Drug Trial Ethics Committee (DTEC)

PI: _____ Department: _____

Co-I_____ Department: _____

Protocol Id: ..... Phase..... Sponsor: ..... CRO .....

Checklist (List of Essential Documents)

	(Please Tick)
1. EC fees receipt (as per SOP)	
2. Undertaking by PI	
3. CV, MRC, GCP Certificates of Principal Investigator and Co-investigators	
4. Investigator's Brochure (IB) Ver. _____	
5. CRFs (Case Report Forms) Ver. _____	
6. Study protocol Ver. _____	
7. List of trials conducted (Recruitment open/follow up completed/in closeout process)	
8. Letter from PI to declare the Phase and regulatory authorities (DCGI, HMC, ICMR) of the Study	
9. ICF in languages (English☐, Hindi☐, Punjabi☐) Ver. _____	
10. Audio/Visual Recording Consent Form (English☐, Hindi☐, Punjabi ☐) - If mandated by DCGI	
11. DCGI approval Dt: _____	
12. Import/Export License (where applicable)	
13. Serious Adverse Events at any other site where study is going on	
14. CTA (Clinical Trial Agreement) Draft along with Budget sheet of the trial	
15. Complete Insurance Policy of the trial along with Insurance Certificate and schedule showing the name of the Hospital / Principal Investigator's	
16. Name of study team members along with photo copies of their I-Card	
17. List of staff having access to patient identifiers	
18. Clinical Trial Registry of India (CTRI) Number	
19. Self Certificate for Current Study Status	
20. Self Declaration to Submit complete report on study completion	
21. Recruitment Strategies	
22. Proposed delegation log of all study staff	

For DTEC Office use only

Remarks:

Signature