

Standard Operating Procedure for Research Ethical Committee (REC) School of Dentistry, New Giza University

1) Procedure for establishing REC:

Responsibility: Director (Dean of School of dentistry) is responsible for implementing this SOP

Procedure:

1. Committee will be called Research Ethics Committee at School of Dentistry, New Giza University.
2. Dean of School of Dentistry will select and nominate the Chairman and Vice Chairman of the committee.
3. Chairman will select and invite the members to join ethics committee in accordance with the requirements for the formation of ethics committees scientific research according to the Egyptian Clinical Trials Law 2020 and its executive regulations 2022
4. Members will confirm their acceptance to the chairman by providing all the required information for membership.
5. Arrangement should be made for the documentation and maintenance of records of research ethics committee

2) Procedure for conducting REC meetings:

Responsibility: The Chairman and Vice Chairman are responsible for implementing this SOP.

Procedure:

1. Meetings will be held on a monthly basis on scheduled dates.
2. Additional review meetings can also be held with short notice as and in accordance with the need of the workload.
3. All the proposals will be received at least two weeks before the meeting, checked for covering all the announced checklist items and will be collected by the research ethics committee secretary
4. Members will be given at least 10 days' time in advance to review study proposals and the relevant documents.
5. Minutes of the Research Ethical Committee meetings will be documented and signed by the chairman and vice chairman
6. Applicant or investigator may be invited to present the proposal or elaborate on specific issues.
7. External experts may be invited to the meeting or to provide written comment in some proposals, subject to applicable confidentiality agreement.

3) Procedure for submission of research project for review by REC:

Responsibility: All investigators are responsible for implementing this SOP. Each proposal submitted for review to REC must contain number and date in prescribed application form.

Procedure:

1. The Project Investigator must submit an application in a prescribed format along with study protocol and other study related documents necessary for review of the REC
2. All the proposals and documents must be submitted at least two weeks in advance from the scheduled date of REC meeting
3. Every application will be given a REC registration number to be used for all future correspondence and reference.
4. Submission of study related documents for review: If required, apart from a research proposal, REC may ask the investigator to submit other study related documents like a similar or previous studies relevant to point of research
5. In case of any needed changes to the research proposal, it must be submitted to the REC immediately for its review. A covering letter should be submitted mentioning reason/s for modifications and summary of changes and the amended text must be highlighted in the revised Protocol and Protocol Related Documents.
6. All the investigators are required to pay the required fees so they can submit the receipt with the needed documents to the REC secretary .

4) Procedure for preliminary inspection of proposals

Responsibility: The Secretary of REC is responsible for implementing this SOP.

Procedure:

1. All proposals will be collected and compiled by the REC office.
2. In case of missing documents, the investigators will be informed by secretary to complete them and resubmit.

5) Procedure for reviewing the research proposals

Responsibility: All members of REC are responsible for implementing this SOP.

Procedure:

1. Every proposal will be sent at least 10 days before the meeting to all members of REC. They will be evaluated on ethical issues, scientific soundness, and technical excellence of the proposed research before it is taken up for main REC review.

2. The members will assess possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality, and justice issues.
3. Expert opinion of additional members would be obtained if necessary. Every proposal will be collected and compiled by the REC office.
4. All proposals will be distributed in a meeting of the Sub-Committee of two members (**nominated by the chairman and vice chairman**). The two members should be present for the meeting.
5. Decision taken by the Sub-Committee on expedited approval will be brought to the notice of the main committee members at the next regular meeting of the REC.

6) Procedure for decision making regarding the research project

Responsibility

All members of are responsible for the implementing this SOP.

Procedure

In making decision on application for the ethical review of any research proposal, REC will consider the following:

1. Decision will only be taken at meetings where a quorum is complete.
2. Decision will be taken only after reviewing a complete application with all the required documents necessary for proposal.
4. Wherever possible, the decision will be arrived through consensus and not by vote, but when a consensus appears unlikely voting can be resorted to.
5. Rejection of proposal will be supported by clearly stated reasons.

7) Procedure for communicating the decision of REC to the Investigator

Responsibility:

Member Secretary is responsible for implementing this SOP.

Procedure:

1. A decision of the REC will be communicated to the applicant in writing, within 7 days of the meeting at which the decision was taken. All the approvals will be valid for only **five years** or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after five years .
2. An investigator is expected to submit **reply** to the letter of recommended modifications sent by the REC, within 30 days of date of receipt of the letter otherwise he has to reapply again for approval

3. Applicant need to collect a certificate of approval from the REC office/REC Member Secretary.
4. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.

8) Procedure for follow-up of research projects by REC

Responsibility:

All members of the REC and the investigators are responsible for implementing this SOP.

Procedure:

1. REC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
2. Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, REC will conduct the follow up review at shorter intervals based on the need, nature and events of research project.
3. Following instances and events will require the follow-up review:
 - Any protocol amendment likely to affect rights, safety or well being of research subject of conduct of study.
 - Serious or unexpected adverse effect, action taken by investigator, sponsor and regulatory authority.
 - Any event or information that may affect the benefit/risk ratio of the study.
4. A decision of a follow up review will be issued and communicated to the applicant indicating modification/suspension/termination /continuation of the project.
5. In case of premature suspension /termination, the applicant must notify the REC of the reasons for suspension/termination with a summary of results.
6. Applicant (non-thesis project) must inform the time of completion of study and must send the result summary to REC. REC must receive a copy of final summary of study completed from the applicant.

9) Procedure for documentation and archiving of REC

Responsibility: The Member Secretary is responsible for implementing this SoP.

Procedure:

- 1 .All the documents and communications of IEC will be dated, filed and archived in REC office.
- 2 .Only persons, who are authorized by the Chairman of REC, will have the access to the various documents.
3. All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion /termination of the study.
4. At the end of each meeting, every member must return all the research proposals and documents to REC office staff.