



Requirements for submission of a New Research

- 1. A signed and dated REC application form
- 2. Full study protocol
- 3. Protocol summary " in no more than 350 words .
- 4. Site specific consent form in Arabic satisfying essential components. If consent form is more than 5 pages, please submit an additional summary for consent form guided by REC consent form template in no more than 3 pages
- Product brochure for new drug/device including safety information (if applicable) and copies of registration of the drug in other countries (if applicable).
- Questionnaires / study tools to be used in the study in the same language of its use (if applicable);
- Materials to be used (e.g., advertisements) for the recruitment of potential research subjects;
- 8. For clinical trials: **Valid Insurance Certificate** "for not less than one year from the date of application"
- 9. Copy of other local or international RECs approval letters "If applicable"
- 10. C.V of of the principal investigator & co-investigator.
- 11. Cover letter including all submitted documents with their versions and dates

12. Application fees:

Bank check "5000 LE" payable to Cairo University- Faculty of Medicine Research Ethics Committee " الجنة أخلاقيات البحث العلمي، كلية الطب جامعة القاهرة for
studies with nongovernmental source of funding or 400 LE for
governmental or self funded studies .

13. Please submit the following:

- 1 CD including all the above mentioned documents is mandatory.
- 3 hard copies for items: 1,2,5,6,7,8,9,10, 11. "in 3 separate packages"

- 4 hard copies for item 4 "Consent form"
- 12 hard copies for item 3 "Protocol summary"

Notes:

- REC will **not consider** any incomplete or not fully prepared application.
- Deadline for submission is at least 21 days prior to the meeting at which the
 protocol will be reviewed by the REC.
- REC decision letters will be ready 7 days after a decision has been reached.
- To receive a soft copy of submission requirements and application form as well as informed consent guide, please contact REC at <u>kasralainirec@yahoo.com</u>

For further questions: Please contact REC Coordinator Dr. Noha Asem.

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Sincerely

REC Chairman

M. Mohsen Ibrahim, MD

Mehile

Professor of Cardiology Kasr El Ainy Faculty of Medicine,

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