**Initial submission of protocol**

**Sample format of covering letter by Principal Investigator (PI) for initial submission of protocol review for Pharmaceutical & GOVT sponsored / Funded studies.**

Date:

**To**

**Chairperson/The Member Secretary,**

**IEC-AIIMS Raipur**

**Through:** Proper Channel

**Sub:** Submission of clinical trial / trial documents for Ethics Committee review and approval.

**Ref:** Protocol number XXX Version XX dated XXX entitled, “XXXXXXX”.

Dear Sir,

We are conducting a study in our department. XXX sponsor has approached us for the conduct of the abovementioned study. The study will be conducted as per the ICH-GCP, ICMR guidelines and New Drugs Clinical Trial Rule 2019.

**Please find enclosed the following documents for review and approval:**

|  |  |  |
| --- | --- | --- |
| Sr. No. | Document title | Version no. and date |
| 1 |  |  |
| 2 |  |  |

**Also kindly note the following:**

|  |  |  |
| --- | --- | --- |
| 1 | Co-Investigators:  1)  2)  Clinical Research Coordinator:  1)  2) | Signature of co-investigator |
| 2 | If PI is retired/promoted/transferred/suspended/intended to leave the institute(during study period) who will take over the responsibility of PI |  |
| 3 | |  | | --- | | Recruitment Strategy | | 1.  2. |
| 4 | |  | | --- | | Collaboration department signature of HOD required if applicable | |  |
| 5 | |  | | --- | | Study conduct – Sponsor / CRO | |  |
| 6 | |  | | --- | | Funding agency | |  |
| 6a | Intramural – AIIMS Raipur |  |
| 6b | |  | | --- | | Extramural funding (GOVT/NGO/Pharmaceutical industry/International body) | |  |
| 7 | |  | | --- | | Approximate budget per patient and overall budget | |  |
| 8 | |  | | --- | | Name & number of the Indian sites | |  |
| 9 | |  | | --- | | Outside AIIMS Raipur laboratory address (if applicable) | |  |

Note : \* Any funding from outside will not be treated as intramural funded studies.

**Ongoing trial status as PI and as Co-I**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sr No. | Project No. | Title | Recruited Participants | Time given by PI for the project  each day |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |

**Status of trials which are under process as PI and as Co-I**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sr No. | Project No. | Title | Participants to be enrolled | Time given by PI for the projecteach day |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |

With this I would like to request you to review this project and consider for approval.

Thanking you,

Sincerely yours,

Dr. XXXXXXX

Forwarded by Head of the Department

Principal Investigator’s Sign & Seal

Forwarded by Head of the Institute (Director & CEO)