**AX2-V6/SOP03/V6**



**Checklist of Documents**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Item No.** | **Mandatory Documents** | **Yes** | **No** | **NA** |
|  | IEC processing fee **(applicable for pharma sponsored trials)** |  |  |  |
|  | Project Submission Form (both hard and soft copies) duly signed by the Principal Investigator |  |  |  |
|  | 1. Grouping of Project
 |  |  |  |
|  | 1. Project Fact Sheet

 Investigators Declaration Conflict of Interest Consent of Head of the PI’s Department Consent from Working Group |  |  |  |
|  | 1. Project Submission Overview
 |  |  |  |
|  | 1. Budget Sheet for the Proposed Study

 Detailed Budget for the Proposed Study |  |  |  |
|  | Study Protocol |  |  |  |
|  | Lay summary |  |  |  |
|  | Participant Information Sheet & Informed consent forms (ICFs) in English, Marathi & Hindi (and if required any other language) |  |  |  |
|  | Back translations of ICFs (not mandatory for Hindi and Marathi) |  |  |  |
|  | Application for waiver of consent |  |  |  |
|  | Case Record Form |  |  |  |
|  | Questionnaire |  |  |  |
|  | Investigator Brochure |  |  |  |
|  | Package insert/label |  |  |  |
|  | Insurance policy |  |  |  |
|  | DCGI approval letter/ DCGI submission letter |  |  |  |
|  | NOC from DCGI /ICMR/HMSC |  |  |  |
|  | Undertaking By The Investigator |  |  |  |
|  | Clinical Trial Agreement (CTA)/Memorandum of Understanding(MOU)/Material Transfer Agreement(MTA) if applicable |  |  |  |
|  | Brief resume of Principal Investigators and Co-investigators (1 Page each) |  |  |  |
|  | Copy of Good Clinical Practice training certificate for all investigators |  |  |  |
|  | MMC of Principal Investigators and Co-investigators |  |  |  |
|  | Any Other |  |  |  |