

Information to the Applicants:-

- 1) The primary objective of the Ethics Review Committee (ERC), National Eye Hospital, is to protect the mental and physical welfare, rights, dignity and safety of human participants used in research, to facilitate ethical research through efficient and effective review and monitoring processes, to promote ethical standards of human research and to review research in accordance with the *Guidelines of the Ministry of Health* and relevant national and international guidelines.

Link (Version 2007) :

region9.healthresearch.ph/index.php?option=com_phocadownload&view=category&download=22:forum-of-ethi

- 2) All project proposals should be submitted to the ERC *on or before the last day* of each month in order to be taken up for review at the next scheduled meeting.
- 3) Applications for research projects conducted by staff and post-graduate students of the National Eye Hospital will receive priority for review over other proposals. The closing date for all applications will be the last day of each month, or the previous working day if the last day falls on a Saturday, Sunday or a public holiday.
- 4) All documents to be submitted to the ERC to be type written on A4 papers. The application form should be completed in plain English understandable to lay members and all abbreviations should be explained at the time of their first use. All proposals should be typed, single-spaced with a legible font (e.g. Times New Roman, size 11). All pages should be numbered consecutively in the bottom right-hand corner. The completed form should contain sufficient information to enable a thorough ethical review to take place. If a project is deemed to be poorly planned, or may cause inconvenience to participants, or may put participants at risk, without any likelihood of producing worthwhile information or results, it will be rejected or referred back to the applicant for substantial amendment.
- 5) Applications for ERC review are to be submitted in three (03) sets (1 original and 2 copies) along with a soft copy (Microsoft word) of the application form in a CD-ROM, to

the Secretary, Ethics Review Committee, National Eye Hospital, Colombo, by hand. The complete set should comprise the following documents:

- a) Completed application form
- b) Covering letter and summary of the proposal from applicant
- c) Research study protocol with relevant version and date
- d) Patient information documents and patient informed consent forms (ICF) in English with Sinhalese and Tamil translations
- e) Clinical record forms (CRFs)
- f) In case of multi-centre studies listing of other centre(s) and ERC/IRB approval status and copies of ERC/IRB approval letters from other centres (if any)
- g) Principal investigator's curriculum vitae
- h) Product liability letter or insurance certificate (where relevant)
- i) Patient recruitment procedures (e.g. advertisement) if relevant
- j) Patient diary cards (if used)
- k) Required processing fee (see addendum - II) where relevant

The fees levied as processing charges of individual research applications.

1. The processing fees levied for research submitted by non-institutional members is SLRs. 2000/=.
2. The processing fees levied for industry sponsored studies irrespective of affiliation of the investigators is SLRs 10,000/=.
3. The fees levied for protocol amendments for studies sponsored by industry irrespective of affiliation of the investigators is SLRs 5,000/=.