Annexure 5
Initial Review Submission Form for Research Proposal

Project no. _____(to be alloted by the office)

1. Principal Investigator_____ Mobile _____ E-mail_____

2. Project submitted under (Tick appropriately)

a. Inital Review Application
b. Resubmission of Study with Corrections
c. Protocol Amendment or any other amendments
d. Interim Status Reports
e. Study Completion / Termination

3. Full Title of research Project:_____

_____

4. Name of Principal Investigators/ co-investigators with designation and department	Role & Responsibility *(choose from list A to Q)	Conflict of interest Yes /NO If Yes Please specify	Signature & Date
4.a			
4.b			
4.c			
4.d			
4.e			

* Choose From the Following list

A. Concept B. Design C. Screening of patients/participants D.Selection &Recruitment and consenting of patients E. Laboratory investigations F. Laboratory report interpretation G. Treatment decision H. Patient evalution I. AE and SAE management, evalution and reporting	J. Examination of patients on follow-up K. Data collection and monitoring of data L. Interpretation of data M. Statistical analysis &Interpretation. N. Maintaining patients/participants file and master file of project O. Drafting Final report P. Publication Q. Any other, please specify

5. Number of Ongoing Projects with Principal Investigator _____
(not to exceed 5)

1. Type of Trial / Study _____
2. Tick the appropriate one:
   a. Uncontrolled Trials / Controlled Trial
   b. Single Centre / Multi centre (IEC Clearance must be provided)
   c. Funding Yes / No
   d. If Yes Institutional / Pharmaceutics/ Industry / NGO / Any other

7. Objectives of the study	1	
	2	
	3	

	4	
8. Justification for conduct of this study		
9. Materials and methods	9.1 Number of Patients/ Participants	
	9.2 Inclusion criteria	Justification
	a)	
	b)	
	c)	
	d)	
	9.3 Exclusion criteria	Justification
	a)	
	b)	
	c)	
	d)	
	9.4 Control (s)	
	9.5 Study Design	
	9.6 Investigations specifically related to project	
	9.7 Who will bear the cost of investigation Patient/ Institution/ Sponsor/ Principal Investigator	
	9.8 Permission to use copyrighted Questionaire/proforma	
	9.9 Approximate duration of project	
10. Procedure to maintain confidentiality of subject		
11. Questionnaire / proforma	Attached English version Attached Local Langauge version	
12. Participant informed Consent Form and Information sheet	Attached English version Attached Local Langauge version	
13. Attached documents	1 Covering letter, through proper channel. 2 Copy of the detailed protocol 3 Brief CV of Investigators (including No. of projects with Principal Investigator) 4 In case of multicentric study,IEC clearance of other centres must be provided	