Faculty of Medicine - Cairo University

Ethical Review Board

Policies & Procedures

Manual

Introduction;

It is the policy of Faculty of Medicine, Cairo University to respect and protect the rights and welfare of individuals.
Institutional Review Boards (IRB) at Faculty of Medicine, Cairo University is an ethical committee established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

Guidelines:

In the conduct of research and/or actions of this institution is guided by the principles set forth in the international reports and guidelines named Helsinki Declaration and the International Ethical Guidelines For Biomedical Research Involving Human Subjects issued by the Council For International Organizations Of Medical Sciences (CIOMS).
This committee will operates within the framework of the Egyptian policies and laws and the international guidelines will be explained and applied within the framework of the Egyptian laws.

Construction of committee:

The Faculty of Medicine, Cairo University Institutional Review Board (IRB) is a standing committee, constituted according to decision no for the year 2002 issued in 2002 by the Dean of Faculty of Medicine, Cairo University and the approval of the Faculty Council dated for the year 2002 and approval of the Cairo University Council dated 2003.

Membership of the committee:

The executive committee is formed of:

1. The Chair,
2. The Executive Director,
3. The Chairs of the Sub-Committees,
4. The Administrator.

The Institutional Review Board (IRB) for Faculty of Medicine, Cairo University is comprised of 40 individuals to be divided over 4 subcommittees. The members are of varying medial specialties, disciplines, gender and expertise from the scientific and the non-scientific community.
The responsibility for appointing the IRB Chair and some members of unique expertise rests with the Dean of Faculty of Medicine, Cairo University while the different departments will appoint the majority of the members in response to a written request from the IRB chair including the number of members to be appointed.
Members of IRB are unpaid and they carry the job as part of the institutional commitment to Faculty of Medicine, Cairo University. Members from outside are also unpaid and it is considered as a volunteer work for them.
There is a chair for the committee who is responsible of maintaining the scientific and logistic aspects of IRB work.
The executive director helps the Chair especially with the logistic aspect.
The administrator is responsible for secretary and administrative work.
Membership will change periodically every three years where one third of the members being rotated off the committee at the end of each year. This mechanism provides an opportunity for a variety of individuals to participate in the work of the review committee, encourages the development of a collective memory in the review committee, educates new members, facilitates project monitoring and avoids repetitive discussions of the same issues.

The mission, goal and objectives of Faculty of Medicine, Cairo University IRB are as follow:

Mission:

Improving scientific knowledge by ensuring proper conduct of medical, social and behavioral research.

Goal:

Protecting the rights and welfare of human subjects; participating in medical, social and behavioral research.

Objectives:

IRB review is grounded on the following ethical principles:

- Respect for person;
- Beneficence &
- Justice/equity

So, IRB will work to:

1. Ensure that research is relevant to community and is not providing benefit to other communities disproportionately.
2. Ensure absence of harm to individuals and/or societies for being participating in research.
3. Guarantee that individuals and/or societies participating in research will get a benefit out of such research.
4. Ensure respect for individuals and/or societies participating in research regarding their values, culture & privacy.
5. Make sure that every individual is fully informed before being enrolled in the research to be able to make an independent decision whether to participate or not.
6. Justice by fair distribution of burdens and benefits both on individual and community levels.
7. Prevent use of vulnerable populations disproportionately.

What is " research?"

Means systematic investigation designed to develop or contribute to generalizable knowledge, whether or not it is supported or funded under a program, which is considered research for other purposes.

Who are " human subjects?"

Means living individuals about whom an investigator (whether professional or student) conducting research obtains:

(1) data through intervention or interaction, or
(2) identifiable human materials,
(3) identifiable private information.

Authority of IRB:

The IRB has the authority to approve, to require modification as a condition of approval, and to disapprove proposed activities that are with the scope of its authority. In addition, the IRB has the authority to verify that ongoing studies comply with regulations, and it may suspend or terminate approval for ongoing studies under its jurisdiction.

Furthermore, the IRB has the authority to determine whether or not any activity requires review by the IRB.

Failure to observe the policies and procedures described here will be considered serious misconduct, which is potentially harming human subjects participating in such research.

Approval of a Protocol by officials at any level at the Cairo University is not a substitute for IRB approval. Effectively, therefore, there is no possibility of appeal of IRB disapproval to a higher institutional level.
IRB decision is valid after being signed by the Dean of the Faculty and the Vice Dean for Higher Education and Research.
All investigators considering research involving human subjects should contact the IRB Office for getting forms to be completed and may be personal assistance if requested.

The scope of authority of IRB policies:

These policies and procedures apply to all research activities conducted under the auspices of Faculty of Medicine, Cairo University. Also it applies to all development, training, and improvement or other related activities containing a research and development component. Research is considered to be conducted under the auspices of Faculty of Medicine, Cairo University when it is supported financially or by in kind services of Faculty of Medicine, Cairo University, when the research will take place at Faculty of Medicine, Cairo University, when the research will involve participation by Faculty of Medicine, Cairo University employees, or when the use of a Faculty of Medicine, Cairo University affiliation is made in correspondence with research subjects or agreements with research sponsors.
In accordance with system policy, all research activities within Faculty of Medicine, Cairo University, which involve human subjects, regardless of the level of risk foreseen, require IRB review and approval or exemption, prior to the initiation of the activity.

Conflict of interest:

The IRB will make sure of the independence of the committee from investigators and will exclude any member/s with a direct interest in a proposal from participating in its review and assessment.

IRB meetings:

Time:

One of the four committees will meet regularly; once every week (every Thursday). If is happen to be a holiday then, IRB will meet next week.
Dates and times of meetings will be advertised to help investigators to determine time to submit their proposals.

Who could attend the meetings?

Meeting is valid if at least 5 members of the committee attend the review process.
The principal investigator has the right and is encouraged to attend the review meeting of his/her protocol but should absent themselves from confidential discussions and final assessment of the proposal.
Outside scientist could be invited by the IRB to review proposals that is in a field in which there is no expertise within the review committee membership.

Functions of the ethical committee:

1. **Primary review of research protocols:** IRB must ensure that:
    1.1. Research topic is important and will add to scientific knowledge.
    1.2. Research topic is relevant to institutional and community interests.
    1.3. Research design is appropriate, able to test the research hypothesis and study instruments are acceptable.
    1.4. Adequacy of toxicological and pharmacological data for the drug or instrument to be used.
    1.5. Training and experience of clinical staff.

1.6. Adequacy of clinical research facilities at study site.
1.7. Benefit gain from research is outweighing expected risk by a considerable amount, according to IRB judgment. Such benefits should be sensed on both individual and society levels.
1.8. Necessary measures are taken to minimize any anticipated risks and boost benefits.
1.9. Selection of subjects is equitable, and there is a fair distribution of benefits and burdens at individual and society levels.
1.10. Appropriate safeguards to protect the rights and welfare of vulnerable subjects as children, women and prisoners.
1.11. Informed consent is sought in a written form from all research subjects, in language understandable to the subject and under conditions that minimize the possibility of coercion or undue influence.
1.12. Assurance that the budget for the project does not include undue inducement for subject participation, apart from legitimate compensation for travel and lost earnings.
1.13. Privacy of individuals and confidentiality of data is protected and maintained.
1.14. Any additional issues according to type, design and setting of the research.

2. **Further review of any notification** to IRB by researchers regarding changes in protocol, consent form, recruitment procedures or unanticipated adverse events to participants.
3. **Follow-up, monitoring and continued review** of approved research protocols to ensure compliance with approved protocols. This review would be annually for projects encountering minimal risks and every 6 months for projects with greater than minimal risks.
4. **Supervising publication** coming out of the project to ensure confidentiality is maintained.

Types of reviews:

Full Board Review

Protocols are circulated to all Board members for review and comment. Issues of clarification often emerge during the review.

Facilitated Review

The review process is carried out as a full IRB review. Materials are assigned first to the Chair of the IRB who acts as the Primary Reviewer for the protocol. Protocols are also provided to all IRB members. Protocols are not presented at length to the IRB and/or discussed by the full committee unless there is concern voiced by a member of the IRB.

Expedited Review

The review is carried out by one member who informs other members with the approval decision. In case of disapproval, the whole committee should make the decision. It is applied for minimal risk studies or minor changes in approved protocols.

Exemptions

The IRB may determine that research is exempt from IRB approval. Members of the Executive Committee determine on behalf of the IRB whether exemptions will be granted. It is applicable for researches involving unidentifiable persons of for publicly available data**.**

Categories of recommendation:

The IRB may act on a protocol in one of the following ways:

1. Protocol is **approved;**
2. Protocol is **approved after clarification**; indicating that the proposal is approved if clarifications requested are satisfactory to the committee. Clarifications must be sent within 60 days of notification to the investigator or the protocol will be closed and will require re-submission in its entirety to be reconsidered.
3. Protocol is **approved after amendment**(s), indicating that approval is conditioned on incorporation of the specified amendment(s).
4. Protocol is **deferred** indicating that it is not approved as submitted but it can be re-assessed after revision to address the specified reason(s) for deferment.
5. Protocol is **disapproved**.

Time needed for action:

All Protocols must be submitted to the IRB for review, regardless of the investigator's perception of degree of risk involved.
Full Board review is required for the majority of protocols submitted. Full Board review takes a minimum of 3 weeks from the date of submission before action may be recommended.
Protocols that qualify for **expedited review** may receive action within 2 weeks of submission if no substantive issues are raised in the review.
Exemption requests may receive action within several days of submission.

Cost of ethical review of researches:

Faculty of Medicine, Cairo University will provide the necessary supplies for IRB work including an office, stationary, administrative and technical support through its staff.
The Faculty will pay the cost of review of researches conducted by its staff as long as the Faculty is the funding body. Also, researches for thesis of master and doctorate degrees for student registered at the faculty will be exempted.
For researches funded by an external body, the Faculty will charge 1% of the total budget of the research with a maximum of 10000 LE to cover the administrative & technical cost.

Documentation and archiving:

The administrator will keep minutes of the meetings in general, an agreed written record decisions made at each meeting, research protocols, forms,…etc.
The committee encourages researchers to prepare protocols in the standard format that facilitate its review. Also, forms are available for informed consent guidelines, request for modification, adverse event reporting, final report and expedited review.

Publication:

The committee will issue annual report to increase the understanding of the general public and foster the dialogue with the scientific community. Such report will not include confidential information not indicate individual project review but it would provide overview of the committee work as the number of proposal reviewed, the number approved, ..etc.