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Medical Research Ethics Committee
Standard Operating Procedures

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Medical Research Ethics Committee
Standard Operating Procedures

A. Introduction

The Medical Research Ethics Committee (MREC) of the National Research Centre (NRC) is committed to high quality research on all aspects of the health and behavior of people and such research is only possible through the participation of humans or animals as subjects in research.

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).

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.

B. 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.

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

Vision

MREC vision is to be the best Medical Research Ethics Committee model in the Middle East Region and Africa and internationally in conducting research and offering professional services

The committee is to be one of the leaders in evaluating the ethical conduct of researches locally, regionally and internationally

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.
- 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

- Our MREC believes in working through a Teamwork manner, Confidentiality, Problem Solving, Fairness, Integrity, Justice, non-Prejudice, Secrecy, Equality, Transparency, Responsiveness to the protection of human subjects and animal rights and Independency.

Goals

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

- Protection of human subjects involved in research clinical trials and animal subjects involved in pre-clinical trials.
- Providing ongoing lifelong refresher training of the MREC members to keep their standards competent and expert.
- Raise awareness of the community about research and the human rights in participating in the clinical trials and animal welfare in pre-clinical trials.
- Orientation of young investigators about the standards of writing, conducting and ethical review of the protocols

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- Serving as a facilitator and resource to researchers
- Valuing different types of research, including experiential and clinical trials.
- Promote collaborations with international research agencies

D. Objectives:

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

The MREC will advise investigators in designing research projects in a manner to minimize potential harm to human subjects, and protect the animal welfare review all planned research involving human or animal subjects prior to initiation of the research, approve research that meets established criteria for protection of human subjects, and monitor approved research to ascertain that human subjects are indeed protected.

All human or animal subjects research carried out at NRC must be reviewed and approved or determined exempt by the MREC prior to the involvement of human or animal subjects in research.

Accordingly, the MREC has the responsibilities and authority of:

- Reviewing and approving, requiring modifications in (to secure approval), or disapprove initial and continuing reviews of all research activities;
- The authority to suspend or terminate approval of research that is not being conducted in accordance with the MREC's requirements or that has been associated with unexpected serious harm to subjects.
- The MREC will report to the Vice president of the NRC any unanticipated problems involving risks to subjects and others or serious or continuing noncompliance by investigators.

2. 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.

3. Conduct continuous medical educational (CME) training program to our MREC members to keep them updated by the new controversial ethical research issues which will definitely add to their experience and performance.

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

5. 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 the controversial research ethical issues.

6. 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.

7. Establish the regulatory framework for animal-based research protocol ethical review.

8. We are looking to become a paperless committee with the sustainable development goals of Egypt

E. Constitution of the MREC

The MREC will be constituted to ensure
a) Competent review of the ethical aspects of the research
b) Independence from influences that could affect the performance of unbiased reviews.

1. Chairperson

a. *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 independence of the MREC from institutional influence.

Subsequent appointment of Chairperson: The MREC nominates one of its members to be the chairperson of the committee

b. Qualifications of the chairperson:

The chairperson shall have the following qualifications:

i. Medical Doctor
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 and animal subjects in research

c. 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 by the President of the NRC. The chairperson shall not serve for more than two consecutive four -year terms.

2. **Vice-Chairperson:** The chairperson will choose a vice-chairperson to help him or her in carrying out his or her responsibilities. The vice-chair will carry out the chairperson duties in his/her absence upon written permission from the chairperson.

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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) 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. It is generally accepted that a minimum of nine persons is required to compose a quorum. There is no specific recommendation for a widely acceptable maximum number of persons, but it should be kept in mind that too large committee will make it difficult in reaching 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, so the number is greater than 21 members 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 agreement regarding meeting deliberations, information on research subjects and other related matters
vi. The non-affiliated community representative is exempted from having a College degree to ensure proper representation of a large sector of the community who might not have such qualification.
vii. For reviewing animal research a veterinary consultant is an asset.

d. Conditions of Appointment: Each member shall:

i. Agree to meet all education and training requirements
ii. Sign a confidentiality agreement regarding meeting deliberations, and information on research subjects.

e. Appointment Process

i. Initial Constitution of the MREC

An initial core group of members shall be selected directly by the president of the NRC who mandated the establishment of the MREC. The core committee will identify, interview, and then choose, by consensus the subsequent members of the committee.

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ii. Subsequent appointment of members

The MREC will identify prospective members and review with them the nature and demands of serving on the MREC. If the member is willing to service, then the chair and vice-chair shall seek approval from the relevant head of the department from which the prospective is a member. Upon approval, the full MREC will, by consensus, approve the selection of the prospective member.

iii. Conflicts of interest should be avoided when appointments are made, but if unavoidable, here should be transparency and management of the conflict of interest with regard to such interests on a case by case basis.

f. Terms of Appointment

i. Duration:

Each member shall be appointed for a cycle of 3 years in duration.

ii. Renewal:

At the end of each cycle of appointment, members wishing to stay on should make a written request to the chairperson. Subsequent renewal will depend on prior quality of work and attendance performance and be determined by a consensus of the full committee.

iii. Resignation:

Members wishing to terminate their appointment prior to the 4 year cycle shall send a written letter of resignation to the chairperson two months in advance in order to have enough time to appoint a another member.

iv. 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 meetings
2. Negligence in reviewing protocols
3. Breach of confidentiality agreement
4. Termination shall be decided by a majority vote of the full MREC.

g. Orientation and training of MREC members:

I. Initial Education:

Following appointment the new member will go through the MREC orientation, which consists of an introductory lecture followed by an informational session on practical matters with the MREC chair. Subsequent education may include workshop in research ethics and/ or completion of a training website in research ethics.

II. Continuing education:

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.)

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h. Conflicts of Interest:
MREC will not have a member participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the MREC. Examples of such conflicts of interest could include: a member of the MREC who serves as an investigator on research under consideration by that MREC; or a member who holds a significant financial interest in a sponsor or product under study.

i. Confidentiality:
Service on the MREC includes the review of documents that contain personal, confidential and proprietary information. Members of the MREC are responsible for maintaining all committee documents and proceedings in strict confidence. Such information may not be used for any purpose other than the MREC review and may not be disclosed to anyone outside of the MREC unless permission is granted in writing from the MREC Chair.

4. Independent Consultants
The MREC may, at the discretion of the chair or its members, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the MREC. These individuals may not vote with the MREC. These consultants are not included in determining or establishing a quorum at the meetings but, the meeting minutes will reflect their presence A confidentiality and non-conflict of interest document must be signed before attending the discussions. Invitations are addressed to them officially by sending an e-mail or a letter signed by the head of the committee, and a telephone call is permissible, but this must be recorded in the minutes of the meeting
.

5. Meeting Frequency

The MREC will meet at regular time intervals physically and/or virtually in accordance to the needs of the workloads, but generally it should meet at least once a month on a regularly scheduled day. In certain circumstances, MREC can meet on an “as needed” basis. Scheduled meetings may be cancelled by the chair due to a) insufficient number of applications requiring review at a convened meeting, b) inability to secure a quorum for attendance, or c) other reasons as may arise that make a scheduled meeting unnecessary or otherwise inappropriate.

6. Quorum Requirements

a. The number required to compose a meeting will be half of the members plus one.
b. No quorum will consist entirely of members of one profession (e.g., medicine)
c. Virtual meeting will be accepted as physical attendance under the discretion of the chair or in special circumstances.

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F. MREC Research Review Evaluations Procedures, Criteria and Actions

The MREC is charged with the responsibility for reviewing and monitoring human and animal subject research conducted under the mandate of NRC. Therefore, the first question with respect to MREC review of a project is a determination of whether the project fits the definition of research.

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.

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 which 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.

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)."

4. Submission of Applications for New Studies

a. Persons Submitting: An application for review of the ethics of a proposed research project shall be submitted by the principal investigator of the research or his/ her legal representative

b. Materials Submitted: Each application should consist of the following:

- A signed and dated application form (developed by the MREC)
- Full protocol
- Consent form (in human subjects research) and animal welfare report (in animal research)
- 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.

If the application is incomplete or not fully prepared for review, it is returned to the investigator or a request is made for necessary changes or to provide additional information.

c. Deadlines

i. Submission: The deadline for submission will be at least 21 days prior to the meeting at which the protocol will be reviewed by the MREC.

ii. Investigator notification: investigators will be notified of an MREC decision within 72 hours after a decision has been reached.

5. Review of Applications of New Studies

The NRC MREC will use a primary and secondary reviewer system in which two 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.

a. Member review:

1. A member will be selected to be the primary reviewer of the protocol and will be responsible for:
   a. Completing the primary reviewer form
   b. Presenting the protocol for discussion at the meeting
2. All members shall receive protocols for review at least 1 week prior to the review meeting
3. All members are required to review all submitted materials and be prepared to discuss all protocols at the convened meeting.

b. MREC Evaluation Criteria: The MREC will assess the following review 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.

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- **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 in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- **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 to ensure the confidentiality of data obtained from the subjects.
- **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 safety of research subjects; and the determination of whether a Data Safety Monitoring Board (DSMB) is required.
- **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 (see checklist).
- **Vertebrate animal's research:** any research use vertebrate animal as research subject must submits animal welfare report include the following :
  - 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.
  - 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.
  - 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.
  - All reasonable steps should be taken to avoid or minimize discomfort, distress or pain of animals.
  - 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.
  - 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.

- Investigators and other personnel shall be qualified and trained appropriately for conducting procedures on living animals, including training in the proper and humane care and use of laboratory animals.
- Euthanasia shall be conducted according to the most current guidelines on Euthanasia

- **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 in NRC and in the country of the sponsor shall have responsibility for conducting both scientific and ethical review, 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:

- determine whether the objectives of the research are responsive to the health needs and priorities of Egypt to avoid exploitation of underprivileged communities
- 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.
- Should determine whether the research plan conflicts with the involved community's customs and traditions.

c. Expedited Review

- Certain minimal risk protocols may receive expedited review by the chairperson. All expedited decisions shall be communicated to the next convened meeting of the MREC. The MREC shall establish criteria by which protocols can be reviewed by such an expedited procedure.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

6. Voting and Decision making

a. 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.

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

c. Decisions should be arrived at 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.

d. 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 prior to the meeting if they have a conflict of interest related to a specific protocol slated for review at the meeting, and every effort should be made to ensure

e. Types of decisions allowed:

Approval: Approval of research In the case of an approval with no changes, the research may proceed once the PI receives written documentation of MREC approval.

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 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 clearly delineated at the convened meeting so that subsequent review requires simple verification of concurrence. The research may proceed after the required changes are verified and the designated reviewer approves the protocol.

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.

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.

Suspension and termination of research study by MREC: The chair of the MREC or 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.

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f. 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.

g. Each protocol will be assigned a risk level (minimal risk, greater than minimal risk, or too risky (in the latter case, the protocol will be disapproved) and the follow-up intervals will be determined according to the level of risk of the protocol. In general, duration of approval will be a maximum of one year.

h. MREC Meeting Minutes should be in sufficient detail to show the following:

Attendance at the meetings:

- Date and time meeting starts and ends
- Names of members present
- Names of members absent
- Names of alternates attending in lieu of specified absent members
- Names of consultants present
- Names of investigators present
- Names of guests present

Actions taken by the MREC

- 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.

MREC findings and determinations

The following are required findings and determinations, and must be noted in the minutes with reference to the appropriate national and local regulations:

- Determination of the level of risk for human subjects in the research study

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- Justification for waiver or alteration of informed consent
- Justification for the waiver of the requirement for written documentation of consent
- Justification for approval of research involving children
- Justification for approval of research planned for an emergency setting
- Special protections warranted in specific research projects for groups of subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons.

The secretary of the MREC will be responsible for taking the minutes of the meeting. At each meeting, one member of the committee will take notes and review the minutes to ensure accuracy and completeness.

7. Communication of Decisions

a. A decision of the MREC shall be communicated to the investigator in writing within three days of the meeting.

b. Each decision shall include:

- A clear statement of the decision reached,
- Justifications of any disapproval
- In cases of conditional approval, a list of the conditions needed for approval and its associated justifications
- In cases of a positive decision, a statement of the responsibilities of the investigator (e.g., confirmation of the acceptance of any requirements imposed by the MREC, submission of progress reports, the need to notify the MREC in cases of protocol amendments, changes to recruitment materials, changes to the consent form, and the reporting of any unexpected adverse events or unanticipated problems or termination of the study).
- The date and place of the decision
- Any advice given by the MREC
- Signature of the chairperson

8. 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. Amendments to the protocol
b. Serious and unexpected adverse events
c. Safety reports (if applicable)
d. Reports of any Data and Safety Monitoring Board
e. Unanticipated problems
f. Termination of the study

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The MREC will determine which of the above can be reviewed by an expedited procedure and which requires full committee review

9. Continuing Review

a. Submission: At the time of continuing review, the investigator shall submit the following information for review:

- Enrollment of subjects: gender and age
- Number of subjects withdrawn and reasons for such withdrawal
- Adverse events (Cumulative and type for the previous period since the last review)
- Modifications to the protocol
- Changes of investigators
- Results, if available
- Current informed consent form
- MREC should determine which continuing reviews can be reviewed by an expedited process and which continuing protocols require full committee review.

b. Lapsed studies: A lapsed study is one for which the approval period has expired prior to the renewal of approval by the MREC. If the investigator fails to submit the materials for continuing review prior to the MREC meeting that needs to review the study before the expiration date, then the lapsed study will be classified as inactive. Once a study has lapsed notification should be sent to the investigator ordering that all study-related measures must immediately cease except those necessary for welfare of the human subjects. If the investigator desires to continue a study that has lapsed for more than one month, then the investigator must submit a new application for re-review by the MREC, and must wait for MREC approval before resuming research under the protocol.

G. Waiver of Informed Consent

The MREC may approve a consent procedure, that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the MREC finds and documents that:

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the waiver or alteration

Alternatively, the MREC may waive the requirement for informed consent involving research in the emergency setting.

H. Waiver of written consent

The MREC may waive the requirement for the investigator to obtain a signed consent form...

Such a waiver is allowable if: • The consent document is the only link between the subject and the research and the principal risk of harm would come from a breach of confidentiality. • The research presents no more than a minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context.

The Appeal

The researcher may file an appeal against the committee's decision in writing, via e-mail, or the committee's official website when it is completed, 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 learns of the decision, and a response will be made within a maximum of sixty days from the date he submits the appeal

Keeping paper and digital documents

The principal investigator submits paper documents to the committee in addition to digital documents through electronic submission or through disks. These paper documents are kept in the committee's secretariat for five years from digital (CD/flash memory) or digital memory.

The date the document arrives, then these paper documents are destroyed after making a document execution report and signing it from both the president and the deputy. The chairman, 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 signing.

The execution document contains a statement of the documents that were executed, detailing the title of the research plan in Arabic and English. The date of submission, the name of the principal investigator, the result of the decision of the committee, and the final approval number. All files are transferred from the committee's computer to "Back up." As for digital documents, they are never destroyed, and backup must be done on an external hard or compact discs every five years and keep it in a safe place.

Osama Mahmoud Azmy