AX2-V6.1/SOP03/V6.1

Checklist of Documents

Item No.	Mandatory Documents	Yes	No	NA
1.	IEC processing fee **(applicable for pharma sponsored trials)**			
2.	Project Submission Form (both hard and soft copies) duly signed by the Principal Investigator			
3.	**A.** Grouping of Project			
4.	**B.** Project Fact Sheet Investigators Declaration Conflict of Interest Consent of Head of the PI's Department Consent from Working Group			
5.	**C.** Project Submission Overview			
6.	**D.** Budget Sheet for the Proposed Study Detailed Budget for the Proposed Study			
7.	Study Protocol			
8.	Lay summary			
9.	Participant Information Sheet & Informed consent forms (ICFs) in English, Marathi & Hindi (and if required any other language)			
10.	Back translations of ICFs (not mandatory for Hindi and Marathi)			
11.	Application for waiver of consent			
12.	Case Record Form			
13.	Questionnaire			
14.	Investigator Brochure			
15.	Package insert/label			
16.	Insurance policy			
17.	DCGI approval letter/ DCGI submission letter			
18.	NOC from DCGI /ICMR/HMSC/ DAE Security and Sensitivity Clearance			
19.	Undertaking By The Investigator			
20.	Clinical Trial Agreement (CTA)/Memorandum of Understanding(MOU)/Material Transfer Agreement(MTA) if applicable Contract budget should be included in the CTA(if applicable)			
21.	Brief resume of Principal Investigators and Co-investigators (1 Page each)			
22.	Copy of Good Clinical Practice training certificate for all investigators			

23.	MMC of Principal Investigators and Co-investigators			
24.	Any Other			