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Enhancing Research Ethics Committees in Egypt

Guidelines for Standard Operating Procedures

Standard Operating Procedures (SOPs) describe the policy and procedures that guide Research Ethics Committees (RECs) and . . . serve to enhance the consistency and efficiency of the RECs' ethical review of biomedical research.

Several international guidelines have developed the ethical and scientific standards for carrying out biomedical research involving human subjects.^{1,2,3,4} Compliance with these guidelines helps to ensure the dignity, rights, safety, and well-being of subjects who participate in research. These guidelines also require that an independent ethics review committee perform an ethical and scientific review of biomedical research. Such review committees are commonly called Research Ethics Committees (RECs) or Institutional Review Boards (IRBs). Review of research by an independent committee ensures that the review process is performed free from political, institutional, professional, and market influences. Several countries have developed regulations that require the existence of RECs to ensure the protection of the rights and welfare of subjects who participate in research.^{2,5} Despite the absence of national regulations addressing the need for RECs, these committees have existed in Egypt for several years.

Recently, the World Health Organization (WHO) issued guidelines for the establishment of standard operational procedures (SOPs) for RECs.⁶ SOPs describe the policy and procedures that guide RECs and ensure transparency of how they operate to both the members of their institution and the public. SOPs also serve to enhance the consistency and efficiency of the RECs' ethical review of biomedical research.

At the time of the development of the current project, none of the RECs in Egypt had written SOPs. Guidelines for SOPs would assist individual Egyptian RECs in writing their own SOPs and ensure consistency between existing and future RECs in Egypt. Additionally, SOPs need to be established in accordance with applicable local laws and regulations as well as the customs and cultural traditions of countries in which RECs review research. Accordingly, our aim was to develop model guidelines for SOPs that are relevant to Egypt, which

Due to space limitations and in order to provide access to these documents, the Appendixes are being provided as part of the online version of the December 2006 Monitor. To access the online issue, go to www.acrpnet.org, log on as a member, and click on the link to the December 2006 issue.

could then be further adapted to the local context—that is, institution and community.

Methods

The working group to develop the SOPs consisted of candidates and faculty participating in the two-month Health Research Ethics Training Initiative in Egypt (HRETIE) research ethics certificate course held at the University of Maryland School of Medicine in Baltimore, Md.⁷ Individuals from Egypt consisted of eight physicians and two nurses, representing different sectors of the healthcare profession and institutes in Egypt: the Ministry of Health (S. Hammouda, M. Hassan), the Egyptian Medical Syndicate (R. Afifi), Cairo University (S. Lashin), Ain Shams University (M. El-Setouhy), Alexandria University (H. Kassem), Mansoura University (N. Kandeel, A. El-Nemer), Suez Canal University (N. Moustafa), and the American Navy Medical Research Unit (I. Nakhla).

At the start of the certificate course, the candidates were divided into two working groups representing simulated RECs. Their first task was to develop SOPs for their respective simulated RECs, adapted to existing laws and customs in Egypt. Using the WHO guidelines as a baseline, the working groups provided further specification for many of the WHO statements to develop their respective SOPs. They modified the WHO guidelines when necessary to ensure relevance to the conditions in Egypt. The participants and faculty discussed both sets of SOPs at a general session and subsequently combined them into one document. After the course, the consensus process continued over the next three months through informal e-mail discussions to develop the final model SOPs and associated forms.

Recommendations

The HRETIE Model SOPs are shown in **Appendix I**, and **Appendixes II–VI** show the forms:

- Investigator Submission Form (App. II)
- REC Protocol Review Form (App. III)
- Informed Consent Checklist (App. IV)
- Conflict of Interest Disclosure Statement (App. V)
- Statement of Confidentiality (App. VI)

An important element of the SOPs is a statement of the authority under which an REC is established. To ensure that their decisions are authoritative, RECs must receive a mandate from a high-ranking institutional official (e.g., Dean, President, or Minister of Health). In addition, the SOPs should state their authority to review, make decisions (including approval and disapproval) regarding the acceptability of the research, and monitor the ongoing research activities.

Independence and competence are the two hallmarks of an REC. Hence, RECs should be multidisciplinary and multisectorial in composition. Members need to be independent from political, institutional, professional, and market influences, and they must demonstrate competence and efficiency in their work.

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Guidelines on the qualifications, appointment process, duties, and terms of appointment for the chair, vice chair, and members need to be explicit. As a general rule, high institutional officials (e.g., Dean, President, etc.), should not be included as members of the REC to ensure the committee's political and institutional independence. There also need to be statements regarding member orientation and education, as well as information regarding the definition and management of potential conflicts of interest.

The SOPs should define the REC's review and evaluation process, including information regarding the frequency of the meetings, quorum requirements, guidelines to investigators concerning submission of applications for initial and continuing reviews, the criteria the REC will use to review and evaluate research, the mechanism for decision making, the types of decisions to be rendered, the method for communicating decisions to investigators, and the opportunity for appeals by investigators. The REC should also define investigator obligations regarding submission of reports, such as adverse events, protocol changes, unanticipated problems, and safety reports. Finally, the REC must define its record-keeping process and documentation methods.

The model SOPs provide further specifications of the WHO guidelines rather than a mere reiteration of the guidelines. These specifications take into consideration the conditions existing in the Egyptian legal, academic, and community environments. For example, the model SOPs state specifically the persons (Dean, President, etc.) under whose authority the REC was established (App. I, B.1). Regarding the constitution of the REC, the model SOPs specify the appointment process and qualifications of the chairperson (App. I, D.1a,b,c) and recommend that high-ranking officials not be members to ensure independence of the REC from institutional influences.

The model SOPs also specify the appointment process and qualifications of the REC members. With the exception of the initial appointment process, high-ranking officials are not involved with the appointment of subsequent REC members and should have no authority regarding disqualification of existing members. The SOPs specify that a consensus process be used to appoint members rather than direct appointment. Such recommendations ensure independence from institutional influence.

Other specifications include the following:

- the different levels of risk assigned to a protocol and the requirement that protocols assigned a level of risk that is “too risky” should be disapproved (App. I, E.4b)
- documentation of the informed consent process (App. I, E.4b)
- the REC responsibilities regarding externally sponsored research (App. I, E.4b)
- types of REC decisions allowed (App. I, E.5e)
- recommendations for short-form consent procedures (App. I, G)

Several specifications reflect exigencies influenced by conditions in Egypt. For example, the WHO guidelines state that a quorum should include at least one member whose primary area of expertise is in a nonscientific area and at least one member who is independent of the institution/research site. The HRETIE working group decided that a quorum requirement including both members might be difficult in a country in which RECs are a relatively new phenomenon. Hence, the model SOP requirements for a quorum include the presence only of one member who is not affiliated with the institution.

Another specification inspired by the Egyptian environment involved requiring that the REC consider the assessment of the study design by a separate research committee, if one exists in the institution. Many Egyptian institutions have separate research committees, and the HRETIE working group thought that the REC should work with them for efficiency and political reasons.

Finally, the SOPs specify that there be a mix of junior and senior members on the REC, because there is a tendency in Egypt that only senior members serve on important committees.

To enhance the efficiency of the application and review process of new protocols, we have included examples of an investigator submission form, an REC protocol review form, and an informed consent checklist (Appendixes II, III, and IV). The completion of the REC protocol

review form ensures that all of the essential items in the review process have been considered. This form also contains elements that are specifically relevant to research sponsored by external sponsors (items # 2, 6, and 22). The completion of an informed consent checklist ensures that the informed consent forms include the necessary elements of informed consent; research ethics committees have a tendency to omit some of these elements.⁸

Discussion

We have developed model SOPs for RECs in Egypt. Participants also developed several forms (see Appendixes II-VI) that can help the administrative and review aspects of RECs. The development of SOPs for RECs represents an important administrative process that can contribute to the transparency, independence, quality, consistency, and efficiency of the ethical review of research. We expect that these guidelines for SOPs will be helpful for RECs in Egypt as well as in other developing countries.

The development of SOPs for RECs represents an important administrative process that can contribute to the transparency, independence, quality, consistency, and efficiency of the ethical review of research.

The importance of having written SOPs is witnessed by the many guidelines that have mentioned their value, the frequent development of such documents in other countries, and the announcement of conferences on devel-

oping SOPs during the last several years in different parts of the world.^{9,10,11} All of these events represent a global phenomenon regarding the importance of SOPs.

The model SOPs clearly define the role and authority of RECs regarding the protection of the rights and welfare of research subjects. The SOPs make transparent the authority of the RECs and their review mechanism. Such transparency ensures the development of trust between RECs, the research staff, and the community they serve. Written SOPs also enhance the likelihood that the RECs will be consistent in their procedures and be free from personal bias in their review process. In addition, for a developing country like Egypt, the SOPs help to clarify the function of RECs regarding their role in the protection of Egyptian citizens against exploitation in collaborative international research funded by external sponsors.

Because the HRETIE model SOPs do not represent the mere reiteration of the WHO guidelines, they reflect the conditions existing in the legal, academic, and social fabric of Egyptian society. Other developing countries might find several aspects of these SOPs to be relevant to their research environment as well.

A frequent concern of investigators is the perceived administrative shortcomings of having another committee review their research, which can lead to delays in the start of research and increase the administrative burdens for investigators. The associated investigator submission and REC protocol review forms should improve the efficiency of the RECs as well as enhance the protection of the rights and welfare of the research subjects.

A potential shortcoming of the model SOPs is that they were developed by a small group of individuals that might not have been representative of those who constitute the many different RECs existing in different parts of the country. However, they should serve as a template for individual RECs as they begin to write their own SOPs. The final SOPs

should be adapted to the institutional and community context in which the REC exists. Hence, RECs in Egypt are urged to use these model SOPs, but also to focus on the sections that need to be sensitive to the local context. Feedback from existing RECs in Egypt on the relevancy of these SOPs would help refine further iterations of this first attempt to develop model SOPs.

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A P P E N D I X I

Research Ethics Committee Standard Operating Procedures

Italic text in brackets [] indicate instructions to the reader.

A. Introduction

The *[state name of Faculty or Institution]* is committed to high-quality research on all aspects of the health and behavior of people, and such research is possible only through the participation of humans 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 and *[state other document(s) if relevant]*. These principles 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.

B. Assurances

The *[state Dean or President or other high-ranking official]* will oversee the research practices in the *[state Faculty or Institute]* and assures that these practices will conform to the principles of research ethics. Part of this assurance includes the establishment of an appropriately constituted Research Ethics Committee (REC), which shall have the responsibility to review and monitor research involving human subjects.

C. REC Mission and Authority

1. Scope and Purpose

The purpose of the REC is to protect the rights, safety, and welfare of all research subjects. To achieve this, the REC must advise investigators in designing research projects in a manner to minimize potential harm to human subjects, review all planned research involving human 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.

2. REC Responsibility and Authority

All human subjects research carried out at [state name of Faculty or Institution] must be reviewed and approved or determined exempt by the REC prior to the involvement of human subjects in research.

Accordingly, the REC has the following responsibilities and authority:

- The REC shall review and have authority to approve, require modifications in (to secure approval), or disapprove initial and continuing reviews of all research activities.
- The REC shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the REC's requirements or that has been associated with unexpected serious harm to subjects.
- The REC must report to the [Dean or President] unanticipated problems involving risks to subjects and others or serious or continuing noncompliance by investigators.

D. Constitution of the REC

The REC will be constituted to ensure a) competent review of the ethical aspects of the research and b) independence from influences that could affect the performance of unbiased reviews.

1. Chairperson

a. Appointment: The chairperson will be appointed directly by the [Dean or President or other high-ranking official of the Faculty or the Institute, neither of which should be involved in the committee to ensure independence of the REC from institutional influence].

[Alternatively, to ensure more independence, the chairperson could be elected by the Faculty Council or by an initial core group of a committee (members with experience in research ethics) who were appointed by a high-ranking institutional official.]

b. Qualifications of the chair: The chairperson shall have the following qualifications:

- i. A professor on the academic staff (if in a university)
- 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 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 reappointment by the [Dean of the Faculty or the President of the Institution]. The chairperson shall not serve for more than two consecutive three-year terms. [To ensure more independence, the chairperson's appointment could be renewed by a Faculty Council.]

d. Responsibilities: The chairperson shall be responsible for the actions of the REC, including the scheduling of regular meetings and communications between the REC, members of the research staff, and institutional officials. It is expected that the chairperson will preside over more than three-quarters of the convened meetings of the REC.

e. 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.

2. Members of the RECs

a. Members: Members of the RECs will reflect a multidisciplinary and multisectorial 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, and a mix of medical, scientific, and nonscientific persons including nonaffiliated lay representatives (e.g.,

lawyer, journalist) to reflect the different viewpoints of the community.

b. Numbers: The number of persons in the REC should be kept fairly small, between seven and 11 members. It is generally accepted that a minimum of five 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 a REC will make it difficult in reaching consensus. Hence, 12-15 is the maximum recommended number.

c. Qualifications: Members will include the following:

- i. holding at least a college degree
- ii. the nonaffiliated 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
- iii. have an interest in research issues and research ethics
- iv. be reputable and trustworthy
- v. be willing to volunteer their time and effort
- vi. be willing to sign a confidentiality agreement regarding meeting deliberations, applications, information on research subjects, and other related matters

d. Conditions of Appointment: Each member shall:

- i. agree to meet all education and training requirements
- ii. sign a confidentiality agreement regarding meeting deliberations, applications, and information on research subjects

e. Appointment Process

- i. Initial constitution of the REC: An initial core group of members shall be selected directly by [Dean, President, or Faculty Council]. This core committee will identify, interview, and then choose by consensus the

subsequent members of the committee.

- ii. Appointment of subsequent members: The REC will identify prospective members and review with them the nature and demands of serving on the REC. If the member is willing to serve, then the chair and vice-chair shall seek approval from a governing body of the department or faculty (e.g., faculty council). Upon approval, the full REC will, by consensus, approve the selection of the prospective member.
- iii. Conflicts of interest should be avoided when appointments are made, but if unavoidable, there 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 three 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 three-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 REC by a written letter from the chairperson if any of the following occurs:
 - 1) Failure to attend three consecutive meetings without permission or more than half of the meetings per year
 - 2) Negligence in reviewing protocols
 - 3) Breach of confidentiality agreement

- 4) Termination shall be decided by a majority vote of the full REC.

g. Orientation and Training of IRB Members:

Initial Education: Following appointment the new member will go through the REC orientation, which consists of an introductory lecture followed by an informational session on practical matters with the REC chair. Subsequent education may take one of the following types:

- i. Previously held workshop (of at least two days duration) in research ethics
- ii. Successful completion of a Web site training course in research ethics.

Continuing education: An REC should set standards for continuing education of its members every three years (e.g., regularly scheduled review of published articles in research ethics, attendance at workshops, lectures, seminars, etc.).

h. Conflicts of Interest: No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

Examples of such conflicts of interest could include: a member of the IRB who serves as an investigator on research under consideration by that IRB; or a member who holds a significant financial interest in a sponsor or product under study.

3. Independent Consultants

The REC 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 REC. These individuals may not vote with the REC. Consultants are not included in determining or establishing a quorum at the meetings. REC

meeting minutes reflect the presence of consultants.

E. REC Research Review Evaluations Procedures, Criteria, and Actions

The REC is charged with the responsibility for reviewing and monitoring human subject research conducted under the mandate of *[name of Faculty or Institution]*. Therefore, the first question with respect to REC review of a project is a determination of whether the project fits the definition of research.

a. Is It 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 should be a systematic design 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, which includes experiments, observational studies, surveys, tests, and recordings.

b. Does It Involve Human Subjects? A human subject is defined as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) 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” (such as a public restroom) “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 healthcare 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.

1. Meeting Frequency

The REC will meet at regular time intervals in accordance with the needs of the workloads. Generally the REC should meet at least once a month on a regularly scheduled day (for example, every two weeks, every month, etc.). In certain circumstances, RECs can meet on an “as needed” basis.

Scheduled meetings may be cancelled by the chair due to a) an 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.

2. Quorum Requirements

a. The number required to compose a meeting will be half of the members with a minimum of five.

b. No quorum will consist entirely of members of one profession (e.g., medicine) or gender.

c. A quorum will include at least one member who is non-affiliated with the institution.

3. Submission of Applications for New Studies

a. Persons Submitting: The principal investigator should submit an application for review of the ethics of a proposed research project.

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

- A signed and dated application form (developed by the REC)
- Full protocol
- Consent form
- Product brochure for new drug/device
- Time plan for the study
- CVs for the principal and co-investigators

- Copies of actual questionnaires to be used in the study
- Copies of materials to be used (e.g., advertisements) for the recruitment of potential 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 otherwise not fully prepared for review, the REC shall return it to the investigator with a request for necessary changes and additional information.

c. Deadlines:

- i. Submission: The deadline for submission will be at least 15 days prior to the date of the meeting review.
- ii. Investigator notification: Investigators will be notified of an REC decision within 48 hours after a decision has been reached.

4. Review of Applications of New Studies

[An REC may elect to use a primary reviewer system in which one or more members are assigned to lead the review and present the protocol for discussion at the convened meeting. Alternatively, all REC members are 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 one week prior to the review meeting
3. All members are required to review all submitted materials and be pre-

pared to discuss all protocols at the convened meeting.

b. REC Evaluation Criteria: The REC will assess the following review criteria:

- Acceptable Social Value to the community/country.
- Scientific Design: The REC will consider the assessment of scientific design as determined by a separate Research Committee. The REC will consider elements of scientific design, related to ethical issues, 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. Selection of subjects is one important means of ensuring that the burdens and benefits of research are distributed equitably. In making this assessment the REC 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 REC will determine the appropriateness of additional safeguards to provide added protection to vulnerable populations.
- Analysis of Risks and Benefits: The REC 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 unnecessar-

ily 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 direct benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result from the research project. Each protocol will be assigned a risk level (minimal risk, greater than minimal risk, or too risky (in the last case, the protocol will be disapproved).

- Privacy of Subjects and Confidentiality Procedures to Protect Subjects' Data: The REC 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 REC 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 REC, informed consent must be sought from each prospective subject or the subject's legally authorized representative. The REC shall also:
 - Review the adequacy, completeness, and understandability of written and oral information.
 - Determine whether signed, written informed consent can be waived and the validity of alternative procedures to document the provision of informed consent (e.g., thumbprint or verbal, witnessed consent).
 - Determine whether informed consent could be obtained from

the subject's legally acceptable representative.

- Determine whether the informed consent document contains the required basic elements of consent (see checklist).
- 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 in collaboration with or with the agreement of the appropriate authorities, institutions, and personnel of Egypt. In such externally sponsored research, the REC in [*state the name of the Faculty or Institution*] 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 REC at [*state the name of Faculty or Institution*] 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.
 - 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 REC. The REC 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.

5. Voting and Decision Making

a. Participation: All members who attended the meeting and discussed the protocol 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, without identification by names. 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. Quorum: Decisions should be made at meetings where a quorum is present.

c. Consensus: 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. Conflict of Interest: When an REC member has a conflict of interest (see D.2(h):Member 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, REC 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 transparency by full disclosure of such conflict of interest.

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 REC approval.
- **Approval with minor changes:** The REC 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 REC 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 REC 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 REC.

- **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 REC:** The chair of the REC or the convened REC 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 is suspended, the convened REC should review the study and either require changes to the protocol, allow the study to restart, or terminate the study. Though the chair may suspend a study, only the convened IRB can make the decision to terminate a study.

f. Appeal of REC Decisions: Investigators may appeal the REC’s decisions. At the discretion of the chair, the investigator may make such an appeal in writing to the REC. At the REC’s discretion, the investigator may be invited to the REC meeting at which his or her appeal will be considered.

g. 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. REC Meeting Minutes should be in sufficient detail to show the following:

Attendance at the meeting:

- 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 REC:

- Actions taken by the REC 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 (see 7.4 below);
- For each protocol in which changes are stipulated by the REC, 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.

REC findings and determinations:

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

- Determination of the level of risk for human subjects in the research study (no citation required);
- 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 and other vulnerable groups;
- Justification for approval of research planned for an emergency setting; and
- 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, prison-

ers, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

The secretary of the REC 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.

6. Communication of Decisions

a. A decision of the REC shall be communicated to the investigator in writing within three working 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 is issued (e.g., confirmation of the acceptance of any requirements imposed by the REC, submission of progress reports, the need to notify the REC 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 REC
- Signature of the chairperson

7. 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:

- Amendments to the protocol

- Serious and unexpected adverse events
- Safety reports (if applicable)
- Reports of any Data and Safety Monitoring Board
- Unanticipated problems
- Termination of the study

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

8. 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

RECs 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 REC. If the investigator fails to submit the materials for continuing review prior to the REC 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 REC,

and must wait for REC approval before resuming research under the protocol.

F. Waiver of Informed Consent

The REC 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 REC finds and documents that:

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

Alternatively, the REC may waive the requirement for informed consent involving research in the emergency setting. *[RECs must develop criteria under which informed consent may be waived.]*

G. Short Form Consent Procedures

There may be circumstances when a subject is unable to read the full consent document (e.g., when the subject is illiterate or does not speak the language in which the consent document is written). In such cases, a short form may be used. A short form is a written consent document stating that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation (not a member of the research team). Also, the REC shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

A P P E N D I X II

Investigator Application Form

1. Name of Researcher: _____

2. Name of Institution/Department: _____

3. Address of Researcher: _____

a. e-mail: _____

b. Phone number: _____

c. Fax number: _____

4. Name(s) of Co-Investigator(s) _____

5. Grade of Protocol

MD MS PhD Other

Domestic

Multicentre within Egypt

International

6. Title of the research _____

7. Type of research (check all that apply):

Drug trial:	<input type="checkbox"/>	Survey Study:	<input type="checkbox"/>
Surgical Techniques:	<input type="checkbox"/>	Blood sampling:	<input type="checkbox"/>
Invasive Techniques:	<input type="checkbox"/>	Review of records:	<input type="checkbox"/>
Devise Study:	<input type="checkbox"/>		

8. Subjects of research:

Children (< 18 years)
Adults (≥ 18 years)
Vulnerable groups: Yes: No:

If yes, please describe: _____

9. Request is being made to waive informed consent: Yes: No:

If yes, please explain why: _____

10. The research is for the good of society: Yes: No:

11. Study Design (check all that apply):

a. Phase Type: I: II: III: IV:
b. Randomization: Yes: No:
c. Placebo: Yes: No:
d. Genetic sampling Yes: No:
e. Other _____

12. Facilities for the research are available: Yes: No:

13. List the risks of the study: _____

14. List the potential benefits, if any, to the subjects: _____

15. The risks are reasonable to the potential direct benefits to the subjects, if any, or to the knowledge to be gained: Yes: No:

16. Privacy and confidentiality of subjects are assured Yes: No:

17. It is clearly stated that the subject of the research could quit at anytime without penalty or loss of any benefits to which they would otherwise be entitled: Yes: No:

18. Informed consent form is attached Yes: No:

SIGNATURE OF PRINCIPAL INVESTIGATOR

DATE

APPENDIX III

REC Checklist for Initial Review

Title of Research: _____

Principal Investigator: _____

Primary Reviewer for the REC: _____

	YES	NO	N/A
Social Value			
1. Does the research have the potential to enhance the future health of society?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Has the community been involved with the planning of the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Scientific Design			
3. Has a scientific committee approved the research?	<input type="checkbox"/>	<input type="checkbox"/>	
If No, are the elements of the study design (e.g., hypothesis, objectives, sample size, statistics, etc.) adequate to produce valid results?	<input type="checkbox"/>	<input type="checkbox"/>	
4. Will the research be performed by qualified investigators and at proper facilities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Does the study involve a placebo group, and if so, is there justification for including such a group?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Does the control group adequately represent the local standard of care?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Are the experimental procedures adequately described?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Are there any other scientific issues that need to be addressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Subject Recruitment			
9. Is it clear who will be enrolled as research subjects or whose records will be used in the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	YES	NO	N/A
10. Is the selection of subjects fair and equitable? (Consider purpose, setting, inclusion, and exclusion criteria)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Does the study have the potential for enrolling subjects who might be decisionally impaired?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If Yes, a. will there be proxy consent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. should the investigator assess the capacity of subjects to make their own decisions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Does the study involve any vulnerable groups? (e.g., pregnant women and fetuses, children, prisoners, decisionally impaired, institutionalized, socially or economically disadvantaged individuals, employees, students)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If Yes: a. are additional safeguards needed to protect the rights and welfare of the vulnerable groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. state which ones are needed _____ _____			
13. Does any compensation for participation (e.g., financial, prospects of free medical care, etc.) represent an undue inducement to participate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Does the recruitment setting present any potential for coercion?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Were all recruitment materials submitted? (posters, brochures, contact letters, TV, radio, newspaper ads)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Are the recruitment materials acceptable as submitted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Risk/Benefit Analysis			
Risks			
17. Are there physical or medical risks related to study participation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Are there psychological or emotional risks related to study subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Are there social, economic, or legal risks related to study participation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Are there risks to society in general?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Are risks adequately minimized?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. If not, how can risks be further minimized? _____ _____			
23. What is the risk level of the research?			
<input type="checkbox"/> Minimal Risk <input type="checkbox"/> Above Minimal Risk <input type="checkbox"/> Too Risky			
Benefits			
24. Are there potential direct benefits to individual research subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Are there potential benefits for the future health of society?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Will the community/country benefit from the results of the research after the research is over?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	YES	NO	N/A
27. Have any post-trial agreements been developed with the sponsor/investigators?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Analysis of Risks and Benefits			
28. Are the risks to subjects reasonable in relation to the anticipated benefits to the subjects and/or society?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Confidentiality			
29. Are there adequate safeguards to protect subject privacy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Are there adequate provisions to protect the confidentiality of the data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stored Tissue Samples			
31. Will there be any storage of tissue samples (blood/tissues)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. Will there be any genetic analysis of the stored tissue samples?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. Will a code be used to label the stored tissues? If yes, will the code contain any information that can potentially identify the subject?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. Will subjects have the option to withdraw their samples at any time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. How long will the samples be stored? _____			
36. Based on questions 32-35, are there safeguards to protect the privacy and confidentiality of the stored samples and the information from the stored samples?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. Will any stored samples be shipped out of the country?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Informed Consent			
38. Is the researcher requesting access to records without informed consent? If yes, explain why this is justifiable: _____ _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39. Is the informed consent checklist completed, and is the consent form adequate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40. Is the short consent form needed for individuals who are illiterate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Safety Monitoring			
41. Are there procedures to monitor the safety data (i.e., serious adverse events, reasons for withdrawal/discontinuation) collected to ensure the safety of subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42. Is there a Data and Safety Monitoring Board (DSMB)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43. Are there any planned interim analyses?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Recommendation

Approval

List nonbinding suggestions, if relevant: _____

Approval with Modifications

List modifications _____

Deferral

List issues _____

Disapproval

List issues _____

SIGNATURE OF PRIMARY REVIEWER

DATE

APPENDIX IV

Elements of Informed Consent

Checkboxes to be completed by reviewers

Elements of Informed Consent

YES NO N/A

1. Description of Research:

- | | | | |
|--|--------------------------|--------------------------|--------------------------|
| A statement that the study involves research | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| An explanation of the purposes of the research | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Expected duration of the subject's participation | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| A description of the procedures to be followed | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Probability of random assignment to each intervention | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Identification of any procedures that are experimental | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

2. Risks and Discomforts:

- | | | | |
|---|--------------------------|--------------------------|--------------------------|
| A description of any reasonably foreseeable risks or discomforts to the subject | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|---|--------------------------|--------------------------|--------------------------|

3. Benefits:

- | | | | |
|---|--------------------------|--------------------------|--------------------------|
| A description of any benefits to the subject or to others, which may reasonably be expected from the research | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|---|--------------------------|--------------------------|--------------------------|

4. Alternatives:

- | | | | |
|---|--------------------------|--------------------------|--------------------------|
| A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|---|--------------------------|--------------------------|--------------------------|

5. Confidentiality:

- | | | | |
|---|--------------------------|--------------------------|--------------------------|
| A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and, if relevant, that other agencies might inspect the records | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|---|--------------------------|--------------------------|--------------------------|

YES NO N/A

6. Compensation for Injury:

For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained

7. Research Questions:

An explanation of whom to contact for answers to pertinent questions about the research, whom to contact for questions regarding research subjects' rights, and whom to contact in the event of a research-related injury to the subject

8. Voluntary Participation:

A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

Additional Elements of Informed Consent (When Appropriate):

- 1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
 - 2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
 - 3. Any additional costs to the subject that may result from participation in the research.
 - 4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
 - 5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
 - 6. The approximate number of subjects involved in the study.
-

A P P E N D I X V

Financial Conflict-of-Interest Disclosure Statement

It is important that the review of research not be biased or compromised by any conflicting financial interests or other potential or actual personal gain of a member. A conflict of interest arises when a member is or might be in a position to put his or her own interest before the best interests of research subjects. The term financial conflict of interest addresses when an REC member has a significant financial interest in an agency or company that is providing funding for a particular research project. It is recognized that many potential conflicts of interest do not constitute actual conflicts or might be acceptable with proper safeguards.

REC Member Disclosure and Certification:

Do you, your spouse, or dependent children have any financial interests related to the work to be conducted under the proposed project?

No Yes

A. Management

Do you, your spouse, or children hold a position of management or employment with this entity?

No Yes, please indicate the position _____

B. Income

Do you, your spouse, or children receive income from this entity?

No Yes, please indicate the nature of the income and the amount:

Honoraria _____ Consulting _____

Salary _____ Other _____

C. Equity

Do you, your spouse, or your children hold an equity interest in this entity?

No Yes, please indicate the nature of this equity (e.g., bonds, stocks, options, other) and the value of this equity interest _____

I acknowledge my responsibility to disclose any new reportable financial interests obtained during the term of the project. I certify that this is a complete disclosure of my financial disclosure of my financial interests related to the proposed project.

SIGNATURE

PRINTED NAME

DATE

A P P E N D I X VI
Statement of Confidentiality

____ [Name of REC] _____ agrees, subject to the conditions below, to disclose information in confidence to
____ [Name of Recipient] _____ relating to projects being evaluated by _____.

____ [Name of Recipient] _____ agrees as follows with respect to the confidentiality of such information:

1. _____ will not disclose or use any such confidential information (other than to the extent reasonably necessary to perform obligations as directed by ____ [Name of REC] ____.) unless:
 - 1.1 the subject matter was already known to _____ prior to its disclosure to _____, as evidenced by written documents;
 - 1.2 the subject matter was or becomes generally public knowledge; or
 - 1.3 the subject matter is made known to _____ by a third party who by such a disclosure is not in breach of duty or obligation toward _____.
2. Neither ____ [recipient] ____ nor ____ [recipient] ____'s agents or employees shall distribute or disclose any such confidential information without the prior written consent of ____ [Name of REC] ____.
3. For purposes of this Statement, _____ considers and will treat as confidential information all business, clinical, and procedural information shared by _____.

SIGNATURE OF REC OFFICIAL

SIGNATURE OF RECIPIENT

DATE

DATE