**Check List for Protocol Submission**

**Check List of Documents for Protocol Submission to Institutional Ethics Committee to be filled in by study team.**

\* Compulsory documents

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **SN** | **Document** | **Yes** | **No** | **NA** | **Comments** |
|  | \*Cover Letter to Member Secretary/ Chairperson. |  |  |  |  |
| 1 | \*Project Protocol in prescribed format  |  |  |  |  |
| 2 | \*Summary/Abstract of protocol (in not more than 500 words). |  |  |  |  |
| 3 | \*Ethical Consideration & justification (Benefits, risk, Confidentiality) |  |  |  |  |
| 4 | \*Data management  |  |  |  |  |
| 5 | \*Informed consent Part 1 (Patient information sheet) in English, |  |  |  |  |
| 6 | \*Informed consent Part 1 (Patient information sheet) in Regional languages (Hindi and/or Urdu) |  |  |  |  |
| 7. | \*Informed consent document Part 2 in English, |  |  |  |  |
| 8. | \*Informed consent documents Part 2 in Regional languages (Hindi and/or Urdu) |  |  |  |  |
| 9. | \*Research participants Questionnaire/s |  |  |  |  |
| 10. | Current Status of Ongoing Studies approved by IEC and conducted by PI (title, no of participant, SAE at the site ) |  |  |  |  |
| 11 | Ethics Committee clearance of other centers |  |  |  |  |
| 12 | Brief current curriculum vitae of PI and Co PI. (Compulsory for regulatory studies) |  |  |  |  |
| 13 | Case Record Form (Compulsory for Clinical trials) |  |  |  |  |
| 14 | Research participants recruitment procedures: advertisement, notices  |  |  |  |  |
| 15 | GCP training certificates of all PI and Co-PI (last 3years, (Compulsory for Clinical trials, highly suggested for all studies) |  |  |  |  |
| 16 | Log of delegation of responsibility of the study team members (Compulsory for regulatory studies) |  |  |  |  |
|  | **In case of Clinical Trial / interventional studies** |
| 17 | Information on Clinical Trials |  |  |  |  |
| 18 | Contact Address of Sponsor |  |  |  |  |
| 19 | Total Budget |  |  |  |  |
| 20 | Research participants selection |  |  |  |  |
| 21 | Privacy and confidentiality |  |  |  |  |
| 22 | Use of biological/ hazardous materials |  |  |  |  |
| 23 | Risks & Benefits |  |  |  |  |
| 24 | Data Monitoring |  |  |  |  |
| 25 | Consent |  |  |  |  |
| 26 | Compensation for participation |  |  |  |  |
| 27 | Undertaking by Principal Investigator regarding compensation for study related injury |  |  |  |  |
| 28 | Statement on conflict of interest |  |  |  |  |
| 29 | Insurance  |  |  |  |  |
| 30 | Clinical Trial Agreement for drug trial / Memorandum of Understanding, as applicable, for collaborator & Govt sponsored trials |  |  |  |  |