INSTITUTIONAL ETHICS COMMITTEE – HUMAN RESEARCH (IEC-HR)
UNIVERSITY COLLEGE OF MEDICAL SCIENCE, UNIVERSITY OF DELHI, DELHI -95
E-mail ID: iechrucms@gmail.com ; Office: Room 303, 3rd Floor College Building UCMS.
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IEC-HR Proposal No.: IECHR -20 - -

Form to be filled & 1PDF containing all attachments mailed by the Principal Investigator (PI) only & 2 hard copies submitted

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

_____

2. **Proposal for** **PG/ PHD/ Intramural/ Extramural/ STS/ Others** _____
3. **Status** **NEW / REVISED**
4. **Principal Investigator** (*in capital letters*) ____ _____

(For STS/PG/PhD proposals – the student should be the PI)

Designation of PI ___ _____

Correspondence Address __ _____

Phone Number of PI _____ Email ID of PI ----------

5. **Special Request to be considered for (Tick ONE)** (see details on pages 10-12)

☐ **EXEMPTION FROM REVIEW**

☐ **EXPEDITED REVIEW**

☐ **WAIVER OF CONSENT**

Provide justification for the above request: …….

6. **Details of Other Investigators (Supervisors, co-supervisors, co-investigators):**

Name	Designation Qualification	Telephone No E mail ID	Signature

7. 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 _____

8. 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 / Qualitative Research / Case Series / Descriptive cohort

Analytical

Observational (Cross sectional / Cohort / Case Control)

Experimental (Randomized / Non-randomized)

Any other (please mention)

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)

10. 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?	Yes	No
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission : Copy of permission letter attached	Yes	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 else-where? **If Yes**, attach details	Yes	No

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. Participant Selection (*Tick appropriately or write NA if not applicable*)

a) Number of participants
b) Duration of study
c) Will the participants from all 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 participants Patients / Healthy Volunteers / Relatives / Students / Animals
f) Are any of the following groups selectively involved in the study

i. Pregnant Women
ii. Children
iii. Elderly
iv. Fetus
v. Illiterate
vi. Persons with disabilities
vii. Intellectual Impairment
viii. Terminally ill
ix. Critically ill
x. Economically and socially backward groups
xi Others

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

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 clearance from Health Ministry's Screening Committee (HMSC) for international collaboration Yes / No

14. 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)

If yes, has approval for use of rDNA products been obtained from Dept of Biotechnology (Yes/No)

d) Use of pre-existing samples (Yes/No)

If yes, has re-consent for present research been obtained from the Participant? (Yes/No)

e) Collection for banking for future research on left over samples (Yes/No)

If yes, has consent for banking of left over sample been obtained from the Participant? (Yes/No)

Has type of future research been explained to participant and consent obtained separately for the same? *see Annexure 1* (page 10) (Yes/No)

How does the PI plan to archive the samples?

f) Use of ionizing radiation/radioisotopes (Yes/No)

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

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

h) Ensure proper disposal of material (Yes/No)

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. 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

i. If yes, the reporting will be done to

Sponsor Ethics Committee DSMB

ii. Is there a plan for interim data analysis Yes/ No

iii. Are there plans for storage and maintenance of all trial databases? Yes/No

If yes, for how long?_____

17. Consent and Assent (if applicable)

a) Indicate the nature of consent and/or assent 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	Not applicable	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. Counselor
e. Research staff
f. Any other _____

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

18. Risks and Benefits *(refer Risk categorization table below)*

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

i. Physical less than minimal / Minimal / Low risk / High risk
ii. Social less than minimal / Minimal / Low risk / High risk
iii. Psychological less than minimal / Minimal / Low risk / High risk

c) Is there benefit to the participant Yes / No

i. Direct
ii. Indirect
iii. Benefit to the society
iv. Benefit to the body of science

Risk categorisation

Type of risk	Definition/Description
Less than minimal	Probability of harm or discomfort is nil or not expected
Minimal risk	Probability of harm or discomfort anticipated in the research is not greater than encountered in routine life activities/serious harm or adverse event is unlikely
Minor increase over minimal risk / Low risk	Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. Such research should have a social value. Social risks, psychological harm and discomfort may also fall in this category.
More than minimal / high risk	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk or interventional study.

19. Compensation for participation/TA for visits for study purposes:

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

If yes (please give details) …….

b) Is there compensation for injury? Yes / No

If yes

i. By sponsor
ii. By investigator
iii. By insurance company
iv. By any other_____

20. 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*)

21. Only proposals certified by RPAC/ MRU/ MEU/ Scientific Cell can be submitted to IEC-HR?

Departmental review / PG cell RPAC MRU MEU STS subcommittee

Certificate from RPAC/ MRU/ MEU/ STS sub-committee attached? **Yes / No**

22. Checklist for attached documents (One hard copy AND One soft copy of the following)

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

23. UNDERTAKING BY PRINCIPAL INVESTIGATOR

Title of Study:

Name of Principal Investigator

Designation and Affiliation of PI

I will ensure that **no participant is made to pay for any investigation during the above research work**

and

I declare that **I have not submitted this proposal to ethical committee of GTB hospital for consideration**

and

I declare that the **Questionnaire and Tools used in the above research are not copyrighted**

Or

I have obtained permission for the for the use of Copyrighted Questionnaire /Tools used in my research

(Please select whichever is relevant to your study)

Signature of PI ----------

Name & Designation of PI ---------- Place Date

Signature of Supervisor (for PG thesis & STS) ----------

Name & Designation of Supervisor ---------- Place Date

24. Annexure 1

Certificate of Consent for future use of left over sample

If any of the sample provided for this research is unused or is left over when the research is complete, (tick one choice from each of the following):

Category A

- ☐ I wish my sample to be destroyed immediately.
- ☐ I wish my sample to be destroyed after ……. Years.
- ☐ I give permission for my sample to be stored indefinitely.

Category B

- ☐ I give permission for my sample to be stored and used for future research but only on the same subject as the current research project.
- ☐ I give permission for my sample to be stored and used for future research of any type which has been approved by Institute's RPAC & Ethical committee and reconsented by me.

Category C

- ☐ I want my identity to be removed from my sample.
- ☐ I want my identity to be kept with my sample.

25. PI is required to submit 1 soft copy & 2 hard copies of the proposal at least 15 days prior to the date of IEC meeting. The PI may be required to be present on the day of meeting for any clarifications.

CATEGORIES OF REVIEW: The categories under which the proposals can be considered is listed below (indicative but not necessarily exhaustive):

A. **Consent waiver** can be considered in the following situations:

- research cannot practically be carried out without the waiver and the waiver is scientifically justified
- retrospective studies, where the participants are de-identified / coded or cannot be contacted
- research on anonymized biological samples/data
- certain types of public health studies/surveillance programmes/programme evaluation studies
- research on data available in the public domain
- research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent.
- Attempt should be made to obtain the participant's consent at the earliest.

B. **Exemption from review** can be considered for proposals with less than minimal risk where there are no linked identifiers, for example in the following situations:

- research conducted on data available in the public domain for systematic reviews or meta-analysis
- observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person
- quality control and quality assurance audits in the institution
- comparison of instructional techniques, curricula, or classroom management methods
- consumer acceptance studies related to taste and food quality
- public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

C. **Expedited review** may be considered for *proposals* that pose no more than minimal risk *for example* in the following situations:

- research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples
- research involving clinical documentation materials that are non-identifiable (data, documents, records)
- modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s)
- revised proposals previously approved through expedited review, full review or continuing review of approved proposals
- minor deviations from originally approved research causing no risk or minimal risk
- progress/ annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee
- for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review
- research during emergencies and disasters

D. **Full committee review** will be done for all research proposals presenting more than minimal risk that are not covered under exempt or expedited review; some examples are;

- research involving vulnerable populations, even if the risk is minimal
- research with minor increase over minimal risk
- studies involving deception of participants
- research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee

- amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk
- major deviations and violations in the protocol
- any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment
- research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need
- Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

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