**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.

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| **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**

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| --- | --- | --- |
| 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:** |