

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

Academic Research Protocol Submission checklist for IEC CNBC

Submission Date:

Name of PI:

Designation, Department & Phone No:

E-mail id:

Title of Study:

S.No	Documents	Yes/No/NA/Any clarification
1	Application forwarded by the <i>HOD with stamp and date</i> to the Member Secretary IEC	
2	Recommendation letter from Department Scientific Committee consisting of three faculty members other than Principal Investigator and Co-investigator <i>with stamp signature, stamp & date</i>	
3	Summary of the protocol	
4	List of study teams with signature and stamp of all investigator <i>with signature, stamp & date</i>	
5	C.V. of the Principal Investigator & Co-Investigators (<i>including details of ongoing research projects</i> , date of start and duration, source and amount of funding)	
6	Protocol proper	
7	Patient Information Sheet (Hindi & English)	
8	Written Informed Consent form in Hindi & English	
9	Assent sheet (Hindi & English)	
10	Statement of conflict of interest, if any	
11	An agreement to report Serious Adverse Events (SAE) to IEC	
12	CTRI Registration number for the study	
13	Soft copy of approved protocol (PDF format in CD)	

PI Signature

Signature of Member Secretary

Research Protocol (for Non Funded Project) Submission Checklist for IEC CNBC

Submission Date:

Name of PI:

Designation, Department & Phone No:

E-mail ID

Title

S. No.	Documents	Yes/No/NA/Any clarification
1	Application forwarded by the HOD with Signature, stamp and date	
2	Recommendation letter from Department Scientific Committee consisting of three faculty members other than Principal Investigator and Co- investigator with signature, stamp & date.	
3	Index of documents with stickers at appropriate places	
4	Summary of the Protocol	
5	List of study teams with signature and stamp of all investigator with signature, stamp and date	
6	C.V of the Principal Investigator & Co-Investigator (including details of ongoing research projects, date of state and duration, source and amount of funding)	
7	Protocol proper	
8	Patient Information Sheet (Hindi & English)	
9	Written Informed Consent form in Hindi & English	
10	Assent sheet (Hindi & English)	
11	Statement of Conflict of interest, if any.	
12	An agreement to report Serious Adverse Events (SAE) to IEC	
13	CTRI Registration Number for the study (if applicable)	
14	Soft copy of approved protocol (PDF format in CD)	

PI Signature

Signature of Member Secretary

Research Protocol (for Funded Project) Submission Checklist for IEC CNBC

Submission Date:

Name of PI:

Designation, Department & Phone No:

E-mail ID

Title

S. No.	Documents	Yes/No/NA/Any clarification
1	Application forwarded by the HOD with Signature, stamp and date	
2	Recommendation letter from Department Scientific Committee consisting of three faculty members other than Principal Investigator and Co- investigator with signature, stamp & date.	
3	Acceptance letter from the sponsor	
4	Summary of the Protocol	
5	List of study teams with signature and stamp of all investigator with signature, stamp and date	
6	C.V of the Principal Investigator & Co-Investigator (including details of ongoing research projects, date of state and duration, source and amount of funding)	
7	Protocol proper	
8	Indemnity bond/Insurance coverage	
9	Patient Information Sheet (Hindi & English)	
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13	An agreement to report Serious Adverse Events (SAE) to IEC	
14	Funding/Financial disclosure & Budget details	
15	Crossed cheque/Draft worth Rs. 10,000/- in the name of CNBC, Society for promotion for Medical Research as processing fee	
16	CTRI Registration Number for the study (if applicable)	
17	Soft copy of approved protocol (PDF format in CD)	

PI Signature**Signature of Member Secretary**