



INSTITUTIONAL ETHICS COMMITTEE – HUMAN RESEARCH (IEC-HR)
UNIVERSITY COLLEGE OF MEDICAL SCIENCES
UNIVERSITY OF DELHI, DELHI 110095

Form to be filled by the Principal Investigator (PI) for submission
(For attachment to each copy of the proposal)

Serial No
(IEC Office)

1. **Proposal Title** (in capital letters) _____

2. **Proposal for** PG PHD INTRAMURAL EXTRAMURAL STS
OTHER _____

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 <i>(Indicate Supervisor/Chief Supervisor in case of thesis)</i>	Designation Qualifications	Correspondence Address Telephone Number Email ID	Signature



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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)



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8. Clinical Trials

Drug /Vaccines/Device/Herbal Remedies :		
Does the study involve use of :		
Drug <input type="checkbox"/>	Devices <input type="checkbox"/>	Vaccines <input type="checkbox"/>
Indian Systems of Medicine/ Alternate System of Medicine <input type="checkbox"/>	Any other <input type="checkbox"/>	NA <input type="checkbox"/>
Is it approved and marketed		
In India <input type="checkbox"/>	UK & Europe <input type="checkbox"/>	USA <input type="checkbox"/>
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	No
	Yes	No
Is it an Investigational New Drug? If yes , IND No:	Yes	No
a) Investigator's Brochure submitted	Yes	No
b) <i>In vitro</i> studies data	Yes	No
c) Preclinical Studies done	Yes	No
d) Clinical Study is : Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/>		
e) Are you aware if this study/similar study is being done elsewhere? 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)*



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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 | g. Mentally challenged |
| b. Children | h. Terminally ill |
| c. Elderly | i. Critically ill |
| d. Foetus | j. Economically and socially backward groups |
| e. Illiterate | |
| f. Persons with disabilities | |
- g) Does your research involve special groups
- | | |
|---|--------------------|
| a. Captives or inmates of correctional facilities | d. Students |
| b. Institutionalized inmates | e. Nurses |
| c. Employees of the institution | 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



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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 (<i>attach separately if needed</i>) | |
| 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 clearance from Health Ministry's Screening Committee (HMSC) for international collaboration | Yes / No |



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14. Consent

- a) Indicate the nature of consent being taken in your study
- | | |
|------------|-------------------|
| a. Written | c. Audio-visual |
| b. Oral | 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
- _____



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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 | iii. Brochures |
| ii. Fliers | 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 | c. Benefit to the society |
| b. Indirect | 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 | iii. By insurance company |
| ii. By investigator | iv. By any other _____ |



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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. Checklist for attached documents (11 copies of the following AND Soft copy)

1. Detailed Project proposal	Yes	No	NA
2. Curriculum Vitae of Investigators	Yes	No	NA
3. Project Summary in one page	Yes	No	NA
4. Patient information sheet in English	Yes	No	NA
5. Patient information sheet in Hindi/Vernacular	Yes	No	NA
6. Informed Consent form in English	Yes	No	NA
7. Informed consent form in Hindi/Vernacular	Yes	No	NA
8. Data Collection Form/Patient Record Form	Yes	No	NA
9. Copy of advertisements/Information brochures	Yes	No	NA
10. Copy of clinical trial protocol and/or questionnaire	Yes	No	NA
11. Institutional Ethics Committee clearance from other institutions if multi-center study	Yes	No	NA
12. Institutional Animal Ethics Committee clearance if needed	Yes	No	NA
13. HMSC/DCGI/DBT/BARC clearance if obtained	Yes	No	NA

Place:
Date:

Signature & Designation of PI/Co-PI/Collaborator



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Checklist for attached documents (to be filled by the Research Cell)

Document	Checked	Comments
1. Detailed Project proposal		
2. Curriculum Vitae of Investigators		
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Checked by _____