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

CHECKLIST FOR REVIEWERS ON INFORMED CONSENT DOCUMENT

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

1	Essential Elements	Observation [Present/ not present/ not applicable]
	Statement 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	
	Description of any reasonably foreseeable risks or discomforts to the subject	
	Description of any benefits to the subject or others reasonably expected from research. If no benefit is expected subject should be made aware of this.	
	Disclosure of specific appropriate alternative procedures or therapies available to the subject.	
	Statement describing the extent to which confidentiality of records identifying the subject will be maintained and who will have access to subject'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 subject in the event of a trial-related injury	
	An explanation about whom to contact for trial related queries, rights of subjects and in the event of any injury	
	The anticipated prorated payment, if any, to the subject for participating in the trial subject's responsibilities on participation in the trial	
	Statement that participation is voluntary, that the subject 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	

	Statement that there is a possibility of failure of IP to provide intended therapeutic effect	
	Statement that in case of placebo controlled trials, the placebo administered to the subjects shall not have any therapeutic effect	
2	**Additional elements, which may be required**	
	Statement of foreseeable circumstances under which the subject's participation may be terminated by the Investigator without the subject's consent	
	Additional costs to the subject that may result from participation in the study	
	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by subject	
	Statement that the subject or subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the subject's willingness to continue participation will be provided	
	A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable	
	Approximate number of subjects to be enrolled in the study	
3	**Any other pertinent information**	

Signature with date

Primary Reviewer: **Yes/ No**