IECHR INITIAL SUBMISSION APPLICATION

Form to be filled by the Principal Investigator (PI) for submission to INSTITUTIONAL ETHICS COMMITTEE FOR HUMAN RESEARCH (IECHR)

Research Proposal Title

	Name, Designation & Qualifications	**Address Tel no. & Fax Nos. Email ID**	**Signature**
PI			
Co-I / Collaborators			
CRC (If available)			

Please attach detailed Curriculum Vitae of all Investigators dated and signed by the investigators

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Contact Address of Sponsor:
Address for Research Room where documents will be stored during study:
Total Study Budget: _____ **Patient Reimbursement Amount: _____** **Institutional Over head: _____**

1.Type of Study : Single center ☐ Multicentre ☐		
2. Status of Review: New ☐ Revised ☐		
3. Clinical Trials: **Drug /Vaccines/Device/Herbal Remedies :** a. Does the study involve use of: Drug ☐ Devices ☐ Vaccines ☐ Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐ N/A ☐		
b. Is it approved and marketed In India ☐ UK & Europe ☐ USA ☐ Other countries, specify		
c. Does it involve change in use, dosage, route of administration? **If yes**, whether **DCGI's** /Any other Regulatory authority's Permission is obtained? **If yes,** Date of permission:	Yes Yes	No No
d. Is it an Investigational New Drug? **If yes,** IND No:	Yes	No
i. Investigator's Brochure submitted	Yes	No
ii. In vitro studies data	Yes	No

iii. Preclinical Studies done	Yes	No
iv. **Clinical Study is** : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ Bio-Equivalence study ☐		
4. Subject Selection: a. Number of Subjects:		
b. Duration of study:		
c. Will subjects from both gender be recruited	Yes	No
d. Inclusion / exclusion criteria given	Yes	No
e. Type of subjects Volunteers ☐ Patients ☐		
f. Vulnerable subjects Yes ☐ No ☐ (Tick the appropriate boxes) Pregnant women ☐ Children ☐ Elderly ☐ Fetus ☐ Illiterate ☐ Handicapped ☐ Terminally ill ☐ Seriously ill ☐ Mentally Challenged ☐ Economically & Socially backward ☐ any other ☐		
g. Special group subjects Yes ☐ No ☐ (Tick the appropriate boxes) Captives ☐ Institutionalized ☐ Employees ☐ Students ☐ Nurses/Dependent ☐ Armed forces ☐ Staff ☐ Any other ☐		
5. Privacy and confidentiality a. Study involves Direct Identifiers ☐ Indirect Identifiers/coded ☐ Completely anonymised/ delinked ☐		
b. Confidential handling of data by staff	Yes	No
6. Use of biological/ hazardous materials a. Use of fetal tissue or aborts	Yes	No
b. Use of organs or body fluids	Yes	No
c. Use of recombinant/gene therapy **If yes,** has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes Yes	No
d. Use of pre-existing/stored/left over samples	Yes	No
e. Collection for banking/future research	Yes	No
f. Use of ionizing radiation/radioisotopes **If yes,** has Bhabha Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes Yes	No No
g. Use of Infectious/ bio hazardous specimens	Yes	No

h. Proper disposal of material	Yes	No
i. Will any sample collected from the patients be sent abroad?	Yes	No
Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No

Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐

Facility in India inaccessible ☐

Facility available but not being accessed. ☐

If so, reasons…**NA**

7. Consent :

*Written ☐ Oral ☐ Audio-visual ☐

Consent form : (tick the included elements)

No.	Content required in Informed consent form	Yes	No	Not Applicable
1	Understandable language			
2	Alternatives to participation			
3	Statement that study involves research			
4	Confidentiality of records			
5	Sponsor of study			
6	Contact information			
7	Purpose and procedures			
8	Statement that consent is voluntary			
9	Risks & Discomforts			
10	Right to withdraw			
11	Benefits			
12	Consent for future use of biological material			
13	Compensation for participation			
14	Benefits if any on future commercialization			
15	Compensation for study related injury			
16	eg. genetic basis for drug development			

*If written consent is not obtained, give reasons:

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Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐

Research staff ☐ Any other ☐

8. Mention Recruitment Method:		
9. Will any advertising be done for recruitment of subjects? (posters, flyers, brochures, websites – if so kindly attach a copy)	Yes	No
10. Risks & Benefits Is the risk reasonable compared to anticipated benefits to subjects / community / country?	Yes	No
Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐	Yes	No
Is there a benefit a) to the subject ? Direct ☐ Free Treatment ☐ Indirect ☐ b) Benefit to society:		
11. Data Monitoring Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
Is there a plan for reporting of adverse events? **If Yes,** reporting is done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No
Is there a plan for interim analysis of data?	Yes	No
Are there plans for storage and maintenance of all trial databases? **If Yes,** for how long?	Yes	No
Address for Archival Place:		
12.Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:_____	Yes	No
13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by Insurance ☐ by any other company ☐	Yes	No

14. Do you have conflict of interest? (financial/nonfinancial) If Yes, specify:	Yes	No
15. NOC letter from Dean has been submitted?	Yes	No
16. NOC letter from Medical Superintendent has been submitted?	Yes	No
17. Number of ongoing Trials by same PI:	Approved	
	Active	

List of Documents for Submission:

16 Hard copies (one copy signed by investigator) + 1 Soft Copy

No.	Documents	Yes	No	Not Applicable
1	Duly signed IECHR application Form			
2	Study Protocol			
3	Investigator Brochure			
4	Curriculum Vitae of all the Investigators			
5	Informed Consent form in vernacular language & in English			
6	Translation Certificates for translation			
7	Back Translation of Informed Consent form vernacular language to English			
8	Translation Certificates for Back translation			
9	Patient Diary Card in vernacular language & in English			
10	Translation Certificates for translation			
11	Back Translation Patient Diary Card in vernacular language & in English			
12	Translation Certificates for Back translation			
13	Copy of advertisements / **Information brochures**, if any.			
14	Case Record Form			
15	If any HMSC/**DCGI**/DBT/BARC clearance if obtained			
16	Investigator's undertaking & Co-Investigator Undertaking			
17	Copy of Valid Insurance Policy obtained for the present research work			
18	Clinical Trial Agreement between PI and Sponsor			
19	Submission Letter to Regulatory Body			
20	Approval Letter from Regulatory Body			
21	Any Other Document (Specify)			

Name &Designation of PI	Signature & Date of PI

Name & Designation of Co-I	Signature & Date of Co-I

FOR FURTHER COMMUNICATION AND SUBMISSION OF FILLED IN FORM KINDLY CONTACT: Dr. Shreya Shah, (Member Secretary, IECHR), Associate Professor, Department of Pharmacology, 1st Floor, Medical College Baroda.