Form to be filled by the Principal Investigator (PI) for submission

Serial No

(IEC Office)

*(For attachment to each copy of the proposal)*

1. Proposal Title(in capital letters) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. Proposal for PG PhD INTRAMURAL EXTRAMURAL

3. Status NEW / REVISED *(Strike out which is not applicable)*

4. Principal Investigator (*in capital letters*) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(For PG/PhD Dissertations – the student should be the PI)*

Designation of PI \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Correspondence Address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone Number\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email ID \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5. Details of other Investigators/Supervisors

|  |  |  |  |
| --- | --- | --- | --- |
| Name  *(Indicate Supervisor/Chief Supervisor in case of thesis)* | Designation  Qualifications | Correspondence Address  Telephone Number  Email ID | Signature |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**6. Sponsor Information**

(*Tick appropriatelyWrite NA if not applicable)*

Does the study involve an Indian Sponsor? Yes/No

If yes, please indicate if the sponsor is

Government Central/State Details \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Private

Institutional

Does the study involve an international sponsor Yes/No

If yes please provide details

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is this a study sponsored by pharmaceutical industry? Yes/no

If yes, National / Multinational

Please give details,

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Total Budget for the study Rupees \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**7. Type of study**(*Tick appropriately or write NA if not applicable)*

**Type** Animal Study Human Basic Sciences

**Centers** Single center Multi-center

**Type of study**

Descriptive

Cross Sectional Survey Qualitative Research

Analytical

Observational (Cross sectional / Cohort / Case Control)

Experimental (Randomized / Non-randomized)

**8. Clinical Trials**

|  |  |  |
| --- | --- | --- |
| **Drug /Vaccines/Device/Herbal Remedies :**  Does the study involve use of :  Drug Devices Vaccines  Indian Systems of Medicine/ Any other NA  Alternate System of Medicine | | |
| Is it approved and marketed  In India UK & Europe USA  Other countries, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Does it involvea change in use, dosage, route of administration?  **If yes**, whether DCGI’s /Any other Regulatory authority’s  Permission is obtained?  **If yes,** Date of permission : | Yes  Yes | No  No |
| Is it an Investigational New Drug?  **If yes,** IND No: | Yes | No |
| a) Investigator’s Brochure submitted | Yes | No |
| b) *In vitro* studies data | Yes | No |
| c) Preclinical Studies done | Yes | No |
| d) Clinical Study is : Phase I Phase II Phase III Phase IV | | |
| e) Are you aware if this study/similar study is being done elswhere?  **If Yes**, attach details | Yes | No |

**9. Brief description of the proposal**

*Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale*

*(Attach sheet with maximum 500 words)*

**10. Subject Selection**

(*Tick appropriately or write NA if not applicable)*

1. Number of subjects \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Duration of study \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Will the subjects from both genders be recruited for the study Yes / No
   1. If not please give details and reasons
4. Inclusion / Exclusion criteria have been described Yes / No
5. Type of subjects Patients / Healthy Volunteers / Relatives / Students / Animals
6. Are any of the following groups involved in the study
   1. Pregnant Women
   2. Children
   3. Elderly
   4. Fetus
   5. Illiterate
   6. Differently abled
   7. Mentally challenged
   8. Terminally ill
   9. Critically ill
   10. Economically and socially backward groups
7. Does your research involve special groups
   1. Captives or inmates of correctional facilities
   2. Institutionalized inmates
   3. Employees of the institution
   4. Students
   5. Nurses
   6. Dependent staff
   7. Armed forces

**11. Privacy and confidentiality**

(*Tick appropriately or write NA if not applicable)*

1. Does your study involve
   1. Direct Identifiers Yes / No
   2. Indirect identifiers (coding) Yes / No
   3. Completely anonymized or delinked data Yes / No
2. Does your study ensure confidential data handling by staff Yes / No
3. Does your study involve transfer/sharing of data to other investigators outside your institution? If yes, please explain methods to ensure confidentiality

**12. Use of Biological / Hazardous materials**

(*Tick appropriately or write NA if not applicable)*

Does your research involve

1. Use of fetal tissue or abortus Yes / No
2. Use of organs or body fluids Yes / No
3. Use of recombinant or gene therapy Yes / No
   1. If yes, has approval for use of rDNA products been obtained from Department of Biotechnology (DBT) Yes / No
4. Use of pre-existing / stored / left over samples Yes / No
5. Collection for banking or future research Yes / No
6. Use of ionizing radiation / radioisotopes Yes / No
   1. If yes, have you obtained approval for use of radioactive isotopes from Bhaba Atomic Research Centre (BARC) Yes / No
7. Use of infectious / bio-hazardous specimens Yes / No
8. Ensure proper disposal of material Yes / No

**13. Foreign collaboration**

1. Will any sample collected from the patient be sent abroad Yes / No
   1. If yes, please provide justification and details *(attach separately if needed)*
      1. Facility not available in India
      2. Facility not accessible
      3. Facility is available but not being accessed
      4. Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Does your proposal involve foreign collaboration Yes / No
   1. If yes, have you obtained clearance from Health Ministry’s Screening Committee (HMSC) for international collaboration Yes / No

**14. Consent**

1. Indicate the nature of consent being taken in your study
   1. Written
   2. Oral
   3. Audio-visual
   4. Not applicable
2. Has a written consent form been included your submission Yes / No
3. Does the consent form satisfy the following?
   1. Drafted in understandable language Yes / No
   2. Include a statement that the study involves research Yes / No
   3. Include details regarding the sponsor for the study Yes / No
   4. Describe the purpose and procedures for the study Yes / No
   5. Describe the risks and discomforts that may occur due to participation Yes / No
   6. Include the benefits of research and participation (direct/indirect) Yes / No
   7. Involve a statement regarding the compensation for participation Yes / No
   8. Involve statement regarding compensation for study related injury Yes / No
   9. Present alternatives to participation Yes / No
   10. Include details about confidentiality of records Yes / No
   11. Include contact information of the investigators Yes / No
   12. Include a statement indicating that the consent is voluntary Yes / No
   13. Inform patient about right to withdraw at any point during the study Yes / No
   14. Include details about consent for future use of biological material Yes / No
   15. Talk about benefits on future commercialization Yes / No
   16. Describe about the disease condition and prevention Yes / No
4. Who will obtain consent
   1. Principal investigator
   2. Co-investigator
   3. Nurse
   4. Counsellor
   5. Research staff
   6. Any other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. If written consent is not being obtained, please give details

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**15. Advertising**

1. Will there be advertising for recruitment of subjects Yes / No
   1. If yes, then please include a copy of the advertising material
      1. Posters
      2. Fliers
      3. Brochures
      4. Website
      5. Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**16. Risks and Benefits**

1. Is the risk involved in the study reasonable compared to the anticipated benefits Yes / No
2. Is there possibility of discomfort for the participants Yes / No
   1. Physical None / Minimal / More than minimal / High
   2. Social None / Minimal / More than minimal / High
   3. Psychological None / Minimal / More than minimal / High
3. Is there benefit to the participant Yes / No
   1. Direct
   2. Indirect
   3. Benefit to the society
   4. Benefit to the body of science

**17. Data Monitoring**

1. Is there a data and safety monitoring committee / board (DSMB)? Yes / No
2. Is there a plan for reporting adverse events Yes / No
   1. If yes, the reporting will be done to

Sponsor Ethics committee DSMB

* 1. Is there a plan for interim data analysis Yes / No
  2. Are there plans for storage and maintenance of all trial database Yes / No
     1. For how long \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**18. Compensation for participation**

1. Is there compensation for participation in the study? Yes / No
   1. If yes (please give details)
      1. Monetary \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
      2. In kind \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Is there compensation for injury Yes / No
   1. If yes
      1. By sponsor
      2. By investigator
      3. By insurance company
      4. By any other\_\_\_\_\_\_\_

**19. Conflict of interest**

Do you have any conflict of interest in the conduct of this study Yes / No

*(Financial/Non-financial)*

If yes, please give details (*use separate sheets if necessary*)

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**20. Checklistforattacheddocuments**

|  |  |  |  |
| --- | --- | --- | --- |
| Project proposal – 10 Copies | Yes | No | NA |
| Curriculum Vitae of Investigators | Yes | No | NA |
| Brief description of proposal | Yes | No | NA |
| Patient information sheet | Yes | No | NA |
| Informed Consent form | Yes | No | NA |
| Investigator’s brochure for recruiting subjects | Yes | No | NA |
| Copy of advertisements/Information brochures | Yes | No | NA |
| Copy of clinical trial protocol and/or questionnaire | Yes | No | NA |
| Institutional Ethics Committee clearance | Yes | No | NA |
| Institutional Animal Ethics Committee clearance | Yes | No | NA |
| CPCSEA clearance, if any | Yes | No | NA |
| HMSC/DCGI/DBT/BARC clearance if obtained | Yes | No | NA |

Place: Signature & Designation of PI/Co-PI/Collaborator

Date:

**The PI should sign on all the pages of the application**