APPLICATION FOR APPROVAL OF RESEARCH PROPOSAL INVOLOVING THE HUMAN PARTICIPANTS

Institutional Review Board, Government Medical College Bhavnagar

Application type: ☐ **New** ☐ **Revised** **Date:**

For office use only:	
Received date	
Purpose	Dissertation
IRB No.	
Department No.	
IRB meeting no.	
IRB approval date	
Any amendment after approval	☐ Yes/ ☐ No
Amendment approval date	

A) Study title and details of PI:

Study Title		
Name of PI		**Upload your photo in PDF format only, Other formats are not supported** (Affix your passport size photo when you submit hard copy)
Qualification		
Designation		
Address		
Mobile no.		
Email-Id		

(Version 1.0)

Signature of PI:_____

B) Details of all co-investigators/ PG guide:

Sr. No	Co-investigators' name	Designation & Qualifications	Address Mobile number and E-mail ID Signature
1			
2			
3			
4			
5			
Please attach detailed Curriculum Vitae of all Investigators; dated and signed by the investigators (with publications limited to previous 5 years).			

C) Funding details and study budget:

a	Whether your study will receive any funding from any funding agency? If yes, write the name of funding agency	☐ **Yes /** ☐ **No**
b	Complete sponsor details (In case of regulatory trial)	
c	Who will bear the expense of dissertation/ academic research work?	☐ **MCDS/** ☐ **Institution** ☐ **Self**
d	**Overall study budget**	
1	Investigation charges	
2	Equipment charges	
3	Cost of medicines	
4	Stationary cost	
5	Other expenses	
	Total	

(Version 1.0)

D) Study details:

<table>
<tr><td rowspan="6">1</td><td rowspan="6">Type of study</td><td colspan="4">Not applicable
If interventional provide details mentioned below:</td></tr>
<tr><td colspan="2">a) Type of intervention:</td><td colspan="2">Not Applicable</td></tr>
<tr><td colspan="2">b) Does it involve a change in use, dosage, route of administration?</td><td colspan="2">☐ YES/ ☐ NO</td></tr>
<tr><td colspan="2">c) Is it an investigational new drug (IND)?

If yes, DCGI permission taken? (Attach letter)</td><td colspan="2">☐ YES/ ☐ NO

☐ YES/ ☐ NO</td></tr>
<tr><td colspan="2">d) If it is an IND, mention the phase of clinical trial.</td><td colspan="2">☐ Phase 1/ ☐ Phase 2/ ☐ Phase 3</td></tr>
<tr><td colspan="2">e) Approval status in other country, if not approved in India</td><td colspan="2"></td></tr>
<tr><td>2</td><td>Are you aware if this study/similar study is being done elsewhere?</td><td colspan="4">☐ YES / ☐ NO

If yes, attach details with application.</td></tr>
<tr><td>3</td><td>Sample size</td><td colspan="4"></td></tr>
<tr><td>4</td><td>Study duration</td><td colspan="4"></td></tr>
<tr><td>5</td><td>Participants of both sexes will be included?</td><td colspan="4">☐ YES/ ☐ NO</td></tr>
<tr><td rowspan="5">6</td><td rowspan="5">Vulnerable population will be included in study? (Tick accordingly)</td><td>No</td><td>☐</td><td>Terminally ill</td><td>☐</td></tr>
<tr><td>Pregnant lady</td><td>☐</td><td>Mentally challenged</td><td>☐</td></tr>
<tr><td>Elderly</td><td>☐</td><td>Illiterate</td><td>☐</td></tr>
<tr><td>Children</td><td>☐</td><td>Socially and economically backwards</td><td>☐</td></tr>
<tr><td>Handicapped</td><td>☐</td><td>Any other (Specify)</td><td>☐</td></tr>
<tr><td>7</td><td>Special groups in study?</td><td>No</td><td>☐</td><td>Nursing / Dependent staff</td><td>☐</td></tr>
</table>

(Version 1.0)

Signature of PI:_____

	(Tick accordingly)	Students	☐	Armed forces	☐
		Employees	☐	Other (Specify)	☐
8	**Use of biological material in study?**	☐ YES / ☐ NO If yes, provide details of material to be used and precaution to be taken while handling the material on separate sheet.			

E) Ethical consideration:

1	Written informed consent will be obtained? **(Provide participant information sheet and informed consent document for review)**	☐ YES / ☐ NO If No, provide reasons: Do you seek consent waiver from IRB? ☐ YES / ☐ NO

Tick the included elements in Informed consent document

Understandable language	☐	Benefits	☐	Contact information	☐
Statement that study involves research	☐	Statement that consent is voluntary	☐	Compensation for participation	☐
Sponsor of study	☐	Right to withdraw	☐	Compensation for study related injury	☐
Purpose and procedures	☐	Alternatives to participation	☐	Consent for future use of biological material	☐
Risks & Discomforts	☐	Confidentiality of records	☐	Any other (Specify)	☐

2	How will you ensure data confidentiality?	
3	Is the risk reasonable compared to the anticipated benefits to Participants / community?	☐ YES/ ☐ NO
4	Is there physical / social / psychological risk / discomfort?	☐ YES/ ☐ NO If yes, Minimal _____
5	Is there a plan of data monitoring through Data Safety Monitoring Board?	☐ YES/ ☐ NO

(Version 1.0)

6	Is there a plan to report adverse reaction?	☐ YES/ ☐ NO ☐ Not Applicable
7	Is there compensation for study related injury?	☐ YES/ ☐ NO ☐ Not Applicable
8	Is there compensation for participation?	☐ YES/ ☐ NO
9	Is there a plan for interim analysis of data?	☐ YES/ ☐ NO
10	Will any advertising be done for recruitment of Participants**?**	☐ YES/ ☐ NO If yes, attach copy of advertisement to be done.
11	Do you have conflict of interest?	☐ YES/ ☐ NO If yes, specify :
12	Are you planning to publish your data?	☐ YES/ ☐ NO If No, provide reasons:
13	Who will do archival of all the study documents for at least 3 years (5 years in case of regulatory trial) after completion of study? (Provide name and contact details)	

Attached following documents for review along with application:

Sr. No	Documents	Attached
1	Study proposal in prescribed format (For dissertation/ academic research)	☐YES/☐NO/☐NA
2	Case Record Form / Study questionnaire	☐YES/☐NO/☐NA
3	Patient Information Sheet & Informed Consent Documents (English & Gujarati)	☐YES/☐NO/☐NA
4	Minimum 2 relevant full text reference articles	☐YES/☐NO/☐NA
5	Investigator's brochure*	☐YES/☐NO/☐NA
6	DCGI approval letter*	☐YES/☐NO/☐NA
7	Copy of Insurance Policy*	☐YES/☐NO/☐NA
8	Clinical trial agreement*	☐YES/☐NO/☐NA
9	CV of all the investigators	☐YES/☐NO/☐NA
10	Copy of GMC registration certificates	☐YES/☐NO/☐NA
11	Certificate of training of Good Clinical Practice	☐YES/☐NO/☐NA
12	Departmental Scientific committee attendance sheet	☐YES/☐NO/☐NA
13	Investigator's undertaking*	☐YES/☐NO/☐NA
14	Copy of PPT presented in departmental meeting	☐YES/☐NO/☐NA
15	Copy of CTRI registration certificate	☐YES/☐NO/☐NA
16	Participant diary* (English & Gujarati)	☐YES/☐NO/☐NA
17	Any other document (Specify)	

***Documents are required in case of regulatory clinical trial**

We herewith declare that information provided herewith is correct and if there will be any change or deviation from provided details, we are bound to inform that to IRB and take permission for the same.

Sr. no.	Name	PI/ Co-I	Sign	Date
1				
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Signature of PI:_____

Investigator's declaration

Department of
Government Medical College & Sir Takhatsinhji General Hospital Bhavnagar-364001

For the research proposal entitled:

1. We certify that, we have determined that the proposal herein is not unnecessarily duplicative of previously reported research.

2. We certify that, we are qualified and have enough experience to do such a study /and do the study under guidance of my P.G. guide.

3. For procedures listed under proposal, we certify that we have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described herein which may cause less pain or distress to the patient.

4. We certified that, study will be initiated only upon review and approval of scientific intent by IRB, Govt. Medical College, Bhavnagar and getting a certificate from IRB.

5. We will do necessary changes in our study protocol as per the suggestions given by respected IRB members during meeting before getting approval letter and bound to submit the changes to IRB. We will obtain approval from the IRB, Govt. Medical College, Bhavnagar, before making any significant changes in this study. Institutional Biosafety Committee's (IBC) certification of review and concurrence will be taken (Required for studies utilizing DNA agents of human pathogens).

6. We will do our study according to ICH-GCP guidelines and maintain all the study related records. Whenever asked, we are bound to produce to IRB, Govt. Medical College, Bhavnagar.
7. We will report adverse drug reaction to Pharmacovigilance Cell & IRB whenever, we come across the adverse drug reaction while doing research work. (If Applicable)

8. We certify that, we will follow the recommendations of IRB and Govt. of Gujarat rules and regulation issued from time to time.

9. We certify that, record of all premature termination of a study with a summary of the reasons / final report after completion of the study including microfilms, CDs and Video recordings, will submit to the IRB, Govt. Medical College, Bhavnagar.

10. At the time of submission of dissertation to Maharaja Krishnakumarsinhaji University, Bhavnagar, we will also submit (If applicable- for PG students only) our work to any indexed journal and as a proof copy, will be submitted to the IRB office, Dept. of Pharmacology, Govt. Medical College, Bhavnagar.

11. We will submit follow up report at every six months in prescribed format and bound to show project related all the documents.

12. We will also submit the detailed summary of our work in two copies to IRB office after completing the research / dissertation work.

13. Head of Department will be responsible for the archival of all dissertation / research project related documents and data during and after completion of the project.

Sr. no.	Name	PI/ Co-I	Sign	Date
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2				
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