**Check List for Protocol Submission**

Check List of Documents for Protocol Submission to be filled in by the study team

# Protocol submission for initial review

(Tick accordingly; compulsory documents have to be submitted by ticking in the box marked as ‘Yes’) \* Compulsory documents for initial review.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sr. No.** | **Document** | **Yes** | **No** | **Date by which it will be submitted, if pending** | **N**  **A** |
| 1 | \*Project submission application form duly filled |  |  |  |  |
| a. | Covering Letter |  |  |  |  |
| b. | Project proposal – 5 hard copies |  |  |  |  |
| c. | Project proposal – soft copy sent by e-mail/ CD-ROM/ by uploading |  |  |  |  |
| d. | CV of all investigators (including guide) |  |  |  |  |
| e. | Fee for review |  |  |  |  |
| 2 | Approval of Departmental Review Board  (DRB)(for thesis/dissertations proposals) |  |  |  |  |
| 3 | \*Letter to Member Secretary/ Chairperson |  |  |  |  |
| 4 | \*Summary of protocol ( in not more than  500 words) |  |  |  |  |

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| 5 | \*Protocol |  |  |  |  |
| 6 | \*Informed consent document in English |  |  |  |  |
| 7. | \*Informed consent documents in Regional languages (Total No:- ) |  |  |  |  |
| 8. | Back translation of Informed Consent  Documents (if available) |  |  |  |  |
| 9 | Translation and Back translation certificates (if available) |  |  |  |  |
| 10 | \*Case Record Form |  |  |  |  |
| 11 | \*Research participants recruitment procedures: advertisement, notices (If applicable) |  |  |  |  |
| 12 | \*Patient instruction card, identity card, diary etc. |  |  |  |  |
| 13.a | \*Research Participants Questionnaire/s (If applicable) |  |  |  |  |
| 13.b | Research participants confidentiality statement |  |  |  |  |
| 14 | \*Investigator Brochure |  |  |  |  |
| 15 | \*Insurance certificate and policy |  |  |  |  |
| 16 | \*Investigator’s undertaking to DCG(I) |  |  |  |  |
| 17 | DCG(I) approval [if DCGI approval is awaited, the same is mentioned in the covering letter to the IEC] |  |  |  |  |
| 18 | \*Clinical Trial Agreement for drug trial / Memorandum Of Understanding / Copy of clinical trial protocol Material Transfer Agreement (MTA), as applicable, for collaborator & Govt sponsored trials (draft if final not ready) |  |  |  |  |
| 19 | FDA marketing/manufacturing license for herbal formulations/ nutraceutics |  |  |  |  |
| 20 | Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ ionizing radiations |  |  |  |  |
| 21 | Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy |  |  |  |  |
| 22 | a) Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one copy) Or Memorandum of Understanding (as applicable) |  |  |  |  |

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|  | b) Administrative sanction from the Head of the Institution for the samples to be sent to outside institution (one copy)  Or  Material Transfer Agreement (as applicable) |  |  |  |  |
| 23 | \*Budget Sheet for the Proposed Study  (Format for budget sheet stated below)@ |  |  |  |  |
| 24 | \*Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study coordinator ) (one copy only) |  |  |  |  |
| 25 | \*Ethics Committee clearance of other centres (Total No \_\_\_\_\_) |  |  |  |  |
| 26 | \*Log of delegation of responsibility of the study team members - Sample Format Enclosed) |  |  |  |  |
| 27 | \*Document Receipt Form (one copy only) |  |  |  |  |
| 28 | \*Current Status of Ongoing Studies approved by IEC conducted by principal investigator (information may be submitted separately ) |  |  |  |  |
| 29 | Documentation of clinical trial registration (in Clinical Trial Registry of India) / any other WHO platform registry (whenever applicable) |  |  |  |  |
| 30 | \*GCP training certificates of principal investigator, co-investigator/s, study coordinator/s for interventional clinical trial sponsored by pharmaceuticals companies of training taken in last 5 years (one copy only) |  |  |  |  |
| 31 | Any other Documents submitted |  |  |  |  |

**@Budget Sheet for the Proposed Study**

|  |  |  |
| --- | --- | --- |
| 1 | Title of the Project: |  |
| 2 | Name of Principal Investigator (PI) with signature |  |
| 3 | Designation and address of the PI |  |
| 4 | Names of Co-investigators with department/ institution and signature: |  |
| 5 | Source of funding |  |
|  | Address, phone, fax. E-mail of sponsor with the name of the contact person |  |
| 6 | Total Budget for the entire project in Rs. |  |
| 7 | Duration of the Project in months |  |
| 8 | Proposed date of starting the project |  |
| 9 | Direct payments to investigators, if any |  |
| 10 | Any other benefits to the investigators/department/institution |  |
| 11 | Conflict of Interests, if any |  |
| **Name of PI:** | | **Signature & Date:** |