



Cairo University
Faculty of Medicine
Research Ethics Committee

Requirements for submission of an Amendment

1. **3 hard copies** of the following “in the same order and in 3 separate packages”:
 - a. Cover letter including the submitted documents for amendment with their versions and dates
 - b. Signed and dated amendment application form
 - c. Previously submitted **application form**
 - d. Detailed **progress report** including :
 - **Enrollment** of subjects: gender and age in comparison with **targeted** subjects.
 - Number of subjects **withdrawn** and **reasons** for such withdrawal
 - **Adverse events , management and outcome** (Cumulative and type for the previous period since the last review)
 - Results, if available
 - e. **Documents** submitted for **amendment** as following:
 - **New** amended version of the document
 - **Old** “currently approved” version of the document
 - Table of **summary** of changes or track changed versionNB: If the 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.
 - f. **Current REC approval letter.**
2. **1 CD** including all above documents.
3. **Application fees:**
 - Bank check “**3000 LE** “payable to Cairo University- Faculty of Medicine - Research Ethics Committee “ لجنه أخلاقيات البحث العلمي, كلية الطب جامعة القاهرة ” for



studies with nongovernmental source of funding or 100 LE governmental or self funded studies .

Notes:

- REC will **not consider** any incomplete or not fully prepared applications.
- **Deadline** for submission is at least **21 days prior to the meeting** at which 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 forms as well informed consent guide, please contact REC at kasralainirec@Gmail.com.

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

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Sincerely

REC Chairman

M. Mohsen Ibrahim, MD



Professor of Cardiology
Kasr El Ainy Faculty of Medicine,
Cairo University

