Covering Letter (Format)

INSTITUTIONAL ETHICS COMMITTEE

Topiwala National Medical College & BYL Nair Ch. Hospittal Mumbai 400008

Date

To,

The Chairperson / Secretary
IEC, TNMC & BYLNCH
Mumbai

Sir/Madam

I submit hereby documents related to the following research proposal for ethical review

Title : _____

_____

_____

Name of the Principal Investigators: _____

Designation: _____

Sponsor's Name & Address: _____

Thanking you
Yours Sincerely

Principal Investigator

Signature of Head of the Department

Checklist of Enclosed Documents

Encl: List of Documents (11 copies)

1. Application Form – Summary Sheet (Yes / No)
2. Study Protocol (Yes / No)
3. Patient Information Sheet in English / Marathi / Hindi (Pl tick) (Yes / No)
4. Informed Consent Form in English/ Marathi / Hindi (Pl tick) (Yes / No)
5. Assent Form in case of Children of 7 years and above (Yes / No)
6. Translation certificate if any (Yes / No)
7. Case Record Form (Yes / No)
8. Additional Documents: (Yes / No)
   Questionnaire / Patients Diary / Advertisement for recruitment of subjects
9. DCGI permission letter (Yes / No)
10. Investigator Brochure (Yes / No)
11. Agreement between investigator and the sponsor (Clinical Trial Agreement) (Yes / No)
12. Source of Funding and financial requirement (Yes / No)
13. Insurance liability copy (Yes / No)
14. Curriculum Vitae of Investigators (Yes / No)
15. GCP training certificates of the investigators (Yes / No)
16. Undertaking by the investigator (Yes / No)
17. CTRI number in case of clinical trial (Yes / No)
18. Statement of Conflict of Interest (Yes / No)
19. Details of projects on hand with the PI (Yes / No)
20. List of Centers in case of multicentric trial and their EC approvals (Yes / No)
21. Any other relevant documents

Signature of the Principal Investigator

Institutional Ethics Committee

Topiwala National Medical College & BYL Nair Ch. Hospital, Mumbai 400008

IEC Project Submission Application Form (Summary Sheet)

IEC Project No. _____ (to be filled in by IEC)

1. Title of the Study _____

   _____

   _____

2. Details of the Investigators

   a. Principal Investigator (Name & Designation)

      _____

   b. Co-investigator 1 (Name & Designation)

      _____

   c. Co-investigator 2 (Name & Designation)

      _____

3. Number of Projects already with the Principal Investigator:

   a. Ongoing Project (Submit status report with IEC Nos.) _____

   b. Waiting for approval _____

   c. Completed in last 3 years _____

   d. In case of completed projects. Have you submitted completion report to IEC? (Yes / No)

4. Is it a Sponsored Project (Yes / No) If yes, Name of the Sponsor

   _____

5. Financial Requirement: Total Amount _____

   Amount Per completed patient _____

6. What is the justification for the conduct of this study? _____

   _____

   _____

7. What is the Objective of the study? _____

_____

_____

_____

8. Sample Size: at this site_____ If multicentric total number _____

9. What is the duration of the study

   a. Duration of study participants (follow up period)

   b. Expected duration for the completion of project

10. What is the type of study / study design? (Please tick)

   a. Does the study involves

      Use of drugs / vaccine / medical device / new technique / diagnostic kit or

      Laboratory investigations / Others (specify)

   b. Observational / Interventional / Prospective / Retrospective

   c. Cross sectional / Case Control / Cohort

   d. Clinical Trial – Open labeled / Single blind / Double blind

      Phase I / Phase II / Phase III / Phase IV

      Controlled with placebo / existing drug / standard therapy

      Single center / Multicentric

11. Who are the Subjects in the study? (Please tick)

   Patients / Adults / Children / Male / Female (Pregnant / Nonpregnant)

   Illiterate / Literate / Terminally or seriously ill / mentally challenged

   Economically or socially backward / Handicapped

   Institutional employees / Students / Nurses

   Any other (specify)

12. Details of the drug therapy

   a. Is it a New Drug? (Yes / No) If yes Pl tick - New molecule / New route of administration / New indication / New fixed dose drug combination

   b. Is the drug marketed in India / UK & Europe / USA / other countries

   c. Investigator brochure obtained? (Yes / No)

d. Prescribing information leaflet obtained? (Yes / No)

e. Status of DCGI permission?

Not required / Approval obtained / Applied for

13. What are the outcome measures and how will you evaluate the following

a. Efficacy parameters

b. Safety parameters

14. Do you intend to do invasive procedures on the participants? (Yes / No) If yes, give details

a. Which invasive procedures?

b. How many times?

c. In case of blood collections, How much total blood will be withdrawn?

15. Does study involves use of stored / preexisting / left over patient samples (Yes / No)

16. What will you do with the leftover samples?

17. Are you going to collaborate with any other department / laboratory or institute? (Yes / No) If yes, Give details and submit necessary permission letter.

18. Will any sample be sent outside the institute? (Yes / No)

a. Have you obtained the administrative permission from the dean?

b. If sample is exported abroad, have you obtained regulatory permission?

19. Are you going to pay Compensation / Incentive to the participants? (Yes / No) If yes give details

20. Is there physical / social / psychological risk or discomforts in the study?

    a. What is the degree of risk involved?

    No Risk / Less than minimal / Minimal / More than minimal / High risk

21. Have you made any provision for compensation for risks of participation? (yes/No)

    a. What is the plan for coverage for medical risks involved in the study?

    b. Who will bear the expenditure of study related injuries to the participants?

22. What is the benefit to the participants in the study?

23. What is the benefit to the community?

24. Do you have any Conflict of Interest in the present study? Yes / No

    If yes give details

    Financial / Non-financial / Any other.

25. Declaration

    We hereby declare that the information given above is true. We have read and understood this protocol and hereby agree to conduct this study in accordance with this protocol and to comply with all the requirements of ICMR guidelines (2006) and other applicable regulations

    Signatures

    Principal Investigator

    Co-investigators: 1. 2. 3.