**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 |

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| --- |
| Study conduct – Sponsor / CRO  |

 |  |
| 6 |

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| Funding agency  |

 |  |
| 6a | Intramural – AIIMS Raipur |  |
| 6b |

|  |
| --- |
|  Extramural funding (GOVT/NGO/Pharmaceutical industry/International body)  |

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| 7 |

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| --- |
|  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 projecteach 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)