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

(For attachment to each copy of the proposal)

Ref No:
IEC-
HR/20__/__/__

1. Proposal Title (in capital letters) _____

_____

_____

2. Proposal for PG PHD INTRAMURAL EXTRAMURAL STS

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/Collaborators

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

6. Sponsor Information

(Tick appropriately Write 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/ Alternate System of Medicine ☐ Any other ☐ NA ☐

Is it approved and marketed

In India ☐ UK & Europe ☐ USA ☐

Other countries, specify _____

Does it involve a 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)

a) Number of subjects _____

b) Duration of study _____

c) Will the subjects from both genders be recruited for the study Yes / No

   a. If not please give details and reasons

d) Inclusion / Exclusion criteria have been described Yes / No

e) Type of subjects Patients / Healthy Volunteers / Relatives / Students / Animals

f) Are any of the following groups involved in the study

   a. Pregnant Women
   b. Children
   c. Elderly
   d. Petus
   e. Illiterate
   f. Differently abled
   g. Mentally challenged
   h. Terminally ill
   i. Critically ill
   j. Economically and socially backward groups

g) Does your research involve special groups

   a. Captives or inmates of correctional facilities
   b. Institutionalized inmates
   c. Employees of the institution
   d. Students
   e. Nurses
   f. Dependent staff
   g. Armed forces

11. Privacy and confidentiality

(Tick appropriately or write NA if not applicable)

a) Does your study involve

   a. Direct Identifiers Yes / No
   b. Indirect identifiers (coding) Yes / No
   c. Completely anonymized or delinked data Yes / No

b) Does your study ensure confidential data handling by staff Yes / No

c) 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

a) Use of fetal tissue or abortus Yes / No

b) Use of organs or body fluids Yes / No

c) Use of recombinant or gene therapy Yes / No

   a. If yes, has approval for use of rDNA products been obtained from Department of Biotechnology (DBT) Yes / No

d) Use of pre-existing / stored / left over samples Yes / No

e) Collection for banking or future research Yes / No

f) Use of ionizing radiation / radioisotopes Yes / No

   a. If yes, have you obtained approval for use of radioactive isotopes from Bhaba Atomic Research Center (BARC) Yes / No

g) Use of infectious / bio-hazardous specimens Yes / No

h) Ensure proper disposal of material Yes / No

13. Foreign collaboration

a) Will any sample collected from the patient be sent abroad Yes / No

   a. If yes, please provide justification and details *(attach separately if needed)*

      i. Facility not available in India

      ii. Facility not accessible

      iii. Facility is available but not being accessed

      iv. Others _____

b) Does your proposal involve foreign collaboration Yes / No

   a. If yes, have you obtained clearanece from Health Ministry's Screening Committee (HMSC) for international collaboration Yes / No

14. Consent

a) Indicate the nature of consent being taken in your study

a. Written
b. Oral
c. Audio-visual
d. Not applicable

b) Has a written consent form been included your submission Yes / No

c) Does the consent form satisfy the following?

a. Drafted in understandable language Yes / No
b. Include a statement that the study involves research Yes / No
c. Include details regarding the sponsor for the study Yes / No
d. Describe the purpose and procedures for the study Yes / No
e. Describe the risks and discomforts that may occur due to participation Yes / No
f. Include the benefits of research and participation (direct/indirect) Yes / No
g. Involve a statement regarding the compensation for participation Yes / No
h. Involve statement regarding compensation for study related injury Yes / No
i. Present alternatives to participation Yes / No
j. Include details about confidentiality of records Yes / No
k. Include contact information of the investigators Yes / No
l. Include a statement indicating that the consent is voluntary Yes / No
m. Inform patient about right to withdraw at any point during the study Yes / No
n. Include details about consent for future use of biological material Yes / No
o. Talk about benefits on future commercialization Yes / No
p. Describe about the disease condition and prevention Yes / No

d) Who will obtain consent

a. Principal investigator
b. Co-investigator
c. Nurse
d. Counsellor
e. Research staff
f. Any other _____

e) If written consent is not being obtained, please give details

_____

15. Advertising

a) Will there be advertising for recruitment of subjects Yes / No

a. If yes, then please include a copy of the advertising material

i. Posters
ii. Fliers
iii. Brochures
iv. Website
v. Others _____

16. Risks and Benefits

a) Is the risk involved in the study reasonable compared to the anticipated benefits Yes / No

b) Is there possibility of discomfort for the participants Yes / No

a. Physical None / Minimal / More than minimal / High
b. Social None / Minimal / More than minimal / High
c. Psychological None / Minimal / More than minimal / High

c) Is there benefit to the participant Yes / No

a. Direct
b. Indirect
c. Benefit to the society
d. Benefit to the body of science

17. Data Monitoring

a) Is there a data and safety monitoring committee / board (DSMB)? Yes / No

b) Is there a plan for reporting adverse events Yes / No

a. If yes, the reporting will be done to

Sponsor Ethics committee DSMB

b. Is there a plan for interim data analysis Yes / No
c. Are there plans for storage and maintenance of all trial database Yes / No

i. For how long _____

18. Compensation for participation

a) Is there compensation for participation in the study? Yes / No

a. If yes (please give details)

i. Monetary _____
ii. In kind _____

b) Is there compensation for injury Yes / No

a. If yes

i. By sponsor
ii. By investigator
iii. By insurance company
iv. 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*)

20. UNDERTAKING BY PRINCIPAL INVESTIGATOR

Title of Study:
_____
_____
_____

Name of Principal Investigator:_____
Designation and Affiliation:_____

_____

I will ensure that **no participant will be made to pay for any investigations ordered during the said research work**.

AND

I declare that the **questionnaires/tools that are being used in above research are not copyrighted**

or

I have obtained due permissions for use of copyrighted tools/questionnaires in my research.

(Please select the statement relevant to your study)

Signature of PI
_____(Name:_____)

Date

Signature of Supervisor (for PG thesis/STS projects)
_____(Name:_____)
Date

21. Checklist for attached documents

Project proposal – 13 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: