the rights, and welfare of all research subjects

The MREC will advise researchers in designing research projects in a manner that minimizes potential harm to humans, reviewing the protection, rights and welfare of animals before starting research and preserve the environment while not eliminating medicinal plants. MREC will approve research that meets established criteria. The committee will monitor the approved studies to ensure that humans, animals, and plants are actually protected.

Accordingly, the MREC has the responsibilities and authority of:

- Reviewing and approving, requiring modifications (to secure approval) to the research plan or informed consent, or disapproving initial reports and continuing reviews of all research activities;
- The authority to suspend or terminate approval of research that is not being conducted per the MREC's requirements and per the national and international ethical requirements or has been associated with unexpected or unforeseen serious harm to research participants.
- MREC will Inform the Vice President of the National Research Center for Research and International Relations and the concerned authorities about any unexpected problems that involve risks to people or others or serious and continuous non-compliance by researchers in a timely manner. Along, with sending an annual report to the Vice President of the National Research Center on the work of the committee and any other topics it deems appropriate for discussion and decision-making

ii. Offer a balanced range of workshops courses and seminars to young investigators and newly MREC candidates. This will maintain a higher level of research performance through competent investigators and MREC reviewers.

iii. Conduct continuous medical educational training programs to our MREC members to keep them updated on the new controversial ethical research issues which will add to their experience and performance.

iv. Establish channels to communicate with the community to increase the awareness of human subjects about their rights when participating in clinical research trials.

v. Enhance and promote the relationship between our MREC and other peer MREC, investigators and research sponsors at the national and international level to standardize and update the concept and principles of tackling controversial research ethical issues.

vi. Establishing a data and safety monitoring board (DSMB) —as an independent group of experts who monitor patient safety and treatment efficacy data while a clinical trial is ongoing.

vii. We will become a paperless committee with the sustainable development goals of Egypt and the globe

4. Constitution of the MREC

The MREC will be constituted to ensure a competent review of the ethical aspects of the research while maintaining independence from influences that could affect the performance of unbiased reviews.

4.1 Chairperson

- *Appointment:*

The first chairperson will be appointed directly by the President of the NRC. Neither the President nor his or her Vice President of NRC should serve as members of the MREC or its Chair to ensure the independence of the MREC from institutional influence. The Subsequent appointment of the Chairperson will be through MREC nominating one of its members to be the chairperson position

- *Qualifications of the chairperson:*

The chairperson shall have the following qualifications:

i. Medical Doctor Degree
ii. Reasonable experience in performing research
iii. Basic training in research ethics
iv. Reasonable communication skills and leadership characteristics
v. Committed to the protection of human, animal subjects and plants in research

- *Term of appointment:*

The chairperson shall serve for a period of three-years. Afterwards, the appointment of the chairperson could be renewed by re-appointed. The chairperson shall not serve for more than two consecutive three -year terms.

4.2 Vice-Chairperson:

The chairperson will choose a vice-chairperson to help him or her in carrying out his or her responsibilities. This is done at the first meeting of the committee after its establishment or at the first meeting after renewal. The Vice President carries out the duties of the Chairman in the event of his/her absence based on a written authorization from the Chairman and after the Committee's approval of this. This takes place at the first meeting of the Committee after its establishment or at the first meeting after renewal.

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4.3 Members of the MRECs

a. Members:

Members of the MREC will reflect a multidisciplinary and multi-sectorial composition, including relevant scientific expertise (i.e., appropriate to the types of protocols that will be reviewed), balanced age and gender distribution, a mix of junior and senior staff members, a mix of medical/non-medical scientific and non-scientific persons including non-affiliated lay representatives (e.g., lawyer, journalist, religious people and public figures) to reflect the differed viewpoints of the community.

b. Numbers:

The number of persons in the MREC should be kept fairly small, between 11-17 members. However, there is no specific recommendation for a widely acceptable maximum number of persons, but, it should be kept in mind that too large a committee will make it difficult to reach a consensus. However, taking into account that the committee reviews research on humans, laboratory animals, other animals, and medicinal plants, Non-medical research related to the health of humans and animals, the number is greater than that to ensure that different specialties are relatively represented.

c. Qualifications:

members will include the following:

i. Holding at least a college degree
ii. Have an interest in research issues and research ethics
iii. Be reputable and trustworthy
iv. Willing to volunteer their time and effort
v. Willing to sign a confidentiality and conflict of interest agreement regarding meeting deliberations, information on research subjects, and other related matters
vi. The non-affiliated community representative may be exempted from having a College degree to ensure proper representation of a large sector of the community who might not have such qualification.
vii. To review animal research, the veterinary consultant (at least one member) is considered an important asset, and to review plant studies, it is necessary to have one member as an agricultural consultant.

d. Conditions of Appointment:

Each member must agree to meet all education and training requirements and sign an agreement to maintain confidentiality and avoid conflicts of interest.

e. Appointment Process

- First appointment of members of the MREC

An initial core group of members is selected directly by the head of the National Research Center, who mandated the establishment the MREC

- Subsequent appointment of members

- The committee renews its members every three years by including new members representing one-third of its members in each new formation. A member may not serve more than two consecutive terms, each lasting three years.

- The MREC identifies potential members, interviews them, and reviews with them the nature and requirements of service on the committee. If the member is willing to serve, the chair or vice chair of the committee shall obtain approval from the head of the relevant department and Head of NRC in which the potential member is working. After the approval of the department head, the nomination will be presented to the entire members of the MREC.

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- Term period

Each member is appointed for a 3-year term

- Renewal

At the end of each appointment term, members wishing to remain must submit a written request to the President. Subsequent renewal will depend on the previous quality of work assigned to him/ her and attendance performance and will be determined by consensus of the full committee

- Resignation:

Members wishing to terminate their appointment prior to the 3-year term should send a written letter of resignation to the chairperson two months in advance to have enough time to appoint another member.

- Disqualification:

Members may be asked to leave the MREC if any of the following occurs:

1. Failure to attend three consecutive meetings without permission or more than half of the annual sessions without an acceptable excuse
2. Negligence in reviewing protocols
3. Breach of confidentiality agreement
4. Termination shall be decided by a majority vote of the full MREC

f. Conflict of interest and maintaining confidentiality and non-disclosure of information:

Service on the Medical Research Ethics Committee includes reviewing documents that contain personal, confidential and proprietary information of the owner of the research plan or its sponsor and funder. Members of the Medical Research Ethics Committee are responsible for keeping all documents and committee procedures strictly confidential. This information may not be used for any purpose other than reviewing the research outline. It may not be disclosed to anyone outside the MREC unless written permission is obtained from the Chair of the Committee. Accordingly, the MREC will not have a member participate in the initial or ongoing review of any research scheme in which the member has a conflicting interest, except to provide information required by the committee. Examples of conflicts of interest may include, but are not limited to: a committee member who serves as a researcher in the research scheme; or a member who has a financial interest from the body sponsoring or funding the research

g. After the appointment:

Each member must meet all education and training requirements

h. Directing and training committee members:

i. Initial Training:

After the appointment, the new member will undergo the orientation of the MREC, which consists of an introductory lecture followed by an orientation session on practical matters with the Chair of the MREC. Subsequent education may include workshops in research ethics and/ or completion of training at scientific and MREC websites and groups

ii. Continuing Training:

MREC will set standards for continuing education of its members every year (e.g., regularly scheduled review of published articles in research ethics, attendance at workshops, attending sessions etc.)

4.4 Independent Consultants

The MREC may, at the discretion of the Chair or its members, invite individuals with competence in particular areas to assist in the review of issues that require expertise beyond or in addition to that available on the Committee. Note that these individuals are not permitted to vote with members of the MREC, nor are these advisors included in determining or establishing a quorum at meetings. However, the meetings minutes will reflect their attendance in writing after the document on maintaining confidentiality and non-conflict of interest is signed before attending the discussions. The invitation will be formally addressed to them by sending an email or a letter signed by the head of the committee. A telephone call for the invitation is permissible, provided that this is recorded in the minutes of the meeting. Whoever is selected must meet the following conditions:

- To be reputable and trustworthy
- Must have at least a University degree
- To have an interest in scientific research and its ethics
- Avoid conflicts of interest when carrying out work on the committee and ensure transparency regarding these interests
- Protect the confidentiality of information and sign a confidentiality document
- He must have previous experience in the field of consulting
- He must be willing to give his time and effort while agreeing to the requirements of the committee's work and adhering to the principles to which it is committed.
- Preferably those who have completed training courses in the field of scientific research ethics
- Respect the rights and privacy of all participants and the privacy of the committee

5. Meeting Frequency

The MREC will meet at regular time intervals physically or virtually by the needs of the workloads, but generally, it should meet at least once a month on a regularly scheduled day. The meeting date will be determined at the first meeting following the decision on the new formation.

In certain circumstances, MREC can meet on an "as needed" basis. Scheduled meetings may be canceled by the chair due to inability to secure a quorum for attendance, or other reasons as may arise that make a scheduled meeting unnecessary or otherwise inappropriate.

6. Quorum Requirements

- The number required to compose a meeting will be half of the members plus one.
- Quorum will consist entirely of members of one profession (e.g., medicine)
- Virtual meetings will be accepted as physical attendance at the discretion of the chair or in special circumstances.

7. Review and evaluation

The Technical Secretariat will prepare a report on the review and evaluation of all the committee's work in terms of the number of research papers presented to the committee, the periodicity of the committee's meetings, the percentage of members' attendance in general and in detail for each member annually, as well as the percentage of member review of research. The report will be presented to the general committee with a detailed review every six months to the head of the committee, indicating the number and percentage of accepted research directly from the first session, accepted research after accepting amendments, rejected research, expedited research, and so on.

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8. MREC Research Review Evaluations Procedures, Criteria and Actions

The MREC is charged with the responsibility for reviewing and monitoring human and animal subject research as well as the medicinal plants conducted under the mandate of NRC.

8.1 Therefore, the first question with respect to MREC review of a project is a determination of whether the project fits the definition of research.

8.1.1 Is it a research?

Research is defined as "a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Thus, a key aspect of research is that there be a systematic designs in advance, generally utilizing a scientific approach or protocol, for the defined purpose of contributing to generalizable knowledge. Research can encompass a wide variety of activities, including experiments, observational studies, surveys, tests, and recordings.

8.1.2 Does it involve human subjects?

A human subject is defined as "a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information."

Identifiable private information "includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place," and information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a health care record).

Intervention includes physical procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes.

Interaction includes communication between the investigator and the subject. This includes face-to-face, mail, and phone interaction as well as any other mode of communication.

8.1.3 Does it involve vertebrate animal subjects*?*

A Vertebrate animal is defined as "Any animal of the chordate subphylum Vertebrata, which includes the fishes, amphibians, reptiles, birds, and mammals. Vertebrates have an internal skeleton formed of cartilage, bone, or both. The skeleton consists of a backbone (vertebral column)."

8.2 Procedures for submitting and reviewing requests for new studies

8.2.1 *Persons authorized to submit:* A request for ethics review of the proposed research scheme must be submitted by the principal investigator of the research or his or her legal representative.

8.2.2 *Documents Submitted:* Each application to be complete should consist of the following and submitted through the committee's official website:

- A signed and dated application form (developed by the MREC)
- Complete research plan and protocol
- The informed consent form (in human research) and the animal welfare report (in animal research), both developed by MREC
- Product brochure for new drug/device

- Time plan for the study and Copies of actual questionnaires to be used in the study
- CVs for the principal and co-investigators
- Copies of materials to be used (e.g. advertisement) for the recruitment of research subjects.
- Signed investigator assurance agreement to comply with ethical principles and legal requirements set out in relevant laws and guidelines
- A commitment form to preserve the rights of researchers participating in the research
- Signed and dated approval from the department council, the dean of the institute, or any other scientific committee that scientifically evaluated the research,

If the application is incomplete or not fully prepared for review, the protocol will not be reviewed by the committee and the investigator is requested to make the necessary changes or to provide additional information.

8.2.3 Deadlines

8.2.3.1 Submission dates:

The deadline for submission will be at least 14 days before the meeting at which the protocol will be reviewed by the MREC.

8.2.3.2 Investigator notification:

Investigators will be notified of an MREC decision within five working days after a decision has been reached.

8.3 Review of Applications of New Studies

The MREC will use a primary and secondary reviewer system in which two to four members will be assigned to lead the review and present the protocol for discussion at the convened meeting. All MREC members will be provided with detailed materials describing the research so that each member will be able to discuss the protocol at the meeting.

8.3.1 Member review:

A member will be selected to be the primary reviewer of the protocol and will be responsible for:

- Completing the primary reviewer form
- Presenting the protocol for discussion at the meeting

8.3.2 All members shall receive protocols for review at least 1 week before the review meeting and all members are required to review all submitted materials and be prepared to discuss all protocols at the convened meeting.

8.3.3 Expedited Review

Certain research plans with minimal risk that meet the criteria established by the committee may be subject to expedited or urgent review by the committee chair. However, all urgent decisions must be sent to the next meeting of the MREC. “Minimum risk” means that the probability and magnitude of harm or discomfort expected in the research is not in itself greater than that normally encountered in daily life or during routine physical or psychological examinations or tests.

8.4 MREC Evaluation Criteria:

- *Acceptable Social Value* to the community/country

- *Scientific Design:* The MREC will consider the assessment of scientific design as determined by a separate Research Committee. The MREC will consider elements of scientific design not reviewed by the Research Committee (e.g., justification of the use of placebo control arms, inclusion and exclusion criteria, etc.)

- *Recruitment of Research Subjects:* In accordance with Belmont principles, both the burdens and benefits of research should be distributed equitably. In making this assessment the MREC will take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. If such vulnerable populations will be potentially enrolled in research, then the MREC will determine the appropriateness of additional safeguards to provide added protection to vulnerable populations.

- *Analysis of Risks and Benefits:* The MREC will identify all risks (physical, psychological, social, and economic) involved in the research. Risks to subjects must be minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and whenever appropriate, by relying on procedures already being performed on the subjects for diagnostic or treatment purposes. Risks to subjects must be reasonable about anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

8.5 *Privacy of Subjects and Confidentiality Procedures to Protect Subjects' Data*:

The MREC will determine the appropriateness of procedures in place to ensure subject privacy and the confidentiality of data obtained from the subjects.

8.6 *Procedures to Monitor Subjects during the Study:*

The MREC will consider the appropriateness of criteria for prematurely withdrawing research subjects for safety considerations (if applicable); the adequacy of provisions to monitor the safety of research subjects; and the determination of whether a Data Safety Monitoring Board is required.

8.7 *Informed Consent:*

Unless specifically waived by the MREC, informed consent must be sought from each prospective subject or the subject's legally authorized representative. The MREC shall also:

- Review of the adequacy, completeness, and understandability of written and oral information
- Determination of whether signed, written informed consent can be waived and the validity of alternative procedures to document the provision of informed consent
- The determination of whether informed consent could be obtained from the subject's legally acceptable representative.
- Determination of whether the informed consent document contains the required basic elements of consent
- Vertebrate animal's research: any research uses vertebrate animal as research subject must submit animal welfare report include the following:

1 The use, care and transportation of animals for training and for research and testing for the purpose of animal health and the environment must comply with all applicable animal welfare laws.
2 When scientifically appropriate, alternative procedures that reduce the number of animals used, refine the use of whole animals or replace whole animals (e.g., in vitro models, invertebrate organisms) should be considered.
3 For research requiring the use of animals, the species should be carefully selected and the number of animals kept to the minimum required achieving scientifically valid results.
4 All reasonable steps should be taken to avoid or minimize discomfort, distress or pain of animals.
5 Appropriate aseptic technique, anesthesia and postoperative analgesia should be provided if a surgical procedure is required. Muscle relaxants or paralytics are not to be used in place of anesthetics.
6 Care and handling of all animals used for research purposes must be directed by veterinarians or other individuals trained and experienced in the proper care, handling and use of the species being maintained or studied. Veterinary care is to be provided in a timely manner when needed.
7 Investigators and other personnel must be qualified and trained appropriately for conducting procedures on living animals, including training in the proper and humane care and use of laboratory animals.
8 Euthanasia shall be conducted according to the most current guidelines on Euthanasia

8.8 *Externally Sponsored Studies:*

Sometimes research is undertaken in Egypt but sponsored, financed, and sometimes entirely or partly carried out by an external international or national organization or pharmaceutical company with the collaboration or agreement of the appropriate authorities, institutions, and personnel of Egypt. In such externally sponsored research, the MREC and in the country of the sponsor shall have responsibility for conducting both scientific and ethical reviews, as well as the authority to withhold approval of research proposals that fail to meet their scientific or ethical standards. The MREC shall have the following special responsibilities:

1 determine whether the objectives of the research are responsive to the health needs and priorities of Egypt to avoid exploitation of underprivileged communities
2 Obtain information regarding the type of post-trial benefits to the community and Egypt to determine that the burdens and potential benefits of the research have been fairly distributed between the participating countries.
3 Determine whether the research plan conflicts with the customs or traditions of society or its religious and moral values
4 Instructing the principal investigator on the necessity of obtaining ethical approvals from other concerned authorities such as the Egyptian Drug Authority and the Supreme Council for Review of Clinical Research Ethics if this is deemed necessary and required.

9. Voting and Decision making

9-1 General Instructions

- All members who attended the meeting while the protocol was discussed will participate in the voting unless a member has a conflict of interest. Those members physically present for the vote should be recorded as either voting for, against, or abstaining. Members who are excused from the vote (e.g. due to conflict of interest) should physically leave the room, would not be counted in the aforementioned tally, and should be identified by name in the minutes.

- Decisions should be made at meetings where a quorum is present.

- Decisions should be reached through consensus, where possible. In cases where a consensus appears unlikely or when discussions become prolonged, the chairperson shall call for a vote. In such instances, a majority vote will be sufficient to arrive at a decision. In case of a tie, the decision favored by the chairperson shall be determinate.

- When an MREC member has a conflict of interest that requires him/her to excuse himself/herself from discussion of and voting on a particular protocol, that member should leave the meeting room for the duration of the discussion and vote,

except as requested to address questions raised by other members. If the member's conflict of interest causes a loss of quorum, the vote should be postponed to another meeting. For this reason, MREC members should notify the chair in advance of the meeting if they have a conflict of interest related to a specific research plan scheduled to be reviewed at the meeting, and every effort must be made to ensure a quorum even after a member withdraws from the meeting.

- Each research protocol will be assigned a risk level (minimal risk, greater than minimal risk, or extreme risk) and the follow-up periods will be determined according to the specific risk level. The duration of approval will be a maximum of one year and follow-up periods and approval duration can be less than that, depending on the nature of the research and the risks related to it.

9-2 Decision types

1. Approval

In the case of approval with no changes, the research may proceed once the principal investigator receives written documentation of MREC approval.

2. Approval with minor changes

The MREC may determine that a study may be approved with stipulated minor changes or clarifications. Minor changes are those changes that do not involve the potential for increased risk or decreased benefit to the human subjects. Some examples of minor changes are changes in contact information or identity of non-key research personnel, changes in the study title, and changes in the consent form that reflect the minor changes listed earlier.

For minor changes, the Chair or a voting MREC member(s) designated by the chair must ensure that the investigator makes the appropriate changes to the research protocol. Such changes must be delineated at the convened meeting so that subsequent review requires simple verification of concurrence. The committee may authorize some of its members to consider the amendments after they are made by the principal researcher. The research may proceed after verification of the required changes and the approval of the appointed reviewer on these modifications in the research plan. If approved, approval is given without waiting for the committee's appointment in the following month, provided that this approval is presented to the next committee.

3. Deferral

The term "deferral" is used to describe the situation in which the MREC determines that substantive changes must be made before approval may be granted. The investigator's response, including any amended materials, must be reviewed by the convened MREC.

4. Disapproved

The project as proposed is disapproved and may not go forward. Disapproval usually indicates that a proposal requires major changes not likely to be feasible without a complete reassessment of the protocol by the investigator and/or sponsor.

5. Suspension and termination of research study

The convened MREC may suspend a study at any time if it is determined that the study requires further review or evaluation. This determination may be made due to an adverse event, noncompliance or other danger to human subjects. Once a study has been suspended, the convened MREC should review the study and either requires changes to the protocol, allow the study to restart, or terminate the study.

Though the chair may suspend a study, only the convened MREC can make the decision to terminate a study.

6. Appeal of MREC decisions

Investigators may appeal the MREC's decisions. At the discretion of the chair, the investigator may make such an appeal in writing to the MREC. At the MREC's discretion, the investigator may be invited to the MREC meeting at which his or her appeal will be considered.

10. MREC Meeting Minutes

The Secretary of the MREC will be responsible for taking the minutes of the meeting. At each meeting, a committee member will take notes and review the minutes to ensure accuracy and completeness. The minutes of the meeting must include all the details to show the following:

- Date and time the meeting started and ended
- Names of attending members
- Names of absent members
- Names of the consultant's present
- Names of investigators present
- Names of the guests attending
- Actions taken by the MREC at a convened meeting as well as the vote on these actions including the number of members voting for, against, and abstaining, and (if applicable) notation that any members with a conflict of interest (identified by name) were excused and were absent for the discussion and vote.
- The basis for requiring changes in or disapproving research
- For each protocol in which changes are stipulated by the MREC, a determination of whether the changes represent minor modifications that do not require verification by the convened IRB, or whether they are significant, requiring convened IRB review; and, a written summary of the discussion of controversial issues and their resolution.
- The results and decisions of the MREC, which include the following:

1. Determine the level of risk to humans in the research study ((minimal risk, greater than minimal risk, or extreme risk)) and follow-up periods will be determined according to the specific risk level
2. Justification for waiving or changing informed consent, as well as justification for waiving the requirement for written documentation of consent
3. Justification for consenting to research involving children
4. Justification for approval of planned research under emergency circumstances
5. Special protection justified in certain specific research schemes for groups of people who are likely to be more vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons

11. Communication of Decisions

- A decision of the MREC shall be communicated to the investigator in writing within three days of the meeting.
- Each decision shall include:

i. A clear statement of the decision reached and the justifications for any rejection
ii. In cases of conditional approval, a list of conditions necessary for approval and the justifications associated
iii. In cases of a positive decision, a statement of the researcher's responsibilities (e.g. providing progress reports, need for notification in cases of any modifications to the research plan, changes in inclusion or exclusion methods, changes to the informed consent form, reporting any unexpected adverse events or unexpected problems) expected or completion of studies)

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English Standard Operating Procedures		Revision Number	01
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12. Investigators' Responsibilities during Conduct of the Study

During the conduct of the study, the investigator shall submit within a specified period of time (to be determined for each category) the following:

a. Any amendments to the research plan, such as the title of the study, the work plan, or any part of the study protocol, and the reasons for this amendment, knowing that the Ethics Committee must be notified in advance to obtain approval for any amendment before starting to implement it, with explicit approval of those amendments.
b. Sending a periodic report (at least annually or as notified) to the Ethics Committee, including what was done in the study and any expected or unexpected complications or side effects.
c. Serious and unexpected adverse events
d. Safety reports and safety monitoring board (if applicable)
e. Any unexpected problems
f. Termination of the study

13. Dealing with deviations

- In the event of deviation from the study protocol, the principal investigator must notify the committee of the reasons for this deviation and the measures taken to prevent such deviation in the future.
- If the committee discovers this deviation, a letter will be sent via e-mail to the principal investigator within two working days. If the Ethics Committee does not receive a response from the principal investigator within five working days, another e-mail will be sent after five working days. To remind the researcher of the need to send the reasons for deviating from the study protocol.
- In the event of no response within five working days, the study will be suspended and an official letter will be sent to the principal investigator, the official sponsor of the study, the place where the study was conducted, the Supreme Council of Clinical Research Ethics, and the Egyptian Drug Authority (in the case of clinical trials).

14. Dealing with research misconduct

In the event that the committee discovers or receives information about research misconduct from the research team

- The committee will send a letter to the principal investigator within 48 hours requesting a response to these allegations, while suspending the study temporarily until the response arrives, which must be within five working days.
- The committee may request a personal meeting with the principal investigator in the meantime, based on the seriousness of the allegations
- In the event that the committee does not receive a convincing response not to violate proper research conduct, the committee will stop the study completely and send a letter to this effect to each of the principal investigator, the research sponsor, the Egyptian Medicine Authority, and the Supreme Council for Review of Ethics in Clinical Medical Research, along with sending all documents and a decision. The committee refers to Professor Dr., Vice President of the Center for Research Affairs, to take what he deems appropriate

15. The Appeal

The researcher may file an appeal against the committee's decision in writing, via e-mail, or the committee's official website, explaining in it the title of the research and the reasons for the appeal, along with all documents or data that were not attached to the first application upon which the decision was taken in. This should be within sixty days from the date he was notified by the decision, and a response will be made within a maximum of sixty days from the date he/ she submits the appeal

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16. Keeping paper and digital documents

The principal researcher submits paper documents to the committee in addition to digital documents through electronic submission or through digital disks or digital memory (CD/flash memory). These paper documents are kept in the committee's secretariat for a period of five years from the date of the document's arrival. Then these paper documents are destroyed after making a report of the execution of the document and signing it from the president, the vice president, the committee rapporteur, the oldest member of the committee, and the legal member of the committee. The execution document is kept for 25 years from the date of its signing. The execution document contains a statement of the documents that have been executed, including in detail the title of the research plan in Arabic and English, the date of its submission, the name of the principal investigator, the result of the presentation to the committee, and the final approval number. As for digital documents, they should never be destroyed, and all files must be backed up from the committee's computer to an external hard disk every five years and kept in a safe place.

Head of Medical Research Ethics Committee