

## Application for Review of Industry/ Government Initiated Research Proposal [Clinical Trial]

## INSTITUTIONAL ETHICS COMMITTEE

## HM PATEL CENTER FOR MEDICAL CARE AND EDUCATION, KARAMSAD

Proposal Registration [Inward] No: IEC/ HMPCMCE/ / Dated:

<b>Protocol Number</b>		
<b>Protocol Title</b>		
<b>Status of review</b> (mention date of initial approval in case of amendment)	Initial	Amendment [with date of initial review]
<b>Name of Applicant</b>		
<b>Designation</b>		
<b>Department</b>		
<b>Institute</b>		
<b>Contact information</b> (Address, email & phone number)		
<b>Name and Role</b>	<b>Conflict of interest</b>	<b>Signature &amp; Date</b>
1.	Yes / No If yes, declaration attached: Yes / No	
2.	Yes / No If yes, declaration attached: Yes / No	
3.	Yes / No If yes, declaration attached: Yes / No	

<b>Sponsor name and address:</b>	
<b>Type of study:</b>	<b>Local/ Global:</b>
<b>Type of trial:</b>	<b>Single center / Multi center:</b>
<b>Total study duration:</b>	
<b>Study involves use of:</b>	<b>Drug / Device / Vaccine / Nutritional product / .....</b>

<b>Study drug status</b>	<b>Approved</b> (give details)	<b>New Chemical Entity or Not</b> [NCE/ Non NCE]
<b>In vitro studies data</b>		
<b>Preclinical studies done</b>		
<b>Clinical study is phase</b> I/II/III/IV		

**Title of project:**

Proposals not in format would not be accepted. Kindly print on both sides of the page, Save Paper.

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Type of subjects	Volunteers / Patients
Vulnerable population [Yes/ No] (If vulnerable, Tick the appropriate boxes)	<input type="checkbox"/> Pregnant women children elderly fetus illiterate <input type="checkbox"/> Handicapped Terminally ill Seriously ill mentally challenged <input type="checkbox"/> Economically & socially backward Students Employee institutionalized, <input type="checkbox"/> Any other; _____

**Brief description of the proposal - Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures**

<b>Is the risk reasonable compared to the anticipated benefits to subjects / community / country?</b>	1. Yes 2. No	<i>(Elaborate)</i>
<b>Is there physical / social / psychological risk / discomfort?</b>	1. Yes 2. No	<b>If Yes</b> , indicate whether: 1. Minimal or no risk 2. More than minimum risk 3. High risk

<b>Data Monitoring</b> <b>Is there a data &amp; safety monitoring committee/ Board (DSMB)?</b>	1. Yes 2. No
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<b>Is there compensation for participation?</b>	1. Yes 2. No	<b>If Yes</b> , 1. Monetary 2. In kind Specify amount and type:
<b>Is there compensation for injury?</b>	1. Yes 2. No	<b>If Yes</b> , Sponsor/ Investigator/ Insurance/ Any other company
<b>Are biological samples to be taken outside the country?</b>	1. Yes 2. No	<b>If Yes</b> , Permission from CDSCO taken/ not taken

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