Application for Review of Academic Clinical Trial

INSTITUTIONAL ETHICS COMMITTEE
HM PATEL CENTER FOR MEDICAL CARE AND EDUCATION, KARAMSAD

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

Protocol Title		
Status of review (mention date of initial approval in case of amendment)	Initial Amendment [with date of initial review]	
Name of Principal Investigator		
Designation		
Department		
Institute		
Contact information (Address, email & phone number)		
Name of PI & Co-investigators	**Conflict of interest**	**Signature & Date**
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	

Sponsor name and address [if none External, Name of Head of Institute]:	
Type of study:	Local
Type of study:	Single center / Multi center
Total study	

duration:	
Study involves use of:	**Drug / Device / Vaccine / Nutritional product / Procedure/** **……**

Study drug status	**Approved** (give details)
In vitro studies data	
Preclinical studies done	

Type of subjects	**Volunteers / Patients**
Vulnerable population [Yes/ No] (If vulnerable, Tick the appropriate boxes)	Ø Pregnant women/ children/ elderly/ fetus/ illiterate Ø Handicapped/ Terminally ill/ Seriously ill/ Mentally challenged Ø Economically & socially backward/ Students/ Employee/ institutionalized, Ø 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
To be attached separately as per the information required

Is the risk reasonable compared to the anticipated benefits to participants / community / country?	1. Yes 2. No	*(Elaborate)*

Is there physical / social / psychological risk / discomfort?	1. Yes 2. No	**If Yes**, indicate whether: 1. Less than minimal risk 2. Minimal risk 3. Minor increase over minimal risk/ low risk 4. More than minimum risk/ high risk

Is there compensation for participation?	1. Yes 2. No	**If Yes**, 1. Monetary 2. In kind Specify amount and type:
Is there compensation for injury?	1. Yes 2. No	**If Yes**, Sponsor/ Investigator/ Institute
Are biological samples to be taken outside the institute?	1. Yes 2. No	**If Yes,** Permission from Head of Institute taken/ not taken

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Instructions:

- None of the following headings should be omitted or changed
- Use 11/ 12pt Times New Roman/ Calibri, 1.5 spacing
- Write continuous text [except for aims, inclusion or exclusion criteria]
- Use both sides of page to avoid paper wastage
- Only 1 hard copy to be submitted
- Upload the .doc/ .docx file in eEC Software under respective heading
- Highlight changes in ***'red'*** on resubmissions after IEC review
- Submit the hard copy along with application for research proposal as per Annexure 4

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1. Brief summary of intended work:

1.1 Need for the study [including operational definition of variables]

1.2 Review of literature

[to include sufficient information on the disease or medical condition to be studied, the investigational product/process, preclinical and early clinical findings, etc., acceptable review of the known risks and potential benefits of the investigational product/process, how risk acceptable for the expected benefit etc.]

1.3 Objectives of the present study

[to be clear and acceptable, measurable etc.]

2. Material and method:

2.1 Source of data [area or institute from where samples will be collected]

[to include letter of permission from Head of Institute for collection of data for academic trial]

2.2 Methodology [brief description]

- consider feasibility of method in context of resources
- inclusion & exclusion criteria, sampling procedures etc.
- requirement of any investigations or interventions to be conducted on participants

2.3 Plan of statistical analysis [Details of tables, tests and other statistical analysis]

[to include acceptable statistical plan and methods for data analysis, whether sufficient information on the selection of subjects to be included in analysis etc.]

3. Ethical issues:

3.1 Informed consent process [to include, wherever applicable]

- Statements that the study involves research and explanation of the purpose of the research, expected duration of the subject's participation,

- Description of the procedures to be followed, including all invasive procedures; any reasonably foreseeable risks or discomforts to the participant; any benefits to the participant or others reasonably expected from research [if no benefit is expected, participant should be made aware of this]
- Disclosure of specific appropriate alternative procedures or therapies available to the participant
- Statements describing the extent to which confidentiality of records identifying the participant will be maintained and who will have access to participant's medical records, trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials), compensation and/or treatment(s) available to the participant in the event of a trial-related injury, an explanation about whom to contact for trial related queries, rights of participants and in the event of any injury, the anticipated prorated payment, if any, to the participant for participating in the trial, participant's responsibilities on participation in the trial, that participation is voluntary, that the participant can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled, that there is a possibility of failure of IP/ device/ procedure to provide intended therapeutic effect, that in case of placebo controlled trials, the placebo administered to the participants shall not have any therapeutic effect, foreseeable circumstances under which the participant's participation may be terminated by the Investigator without the participant's consent, additional costs to the participant that may result from participation in the study, consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by participant, that the participant or participant's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the participant's willingness to continue participation will be provided, that the particular treatment or procedure may involve risks to the participant (or to the embryo or foetus, if the participant is or may become pregnant), which are currently unforeseeable,
- Approximate number of participants to be enrolled in the study etc.

3.2 Steps proposed for protection of participants from unanticipated harm arising out of the study [Including privacy and confidentiality]

[an acceptable statement on what are the ethical issues in study and how are the issues addressed; are minors involved as participants? - if yes, is there appropriate assent and parental agreement form?; any involvement of other vulnerable participants and methods of their protection to be adopted; acceptable means for protecting privacy and confidentiality of personal information; whether participants will be given access to the personal information and study data]

3.3 Plan of publication at the end of study

[including whether the publication policy is suitable for protecting the confidentiality of participants' personal information?]

3.4 Declaration about amount of funds required and its source

[to also include acceptable insurance or indemnity letter from sponsor]

4. Contribution of the research project

[How the research will benefit the community at large; measures to be undertaken to address the identified problem]

1) Risk assessment: (tick mark what is appropriate)

	Study involves no more than minimal risk
	Study involves more than minimal risk *(tick below)*
	Risk represents minor increase over minimal risk
	Risk represents more than a minor increase over minimal risk

2) Benefit assessment: (tick mark what is appropriate)

	No prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant' disorder or condition
	No prospect of direct benefit to individual participants, but likely to yield generalizable knowledge to further society's understanding or the disorder or condition under study
	The research involves the prospect of direct benefit to individual participants

Few lines on contribution of the academic clinical trial to community at large:

5. References *[to include only those references that are cited in the proposal]*

(Refer to http://www.nlm.nih.gov/bsd/uniform requirements.html for guidance to referencing standards)