INSTITUTIONAL ETHICS COMMITTEE
H. M. PATEL CENTRE FOR MEDICAL CARE & EDUCATION
KARAMSAD, GUJARAT -388325
[Reg. No. ECR/ 331/ Inst/ GJ/ 2013/ RR-16]

REVIEW REPORT FOR RESEARCH PROTOCOLS INVOLVING HUMAN SUBJECTS
[New as well as Amendments]

Study Protocol Title:	
Principal Investigator:	
Date Protocol Received by Reviewer:	

	ITEMS	State (Y) for 'Yes', (N) for 'No', (NR) if not relevant, (NS) if not sure, (NC) if not complete	COMMENTS
1.	GENERAL INFORMATION		
	Is study title appropriate?		
	Is there a protocol identifying number and date?		
	Is the name and address of sponsor stated?		
	Is the name and institution of investigator/s stated?		
	Is the study site appropriate in terms of facilities, expertise, patient populations, etc?		
	Is there sufficient and appropriate expertise and experience in the study team?		
	Is there any conflict of interest among members of the study team? If there is, how is it managed?		
2.	***BACKGROUND/LITERATURE REVIEW		
	Is the literature review complete with sufficient information on the disease or medical condition studied, the investigational product/process, preclinical and early clinical findings, etc.		
	Is there an acceptable review of the known risks and potential benefits of the investigational product/process?		
	Is the risk acceptable for the expected benefit?		

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3.	OBJECTIVES AND PURPOSE		
	Does the study have acceptable societal value or beneficial outcome?		
	Is the objective(s) clear and acceptable?		
4.	***STATEMENT ON ETHICAL ISSUES		
	Is there an acceptable statement on what are the ethical issues in study and how are the issues addressed?		
5.	*TRIAL DESIGN		
	Is the study endpoint(s) clearly stated and acceptable?		
	Is the study design including all procedures appropriate and acceptable?		
	Is the use of placebo, washout, withholding treatment, cross-over, etc, acceptable?		
	Is there acceptable measure taken to minimize bias such as randomization, blinding, maintenance of randomization codes, and procedures for breaking codes, etc?		
	Is there acceptable rationale, description and justification for (a) route of administration, dosage, and treatment periods; (b) device/process specifications?		
	Is the study intervention(s) groups and distribution of subjects in the groups acceptable?		
	Is the expected duration of subject participation acceptable?		
	Is the sequence and duration of all study periods including follow-up, acceptable and necessary?		
	Is there acceptable accountability procedure for investigational products acceptable and monitoring of compliance of subjects?		
	Are there appropriate collection,		

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	storage and use of biospecimens as well as personal information?		
	Is there collection of specimens for pharmacogenomic analysis?		
	Is the specimen optional?		
	Is the specimen necessary and appropriate?		
	Is stored specimen used for future research?		
	Is the future research related to the medical condition and investigational product/process of this study?		
	Is the dignity and privacy of the subject protected in the future research?		
	Is there appropriate criteria for suspending or terminating the study?		
6.	*, **SELECTION AND WITHDRAWAL OF SUBJECTS		
	Is the study population appropriate and clearly described?		
	Is there acceptable number of subjects to be enrolled including reason and calculation for sample size?		
	Are there acceptable inclusion and exclusion criteria?		
	Are there acceptable process, place and timing for obtaining informed consent / assent?		
	Is there acceptable subject withdrawal criteria?		
	Is it clear when and how are subjects withdrawn, what are the follow-up processes, and whether withdrawn subjects are replaced?		
7.	*TREATMENT AND PROCEDURES		
	Are the permitted and not permitted medications / treatments during trial clearly stated and acceptable?		

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	Is there appropriate rescue medication / procedure?		
8.	*ASSESSMENT OF EFFICACY		
	Is there acceptable specification of efficacy parameters, methods and timing for assessment, recording and analysis?		
9.	*ASSESSMENT OF SAFETY		
	Is there acceptable procedure and timing for getting reports of adverse events and inter-current illnesses?		
	Is the process and duration of follow-up of adverse events acceptable?		
10.	*STATISTICS		
	Is there an acceptable statistical plan and methods for data analysis?		
	Is there sufficient information on the selection of subjects to be included in analysis?		
11.	**CONFIDENTIALITY AND SECURITY OF SOURCE DOCUMENTS AND STUDY DATA		
	Is there acceptable means for protecting privacy and confidentiality of personal information?		
	Are subjects given access to the personal information and study data?		
	Is there acceptable duration and means of storage and archival of medical records and study data?		
	Is study data destroyed after period of storage?		
12.	****FINANCE AND INSURANCE		
	Is the insurance or indemnity letter from sponsor acceptable?		
13.	*PUBLICATION POLICY		
	Is the publication policy suitable for protecting the confidentiality of subjects' personal information?		

	ITEMS	State (Y) for 'Yes', (N) for 'No', (NR) if not relevant, (NS) if not sure, (NC) if not complete	COMMENTS
14.	**INVOLVEMENT OF VULNERABLE SUBJECTS		
	Are minors involved as subjects?		
	If minors are involved, is there appropriate assent and parental agreement form?		
	Is there any involvement of other vulnerable subjects?		
	Is there appropriate protection for the vulnerable subjects?		
15.	MISCELLANEOUS		
	Is the grammar and language acceptable?		

ADDITIONAL DOCUMENTS REQUIRED FROM INVESTIGATOR (if any):
OTHER COMMENTS (if any):

RECOMMENDATIONS:

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

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3) Decision: (tick mark what is appropriate)

☐	Approve without modifications
☐	Minor modifications/explanations required
☐	Major modifications/explanations required
☐	Not approved

Mandatory for:
*Clinician
**Lay person, Social Scientist
***Basic Scientist
****Legal Expert

Signature with date

Primary Reviewer: **Yes/ No**