## 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 REVIEW OF CLINICAL TRIAL AGREEMENT (CTA)**

Name of reviewer	
Designation in IEC	
Protocol ID	
Sponsor	
Principal Investigator	

Serial	Details	Observation
No.		[Present/ not present]
1.	Requisite definitions	
2.	Obligations	
3.	Clinical trial governance and compliance	
4.	Liabilities, indemnification and insurance	
5.	Clinical trial subject recruitment and enrollment	
6.	Quality assurance and control	
7.	Handling of investigational products	
8.	Confidentiality	
9.	Intellectual property	
10.	Publicity	
11.	Publication and authorship	
12.	Term and termination	
13.	Financial obligations	
14.	Misconduct and debarment	
15.	Disclosure of financial interest	
16.	Force Majeure	
17.	Relationship between the parties	
18.	Survival of clauses	
19.	Governing laws and dispute resolution	