

**The Institutional Ethics Committee  
B. J. Medical College & Civil Hospital, Ahmedabad**

**ANNEXURE 3**

**Institutional Ethics Committee, B. J. Medical College & Civil Hospital  
Proposal Submission Application Form**

To

**The Member Secretary/ Member coordinator**

Institutional Ethics Committee

B. J. Medical College & Civil Hospital

Ahmedabad.

Dear Sir/Madam,

I/We hereby submit the following study protocol documents for Ethics committee review:

Protocol Number:	Date (D/M/Y)
Protocol Title:	
Principal Investigator:	
Designation:	
Department	
Co-Investigator 1:	
Designation:	Department:
Co-Investigator 2:	

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Designation:	Department:		
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):	

- 1) **Is this a Sponsored Study?**                      Yes                       No   
 If yes, mention the details,  
 Sponsored by Pharmaceutical Company: \_\_\_\_\_  
 International/ National Organization: \_\_\_\_\_  
 Government: \_\_\_\_\_  
 Professional organization: \_\_\_\_\_
  
- 2) **Is this an Academic study?**                      Yes                       No   
 If yes,                      Thesis/Dissertation                       ICMR/KVPY                       Other academic   
 Type of Study                      Prospective                       Retrospective                       Cross-sectional
  
- 3) **Is the study observational or Interventional?** \_\_\_\_\_
  
- 4) **If interventional, does the study involve any deviation from routine/standard practices?**                      Yes                       No
  
- 5) **What is the trial design?**    (please tick the appropriate response)  
 Open labeled                       Single blind   
 Double blind                       Controlled with placebo/ standard treatment
  
- 6) **Does the study involve the use of:**  
 Drug                       Vaccine                       Medical Device                       Alternative Medicine   
 New Technique (Surgical/PT/OT etc)                       Diagnostic kit/Investigations   
 If other, please specify \_\_\_\_\_
  
- 7) **In case of drug/device, is it marketed in India?**    Yes                       No
  
- 8) **Does the study drug involve a change in use, dosage, route of administration?**

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Yes

No

- a. If yes please attach copy of DCGI permission.  
b. If no, Please attach copy of package insert/product insert

**9) What is the study objective?**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**10) Subject selection:**

i) Number of subjects at this site  If multicentre, total number of subjects

ii) Details of trial subjects (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 other, please specify \_\_\_\_\_

**11) Will the study involve use of pre-existing/stored/left over patient samples?**

Yes

No

**12) Will trial subject samples be collected & stored for future research?** Yes  No

**13) Will any patient sample be sent outside the Institution?** Yes  No

If yes, please give details

\_\_\_\_\_

**14) What is the study duration?** \_\_\_\_\_

**15) Assessment parameters:**

i) Efficacy parameters: \_\_\_\_\_

ii) Safety parameters: \_\_\_\_\_

**16) Will any invasive procedure be performed on the patients?** Yes  No

a. If yes, which and how many times? \_\_\_\_\_

b. Is it a standard procedure? \_\_\_\_\_

**17) Will any advertising be done for recruitment of subjects?** Yes  No

(Posters, flyers, Brochure, etc) If yes, kindly attach a copy for EC review

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**18) Will any compensation be provided for participation (traveling allowance)?**

Yes

No

If yes, give details\_\_\_\_\_

**19) Is there any arrangement for compensation/treatment of trial related injury and SAE?**

a. Yes  No

b. Please submit a copy of the insurance policy if it is available

**20) Do you have any Conflict of Interest in the present study?(financial / any other)**

a. Yes  No

**21) If yes, please specify:**

\_\_\_\_\_

**22) What is the degree of risk involved in the study?**

No risk

Very little risk

Moderate risk

High risk

**23) What is the benefit to the trial subject?**

\_\_\_\_\_

**24) What is the benefit of this study to the community?\_\_\_\_\_**

We hereby declare the information given above is true.

Signature of Principal Investigator:\_\_\_\_\_

Signature of Co-Investigator/s:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Please fill the form in legible handwriting or type the information.**

**Write 'Not Applicable' (NA) wherever necessary.**

**Incompletely filled form will not be accepted.**