## **CHECKLIST**

## to verify completeness of documents submitted to IEC-AIIMS Raipur (Version 3.1 - updated on 23.04.2025)

Proposal No (to be filled by IEC)	:	AIIMSRPR/IEC/
Title of the Project:		
(to be filled by Principal Investigator)		

	Documents	To be filled by the Investigator			To be verified
Sr. No.	Documents		No	NA	by IEC office
1	Covering Letter forwarded from the Head of the Department and Head of the Institute				
2	Approval Letter from Institute Research Cell, AIIMS Raipur				
3	Curriculum vitae of Principal investigator and Co- investigators				
4	Form 2 with sign and seal of all investigators				
5	Research proposalas per Form 1A with cover page and index(Research proposal must be signed by Principal Investigator, Co-investigator(s) with date)				
6	Case Record Form / Questionnaires / Tools				
7	Participant / Patient information sheet English and Hindi/other local language.				
8	Consent form in English and Hindi/other local language.  (Tick applicable form as per your project)  i. Form 3A – Consent Form  ii. Form 3AA - Consent Form for nonfunded Project  iii. Form 3B – Consent Form-LAR  iv. Form 3BB - LAR consent form for nonfunded Project				
9	Assent form in English and Hindi /other local language, if applicable.				
10	Form 4 – Application form for expedited review.				
11	Form 5 – Application form for Exemption from Review.				
12	Form 6 – Application form for clinical trials.				
13	Form 7 – Application form for Socio-Behavioral and Public Health Research.				
14	Undertaking to report all Serious Adverse Event (SAE) to IEC-AIIMS Raipur (if applicable).				
15	Undertaking to comply with Good Clinical Practices (GCP) guidelines for human studies and study is not yet initiated.				
16	Waiver and undertaking for retrospective access to sample/data.				
17	Good Clinical Practices (GCP) training certificate				
18	HMSC/DCGI/DBT/BARC clearance if obtained(One Copy)				
19	In case of institutional collaboration, relevant documents through proper channel (One Copy)				
20	Definite undertaking as to who will bear the expenditure of injury related to the project(One Copy)				
21	Permission to use copyrighted Questionnaire/Proforma(One Copy)				

22	Investigator should provide undertaking what they will do the leftover sample tissue(One Copy)		
23	Investigator Broucher		
24	DCGI approval letter		
25	CTRI registration document		
26	Insurance Certificate		
27	Draft Clinical Trial Agreement		
28	Patient Diary		
29	Other IEC approval letter  Note: (1) If approval from more than one Ethics Committee, mention number and attach all approval letter. (2) If rejected by any Ethics Committee, please attach comments of Ethics Committee.		
30	Any other relavantdocument (as per Form 1A, Form 2 or as applicable)		
31	Powerpoint presentation (PPT) as per provided format		
32	Soft copy of all documents submitted on e-EC portal <a href="https://www.iecmanager.org">www.iecmanager.org</a> . Please ensure that <b>latest</b> soft copy is being submitted.		

If any other document, provide the list of documents (attach separate sheet) to be submitted with this research proposal.

Signature of Principal Investigator with date & Seal