ECARP PROJECT SUBMISSION APPLICATION FORM

To
The Chairperson/Secretary
Ethics Committee for Academic Research Projects (ECARP)
TN Medical College & BYL Nair Ch. Hospital, Mumbai 400008.

Dear Sir/Madam,

I/We hereby submit the documents related to the following Research Proposal for Ethics Review:

ECARP Protocol Number:		Date (D/M/Y)	
Protocol Title:			
Principal Investigator:			
Email ID	Mobile Number		
Designation:			
Department:			
Co-Investigator 1:			
Email ID	Mobile Number		
Designation:	Department:		
Co-Investigator 2:			
Email ID	Mobile Number		
Designation:	Department:		
Head of Department Name:			
Email ID	Mobile Number		
Department			
In case of dissertation, Year of Admission to Course			
If additional Collaborator/s present, please attach details and letter of Consent from the Collaborator on a separate page			
No of participants at the site		No of study site(s):	

I. Is this an Academic study? Yes ☐ No ☐

i) Type of Study: Dissertation ☐ ICMR/KVPY ☐ Other academic ☐

ii) Type of Study Prospective ☐ Retrospective ☐ Cross-sectional ☐

iii) Is the study observational or interventional?_____

iv) If interventional, does the study involve any deviation from routine/standard practices?

Yes ☐ No ☐

v) What is the trial design? (please tick the appropriate response)

Open labeled ☐ Single blind /Double blind ☐ Controlled ☐ If yes, Control?

II. i) Does the study involve use of (please tick):

Drug ☐ Vaccine ☐ Medical Device ☐ Alternative systems of Medicine ☐

New Technique (Surgical/PT/OT etc) ☐ Diagnostic kit/Investigations ☐

If other, please specify _____

ii) In case of drug/device, is it marketed in India? Yes ☐ No ☐

iii) In case of drug studies does the study drug involve a change in use, dosage, route of administration? Yes ☐ No ☐

If yes please attach copy of DCGI permission. If no, please attach copy of product insert

III. What is the study objective/s?

IV. Participant selection:

i) Number of participants at this site? _____

ii) If multicenter, total number of participants? _____

iii) Details of trial participants (please tick the appropriate box/es)

a) Adults b) Children c) Pregnant women d) neonates e) elderly

f) illiterate g) seriously/terminally ill h) mentally challenged i) handicapped

j) economically/socially backward k) institutional employees/students l) any other

If any other, please specify_____

V. Will the study involve use of pre-existing/stored/left over patient samples? Yes ☐ No ☐

VI. Will trial participant samples be collected & stored for future research? Yes ☐ No ☐

VII. Will any patient sample be sent outside the Instutution? Yes ☐ No ☐

If yes, please give details & submit a copy of Dean's approval for the same

VIII. What is the study duration (in terms of number of months/years)?

IX. Please state the study period? From (MM/YYYY) to (MM/YYYY)

X. Study Assessment Parameters:

XI. Statistical Analysis Plan:

XII. Expected Study Outcomes:

XIII. Will any invasive procedure be performed on the participants? Yes ☐ No ☐

If yes, please specify the procedure and number of times the procedure will be carried out

Is it a standard procedure? Yes ☐ No ☐ If No, please give details

XIV. Will any advertising be done for recruitment of participants?

(Posters, flyers, Brochure, etc.) if yes, kindly attach a copy for EC review Yes ☐ No ☐

XV. Will any compensation be provided for participation (traveling allowance)? Yes☐ No☐

If yes, please give details

XVI. Is there any arrangement for compensation/treatment of trial related injury? Yes☐No☐
Please submit a copy of the insurance policy if it is available

XVII. Do you have any conflict of interest in the present study? Yes ☐ No ☐
(Financial/ non-financial/any other?) If yes, please specify

XVIII. What is the degree of risk involved in the study?
No risk ☐ Very little risk ☐ Moderate risk ☐ High risk ☐

XIX. What is the benefit to the trial participant?

XX. What is the benefit of this study to the Community?

We hereby declare the information given above is true.

Signature of the Principal Investigator:

Signature of Co-Investigator/s
1. 2. 3.

Forwarded by Head/s of Department/s
1. 2.