

**List of Documents to be submitted to IEC for Drug Trial Protocol approval (10 copies of each document):-**

1. Checklist form for submission of research project.
2. Application forwarded by the HOD *with signature and stamp*
3. Index of documents with stickers at appropriate places
4. Recommendation letter from Departmental Scientific Committee consisting of three faculty members other than Principal Investigator and Co-investigator *with signature, stamp & date.*
5. Acceptance Letter from the sponsor
6. Summary of the protocol
7. List of study teams with signature and stamp of all investigators.
8. C.V of the Principal Investigator & Co-Investigators (*including details of ongoing research projects*, date of start and duration, source and amount of funding)
9. GCP Certificate of PI
10. DCGI clearance
11. Indemnity Bond/Insurance Coverage
12. Protocol proper
13. Patient Information Sheet (Hindi & English) (This should preferably be in proposed format and **Must include:** i) Plans for publication of results- positive or negative while maintaining privacy and confidentiality of study participants ii) Statement describing compensation for study participation including expenses and access to medical care to be given to research participants)
14. Written Informed Consent form in Hindi & English or any other language applicable.
15. Assent sheet (Hindi & English)
16. Statement of conflict of interest, if any.
17. An agreement to report Serious Adverse Events (SAE) to IEC
18. Funding/financial disclosure & Budget details
19. Crossed cheque/ Draft worth Rs.25000/- in the name of CNBC, Society for Promotion of Medical Research as processing fee.
20. Clinical Trial Agreement (CTA)
21. CTRI Registration number for the study
22. Soft copy of approved protocol (PDF format in CD)
23. Contact no. & E-mail ID

**List of Documents to be submitted to IEC for Funded Research Project Protocol approval (10 copies of each document):-**

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14. Assent sheet (Hindi & English)
15. Statement of conflict of interest, if any.
16. An agreement to report Serious Adverse Events (SAE) to IEC
17. Funding/financial disclosure & Budget details
18. Crossed cheque/ Draft worth Rs.10,000/- in the name of CNBC, Society for Promotion of Medical Research as Processing fee
19. CTRI Registration number for the study
20. Soft copy of approved protocol (PDF format in CD)
21. Contact no. & E-mail ID

**List of Documents to be submitted to IEC for Non-Funded Research Project Protocol approval (10 copies of each document):-**

22. Checklist form for submission of research project.
23. Application forwarded by the HOD *with signature, stamp and date.*
24. Index of documents with stickers at appropriate places
25. Recommendation letter from Departmental Scientific Committee consisting of three faculty members other than Principal Investigator and *Co-investigator with signatures, stamp and date.*
26. Summary of the protocol
27. List of study teams *with signature and stamp of all investigators.*
28. C.V of the Principal Investigator & Co-Investigators (*including details of ongoing research projects*, date of start and duration, source and amount of funding)
29. Protocol proper
30. Patient Information Sheet (Hindi & English) (This should preferably be in proposed format and **Must include:** i) Plans for publication of results- positive or negative while maintaining privacy and confidentiality of study participants ii) Statement describing compensation for study participation including expenses and access to medical care to be given to research participants)
31. Written Informed Consent form in Hindi & English or any other language applicable.
32. Assent sheet (Hindi & English)
33. Statement of conflict of interest, if any.
34. An agreement to report Serious Adverse Events (SAE) to IEC
35. CTRI Registration number for the study (if applicable)
36. Soft copy of approved protocol (PDF format in CD)
37. Contact no. & E-mail ID