**CHECKLIST**

 **to verify completeness of documents submitted to IEC-AIIMS Raipur**

**(Version 3.1 - updated on 16.08.2023)**

**Proposal No : AIIMSRPR/IEC/\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

(to be filled by IEC)

**Title of the Project:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(to be filled by Principal Investigator) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| --- | --- | --- | --- |
|  **Sr. No.** | **Documents** | **To be filled by the Investigator** | **To be verified by IEC office** |
| **Yes** | **No** | **NA** |
| 1 | Covering Letter forwarded from the Head of the Department  |  |  |  |  |
| 2 | Approval Letter from Reseach Cell / PG Thesis Review Committee, AIIMS Raipur/ICMR approval  |  |  |  |  |
| 3 | Curriculum vitae of Student/Principal investigator and Guide/Co-guide(s)/Co-investigators  |  |  |  |  |
| 4 | Form 2 with sign and seal of all investigators/Guide/Co-guide(s) |  |  |  |  |
| 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)1. Form 3A – Consent Form
2. Form 3AA - Consent Form for nonfunded Project
3. Form 3B – Consent Form-LAR
4. 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 | Good Clinical Practices (GCP) training certificate  |  |  |  |  |
| 17 | HMSC/DCGI/DBT/BARC clearance if obtained(One Copy) |  |  |  |  |
| 18 | In case of institutional collaboration, relevant documents through proper channel (One Copy) |  |  |  |  |
| 19 | Definite undertaking as to who will bear the expenditure of injury related to the project(One Copy) |  |  |  |  |
| 20 | Permission to use copyrighted Questionnaire/Proforma(One Copy) |  |  |  |  |
| 21 | Investigator should provide undertaking what they will do the leftover sample tissue(One Copy) |  |  |  |  |
| 22 | Investigator Broucher |  |  |  |  |
| 23 | DCGI approval letter |  |  |  |  |
| 24 | CTRI registration document |  |  |  |  |
| 25 | Insurance Certificate |  |  |  |  |
| 26 | Draft Clinical Trial Agreement |  |  |  |  |
| 27 | Patient Diary  |  |  |  |  |
| 28 | 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. |  |  |  |  |
| 29 | Any other relavantdocument (as per Form 1A, Form 2 or as applicable)  |  |  |  |  |
| 30 | Powerpoint presentation (PPT) as per provided format |  |  |  |  |
| 31 | Soft copy of all documents submitted on e-EC portal [www.iecmanager.org](http://www.iecmanager.org). Please ensure that **latest** soft copy is being submitted. |  |  |  |  |

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

Signature of Principal Investigator with date & Seal