CHRISTIAN MEDICAL COLLEGE, VELLORE

FORMAT OF APPLICATION FOR ETHICS COMMITTEE APPROVAL

1. Title of Research Scheme
2. Name and Designation of Principal Investigator and Address of communication.
3. Name of Guide (post-graduate) and Address
4. Name and Designation of Co-Investigator(s) and Address.
5. Department or Institution where the Research will be carried out.
6. Name of the Funding Agency and Address
7. Duration of the scheme
8. Objectives and aims of the study
9. Brief review of literature
10. Brief summary of the methods with the sample size
11. Ethics Committee Concerns (Please Respond)
   a. Are the risk to subjects minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes?
   b. Are the risks to subjects reasonable in relation to:
      1) The benefits that might reasonably be expected as an outcome to the subject or to others.
      2) Provision of free treatment for research related injury.
      3) Compensation of subjects for disability or death resulting from such injury and
      4) The importance of the knowledge that may reasonably be expected to result?
   c. Will informed consent be sought from each positive subject or the subject’s legally authorized representative? Consent should provide sufficient opportunity to consider whether or not to participate and to minimize the possibility of coercion or undue influence. The information should be in a language understandable to the subject or the representative.
   d. Does the research plan make adequate provision for confidentiality and monitoring the data collected to ensure the safety of subjects?
12. Signature of the Principal Investigator
13. Signature of Guide / Head of the Department
14. Consent of Co-Investigator(s) I/We give my/our consent to be a Co-Investigator and provide my/our expertise to the project.

Name   Department   Signature   Date

NOTE:
- Before sending the proposal to Ethics Committee it needs to get approval by the CMC Research Committee.
- The “informed consent form” and “patient information sheet” should be attached along with the proposal in different languages wherever necessary.
- 17 copies of the above format should be sent to the Secretary, Ethics Committee. (Dept. of Biostatistics, CMC, Bagayam)
- For any amendment proposal, kindly mention briefly the type of amendment in the covering letter.