



Faculty of pharmacy, ACU – Ethical Review board manual

Research ethics committee, ACU (REC-ACU) guidelines

Membership

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Mission

The committee carries out its work with the aim of promoting excellence in research and improving management of research.

Goal

The Faculty of Pharmacy at Ahram Canadian University in Egypt has a responsibility to ensure that scientifically valid research is conducted according to accepted ethical practices that promote the rights and welfare of research subjects.

Objectives

- Identifying and weighing up the risks and benefits of a study (considering human subjects, animals, the community, and the environment).
- Recognizing any financial or personal interests that may affect the research.
- Evaluating the recruitment process and any incentives that will be given to the participants.
- Assessing the procedures and methods used to ask for participants' informed consent.
- Ensuring that all the research activities are recorded properly and reported in a responsible, honest, and objective way.



- Guaranteeing fairness, confidentiality, and privacy for all the subjects involved in the study—or at least full transparency about data-sharing in cases where absolute confidentiality is not possible.

Authority of REC-ACU

The REC-ACU has the authority to approve, to require modification as a condition of approval, and to disapprove proposed activities that are within the scope of its authority. In addition, the REC-ACU 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 REC-ACU has the authority to determine whether any activity requires review by the REC-ACU. Failure to observe the policies and procedures described here will be considered serious misconduct.

Approval of a Protocol by officials at any level at the Ahrum Canadian University is not a substitute for REC-ACU approval. Effectively, therefore, there is no possibility of appeal of REC-ACU disapproval to a higher institutional level. REC-ACU decision is valid after being signed by the Dean of the Faculty and the Vice Dean for Higher Education and Research.

Functions of the ethical committee

1. Primary review of research protocols: REC-ACU 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.

2. Further review of any notification to REC-ACU 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.

Categories of recommendations:

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 30 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 reassessed after revision to address the specified reason(s) for deferment.
5. Protocol is disapproved.

Time needed for action: All application forms must be submitted to the REC-ACU in the first two weeks (Day1-Day15) of each month. Full Board review is required for most protocols submitted. Full Board review takes a minimum of 2 weeks from the date of submission before action may be recommended.

Publication: The committee will issue annual report to increase the understanding of the 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.