Standard Operating Procedure (SOP) for Ethics Committee Faculty of Medicine, Alexandria University

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Standard Operating Procedures (SOPs)

Section 1

Ethics Committee

Ethics Committee Faculty of Medicine, Alexandria University (EC) is responsible for the ethical review of all applications (Health Research studies) submitted to it

EC Meetings

1.1 EC meetings are arranged by the Secretariat Office, which is responsible for all administrative aspects of the ethics committee review process. The Secretary of the EC will not participate in the decision-making process of the EC.

EC review of proposals (new submissions)

1.2 The EC will only approve completed applications for ethical review (see 1.3 below). Before applications are submitted to the EC, they will be reviewed by the Secretary for completeness; incomplete applications will be returned to the Principal Investigator (PI) for completion before submission to the EC.

1.3 The following are to be included with each application, depending on the type of study (3 hard copies and one soft copy):

- Completed submission form (Attachment 1).
- Study protocol.
- CV Principal Investigator.
- Informed consent forms, Arabic and English version.
- Investigator Brochure.
- Any further relevant documentation.

(Protocol amendments- IP investigational product labels – CRF case Report form - latest safety information or updates - Insurance certificate - Patients materials)

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Meeting schedules

1.4 Meetings to review applications are held once a month (**third Thursday from every month**). This can be changed according to national vacation days. An extension for the meeting can be held incase of incomplete documents review.

1.5 The minimum time needed for assessment and decisions is from two to six weeks.

Agenda

1.6 The Secretary prepares a draft agenda for each EC meeting for consideration and approval by the EC. The agenda for each meeting will include:

- The date and time of the meeting.
- Minutes of the previous EC meeting.
- Matters arising at the previous meeting(s) that the EC specifically asked to be considered again.
- Declarations of interest relating to items on the agenda.

1.7 The agenda may also include the following when appropriate:

- Items of importance arising from new guidelines or recent publications.
- Matters related to the establishment or membership of the EC.
- Matters related to EC decisions or policy.
- Actions by the Chairman relevant to previous applications.
- Training issues.

Lead Reviewers

1.8 The discussion of each application is facilitated by 3 members of the EC assigned to act as lead reviewers. This duty is randomly assigned by the Secretary (taking into consideration the specialty of the trial) and all the process is supervised by the vice chairman of the committee.

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Distribution of papers for meetings

1.9 New applications for review must normally be received by all EC members at Least 15 working days prior to the EC meeting at which the application will be reviewed.

Attendance of the Principal Investigator

1.10 The PI may be invited to attend the meeting at which his/her application is to be reviewed, in order to respond to requests from the Committee for further information, clarification or reassurance. This participation may be by remote means if the EC Chairman agrees.

1.11 When the PI is unable to attend and is not available to participate by remote means, it is acceptable for another investigator or collaborator to attend Instead, subject to agreement by the EC Chairman. It is not acceptable for a representative of the sponsor to attend in place of the PI.

Quorum requirements and meeting attendance

1.12 The quorum for EC meetings is five members, in the absence of the EC Chairman, Vice-Chairman can act as chairman.

1.13 The Secretary will keep a record of attendance, indicating which members were present for the discussion of each application. EC members are expected to attend the majority of scheduled meetings each year on absence of members 3 consecutive times without excuse he / she will be replaced on the annual renewal.

1.14 Whenever possible the meeting should reach decisions by consensus. If a consensus is not achievable; a formal vote should be taken. All members have The right to vote including the Chairman. The decision of the Committee should be determined by a two thirds majority of those members present. In case of a split decision, external assessment will be carried out by 3 professors of the same specialty of the trial and their opinion will be discussed and voting will be carried out for the second time.

1.15 If any member wishes to record formal dissent from the decision of the EC, this should be recorded in the minutes.

Declarations of interest

1.16 All members must declare any general conflicts of interest they may have in relation to an application for ethical review or any matter for consideration at EC meetings. Each member

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must declare his/her interest at the beginning of each meeting to ensure the independence of the review. His / her vote will be excluded in that subject .Where the Chair has a conflict, that item(s) will be chaired by the Vice-Chair.

1.17 Declaration of Interests defines as follows: "A conflict of interest means when an interest would influence the Decision.

1.18 If an EC member is the PI or key investigator/collaborator in a research proposal, the member may be asked to leave the meeting room and take no part in the discussion, except as outlined in paragraphs 1.10 and 1.11.

1.19 The minutes should record all declarations of interest.

Confidentiality of proceedings

1.20 Meeting must be held on the EC specific room for meeting where member must be able to discuss freely the applications submitted to them. EC meetings must be completely confidential. Any breaches of confidentiality by members will result in termination of their membership.

1.21 The Secretary will be responsible for the collection of all applications reviewed immediately after each meeting.

Responsibilities of the Secretary (under supervision of vice chairman)

1.22 The responsibilities of the EC Secretary are as follows:

- Preparing and issuing the schedule of EC meetings.
- Preparing the draft agenda for review/approval by the IEC.
- Prior review of the applications to ensure their completeness.
- Assigning lead reviewers (under supervision of vice chairman).
- Distributing the agenda and papers.
- Inviting PIs.
- Preparing the venue.
- Recording attendance.
- Ensuring that members have declared an interest in advance of the meeting and mentioning this interest at the beginning of the discussion of that item.
- Advising the meeting as necessary on compliance with Standard Operating Procedures.
- Collecting the applications reviewed immediately after the meeting

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- Making a written record of the meeting.
- Preparing the minutes of the meeting for review and approval at the following meeting.
- Notifying applicants of decisions taken at the meeting and taking other follow-up action as necessary.
- Archiving records.

Minutes

1.23 The minutes of the meeting shall contain a record of the following:

- The members present and absent
- Any interests declared and the decision of the Committee on the participation of the member concerned
- The submission of written comments by members
- A summary of the main ethical issues considered
- The decision of the EC on the applications
- In the case of an approval, any special approval conditions or additional advice to be given to the applicant
- In the case of a rejection, a list of reasons for the decision
- In the case of a conditional opinion, the additional information requested by the EC and the arrangements for considering this information and issuing the final opinion of the EC.

1.24 The minutes are to be presented as the outcome of collective discussion, including written comments made by members following discussion of an application, and should not attribute particular statements to individual members, with the exception of any formal dissent.

Section 2:-

Giving an ethical opinion

Opinions available to the EC

2.1 The EC should reach one of the following opinions on each application reviewed at a meeting:

- Approval.
- Rejection.
- Conditional approval subject to receipt of further information or modifications.
- Held in abeyance for a subsequent meeting pending receipt of further Information.

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2.2 The Chairman should ensure that one of the opinions listed in paragraph 2.1 is taken for every application considered at an EC meeting.

2.3 Where the EC decides that further information or clarification is required before a final opinion can be reached, the Chairman will ensure that:

- The further information or clarification required is specifically identified at the meeting
- Responsibility for considering the further information and issuing the EC's Opinion is clearly agreed upon

2.4 The authority is to the Chairman to issue its opinion following receipt of further information or clarification from the applicant. The following information should be provided in the report:

- The opinion given on the application.
- The members that were involved in considering the further information, if any.

Notification of the opinion to the PI

2.5 The Secretary will notify the PI of the opinion of the EC within 10 working days of the meeting.

2.6 The following information will in all cases be included in the approval letter

- Title of the study.
- Documents reviewed.
- A summary of particular ethical issues considered by the EC.
- EC members' opinion.
- A list of the members who were present for the discussion of the application

Communication with other bodies

2.7 It is the responsibility of the PI to inform other involved bodies/entities, such as collaborators or funding institutions, of relevant decisions taken by the EC.

Section 3

Amendments to research approved by the EC

Definition

3.1 A research study is considered to have commenced when the first participant or patient gives written informed consent to participate. Occasionally, the PI (Sponsor) may revise the terms of the EC application, the protocol or other supporting documentation after approval has been given or after the study has commenced. This revision may be considered a minor, substantial or major amendment.

Types of Amendment

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3.2 There are three types of amendment:

- Minor: of relatively little importance and therefore not considered as substantial (e.g. drug information).
- Substantial: the following changes should normally be regarded as substantial:
    - Changes to the design or methodology of the study, or to background information affecting its scientific value.
    - Changes to the procedures undertaken by participants.
    - Any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study.
    - Changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or caregivers.
    - Change in the use of biological samples.
    - A change of sponsor(s) or sponsor's legal representative.
    - Appointment of a new PI or key collaborator.
    - A change to the responsibility and liability insurance coverage for the study.
    - Appointment of a new PI at a research site.
    - A significant change to the definition of a research site.
    - A change to the definition of the end of the study.
    - Any other significant change to the protocol or the terms of the original.

EC application

- Major: whatever procedural changes alter the risk which participants are exposed to, or the potential benefit, constitutes a major amendment. Examples include:
    - A change in the primary purpose or objective of the research, such as introduction of additional genetic studies.
    - A substantial change in research methodology.
    - Introduction of new classes of investigations or other interventions (rather than simply re-scheduling or modifying those already approved).
    - Recruitment of a new type of participant (especially if these would be regarded as being from vulnerable groups).

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Notice of Amendment

3.4 The EC has the discretion to decide whether or not a proposed amendment is minor, substantial or major.

3.5 The amendment should be seen and noted by the EC Chair. There is normally no requirement to notify the EC as a whole. However, if the Chairman considers that the amendment could affect the EC's previous ethical opinion, the Chairman may decide to include the amendment on the agenda of items to be discussed at the next meeting of the Committee (see 3.4).

3.6 In making this judgment, consideration must be given to how the proposed changes would affect the research. Particular account should be taken of any implications of the amendment for the safety or welfare of participants and of any information that participants might require to give informed consent to continue their participation in the research as amended. Where there is any doubt about the potential implications of the amendment for participants, the amendment should be treated as substantial and ethically reviewed by the EC.

3.7 In principle, minor amendments can go through expedited review by the EC Chairman, substantial and major amendments require approval by the EC.

3.8 Investigator Brochure amendment can go through expedited review by the EC (approval issue only for IB of the initial approval)

Absence of PI

3.8 From time to time, the PI may be absent due to any reasons. For absences of up to one month, the PI is responsible for ensuring that his/her responsibilities as PI are carried out by a suitable temporary replacement and that that replacement is identified to the Secretary.

Extension studies

3.9 An extension study is any study using previously collected data or biological material, medical records or population study information for a new purpose or to test a new hypothesis not envisaged at the time the original consent was obtained.

3.10 It is the responsibility of the EC Chairman or Vice- Chairman to decide if a new application is required for an extension study.

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Section 4

Startup of New Clinical Trials

Purpose

4.1 The purpose of this section is to define a standardized, uniform process for initiating new clinical trials at Alexandria Clinical Research Center.

Approval Process

4.2 The following documents should be forwarded to the EC. Those marked with an asterisk are compulsory (3 copies hard + 1 soft copy):

- Investigator Brochure: this document shows that the relevant and current scientific information about the investigational product has been provided.
- Signed protocol and amendments, if any.
- sample Case Report Form (CRF).
- Informed consent form.
- Insurance statement.
- CV of the PI.

4.3 The approval of the EC must be based at a minimum on:

- Date and document version numbers of protocol and any amendments.
- Informed consent form(s).
- Any other written information to be provided to the subject(s).
- Investigator Brochure.

Monitoring

4.4 During the conduct of the clinical trial

- Progress reports need to be forwarded to the EC every 6 months based on it, decision of Annual renewal of initial study approval will be done.
- Approval expires on annual basis.

Finalization or Termination

4.5 After completion or termination of the trial ,notification letter of study close-out included the final report of the shall be Forwarded to the EC

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Section 5

Monitoring of research given EC approval

General policy on monitoring of research

5.1 EC approval applies for the duration of the research but for some studies (interventional studies) the approval given to any research study should be kept under review. This normally involves the submission of progress reports every 6 months and Final reports and annual study Renewal.

Progress reports

5.2 In those cases where the EC has requested the submission of progress reports, these should be submitted to the EC every 6 months.

Safety reporting

5.3 In research, a Serious Adverse Event (SAE) is defined as an untoward occurrence that:

- Results in death.
- Is life-threatening.
- Requires hospitalization or prolongation of existing hospitalization.
- Results in persistent or significant disability or incapacity.
- Consists of a congenital anomaly or birth defect.
- Is otherwise considered medically significant by the investigator.

5.4 An SAE occurring to a research participant should be reported to the EC where in the opinion of the PI the event was:

- "Related" – that is, it resulted from administration of any of the research Procedures.
- "Unexpected" – that is, the type of event is not listed in the protocol as an unexpected occurrence.

As a consequence, the study will be reconsidered

5.5 Safety report for the safety letters/ SUSARS provided to our Ethics Committee every 6 months for continuing ethical approval**.**

5.6 Any SAEs occurring in the site will need to be reported to the EC within 24 hours of the study team becoming aware of the Serious Adverse Event

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Protocol deviations and violations

5.6 All expected deviations should be submitted to the EC at the beginning of the study and should be classified as minor and major to be approved by EC.

Definitions:-

- **Protocol Deviation:** unintended deviation that results in a serious breach to GCP or in the protocol which necessitates appropriate correction or preventive action taken to prevent its recurrence.
- **Violations:** A violation can occur when there is a consistent variation in practice from trial protocol. A violation can be classified as:-
    - **Major Violations** if there is a significant occurrence which affects participant's safety or integrity of the research. Such Violations need to be reported to the sponsor.

Examples of this include but are not limited to;

- Failure to obtain informed consent (i.e. no documentation in source data or an Informed Consent form)
- Enrolment of subjects that do not meet the inclusion/exclusion criteria
- Undertaking a trial procedure not approved by the IEC and/or the NEC (unless for immediate safety reasons)
- Failure to report an SAE/R/SUSAR to the EC.
- IMP (in vestigational medical product) dispensing/dosing error

- **Minor Violation**: a violation that does not impact on subjects' safety or compromise the integrity of study data. Examples of this maybe; missing original signed consent form (only photocopy present)

The sponsor of a clinical trial shall notify the licensing authority in writing of any serious breach of:-

(a) The conditions and principles of GCP in connection with that trial; or

(b) The protocol relating to that trial, as amended from time to time, within 7 days of becoming aware of that breach.

For the purposes of this regulation, a "serious breach" is a breach which is likely to effect of a significant degree: –

(a) The safety or physical or mental integrity of the subjects of the trial; or

(b) The scientific value of the trial.

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Urgent Safety Measures

5.7 (Implementing a Protocol Deviation under an emergency)
The Investigator may implement a deviation from, or a change of the protocol to eliminate an immediate hazard(s) to trial subjects without prior approval from the REC/NEC. This is defined as an Urgent Safety Measure:
"The sponsor and investigator may take appropriate urgent safety measure to protect clinical trial subjects from any immediate hazard to their health and safety. The measures should be taken immediately". However, in order to meet the legal timelines the investigator must inform IEC/NEC (in parallel) in writing immediately and maximally within 3 days.
The notification form has to be signed by the PI or other medically qualified person who is fully aware of the trial protocol, and authorized to do so by the PI. Alternatively, the form will be signed by the Research Manager.

Responsible Personnel

5.8 The investigator has the responsibility to record and report any violations to the responsible authority, if these are deemed a potential serious breach/urgent safety measure is considered. Deviations need only to be documented on site, in the CRF (case report form) and on the PI's Log of (Protocol and/ or GCP) - Deviations/Violations/"Potential Serious breaches"/"Serious breaches"/"Urgent Safety Measures" and file noted where required. Any corrective and preventative action should also be documented and retained in the site file.

Procedure

5.9 Identification of deviations, violations and potential serious breaches:-

A- Deviations

- **Recording:** Recorded in the case report form, deviations and violations log and file noted if necessary.
- **Reporting:** Minor deviations are not required to be notified to the sponsor, where a deviation is reoccurring and may result in identification of a serious breach; this should be notified to the sponsor.
- **Escalation:** Corrective and preventative actions should be implemented for deviations, according to each case.

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(B) Violations

- **Recording:** Recorded in the case report form, deviations and violations log and file noted if necessary.
- **Reporting:** Violations of GCP, protocol and regulations must be notified to the sponsor within 3 calendar days of becoming aware of that violation.
- **Escalation:** Corrective and preventative actions should be implemented for violations.

If the violation is determined to be a potential serious breach then this would be reported to the competent authority and REC within regulatory timelines.

(C) Follow up reports:

Follow up reports should be made in writing (the serious breaches form can also be used for this) and should ideally:

Be clearly identified as a follow up report.

(D) Timelines

- The Sponsor should define the requirements in their SOPs.
- As with SUSAR reporting, the clock starts when the Sponsor becomes aware of the serious breach.
- Sponsors might need to investigate the deviation to be able to assess whether or not a breach is serious, it should be reported immediately.
- Once identified as a serious breach of the protocol this triggers the 7 days in which to notify the IEC.
- However, the Sponsor should not wait for ALL details of them breach prior to no Timelines
- Sponsors might need to investigate the deviation to be able to assess whether or not a breach is serious.

5.10 The EC should receive a final report within one year of the research terminating. The final report includes information on whether the study achieved its objectives, the main findings and arrangements for publication or dissemination of the research including any feedback to participants.

5.11 The PI or designee completes an application "submission form" (Appendix 1) for EC review of a research protocol for initial full review and submits it to the Vice chairman of EC (Member of EC).

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Section 6

6.1 The sponsor or the PI will pay **5000** LE – in scientific research account – for assessment by EC.
The extension of the project's fees = **2500** LE. The fees of the amendment =**1000** LE for each.
Account number: International Program "Egyptian currency "**945082851/6**.
International Program "USA Dollar $ currency" **408218116/3.**
Bank of Central Bank, This is approved on **24-12-2011**.

Account number: **945082851/6**.
Central Bank, Al Mesallah, Ataren branch,
Address: 3 Mahmoud Azmy Street.
International Program "USA Dollar $ currency" **408218116/3.**
Arab African international bank Fouad Street branch**,**
Address: 73 El Horeya Road- Fouad Street**,**
Swift code: CBEGEGCXXXX.
This is approved on **20-12-2011.**

6.2 Signature:
The chairman is responsible for the signature of all reports released from the EC. In case of his / her absence the vice-chairman is the legible person to replace him/ her.

Section 7

Appeal

7.1 A PI who considers that a decision of the EC is flawed, and where there are substantial and compelling reasons, may appeal that decision in writing to the
EC within one month of receipt of the decision is stating the precise issues upon which the appeal is based.

Annex I

The PI at each research site
In the case of any single or multi-site research, the investigator responsible for the conduct of the research at an individual research site will be known as the PI for that site. There should only be one PI at each site.
Issues relevant to the site-specific assessment
In making a site-specific assessment, the main issue to be considered is the Suitability of the site for the conduct of the research. This involves consideration of the following:

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- **The suitability of the PI, taking into account his/her professional qualifications, knowledge of the research field, expertise in the procedures involved, previous research experience and ability to take any clinical responsibility for the local research team.**
- **The adequacy of the local facilities available for the research.**
- **The arrangements for notifying other local health care staff, which may have an interest in the care of the participants, about the research.**
- **The availability of any extra support that might be required by the researcher as a result of their participation.**

Monitoring of research sites

The provision of ethical approval by the EC for any study does not imply any responsibility of the EC to assure its commencement or completion. If information comes to the attention of the EC that raises questions about the Suitability of the site or investigator, the approval for the site must be reviewed.

Annex II

1- There will be a form which should be delivered to the patient contain the name of responsible personnel and their phone numbers, the day and hours of their responsibility , the hospital that should be reached in case of presence of side effects .

2- This form should be signed by the patient and a copy will be kept in 5the file of the patient.

3- The same will be delivered to the PI and sub PI and this will be considered as an ethical and legal responsibility as they will sign for this document.

4- Protocol wouldn't be accepted except in the presence of these documents.

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Attachment I

Submission Form of a Project

Date of receiving the protocol: ……
Name of principle investigator: ……
Telephone: ……
Department: ……
Title of the Project:……
……
Sponsor: ……**Telephone**: ……
Project start in: / /
Project end in: / /
Duration Expected:
Specialty:
Type of the study: Observational □ **Interventional** □
Study design and type of control:
Number of total subjects in the project:
Participating countries:
Number of subjects in Alexandria:
Samples:
Sent abroad:
Genetic analysis:
Storage for future research:
Informed consent:
Unified in all sites:
PI and sub PI Forms:

1- There will be a form which should be delivered to the patient contain the name of responsible personnel and their phone numbers, the day and hours of their responsibility , the hospital that should be reached in case of presence of side effects .
2- This form should be signed by the patient and a copy will be kept in 5the file of the patient.
3- The same will be delivered to the PI and sub PI and this will be considered as an ethical and legal responsibility as they will sign for this document.
4- Protocol wouldn't be accepted except in the presence of these documents.

Names of the assistant team: **Signature of principal investigator**

Prof. Dr. Maha Ghanem
Chairman of Ethics Committee
Prof. of Forensic Medicine & Toxicology

Issue Date: 1 / 1 / 2020

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