FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY Institutional ETHICS COMMITTEE OF UPUMS, Saifai

Submit one (1) hard copy of the Research Proposal along with Covering letter, a CD/DVD of the proposal and a 'soft copy' along with the following information to the Member Secretary, Institutional Ethics Committee at the IEC office, UPUMS, Saifai.

No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor vetted by the Institution Ethics Committee.

All submissions should be made in the prescribed Format of the IEC with signatures of all the investigators. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Hindi/Concerned local Language, **in a simple layman's language, in a narrative form, directed to Participant/LAR, covering all the points given,** before it can be considered for placing before the IEC. Also ensure that all the pages are numbered.

PROJECT SUBMISSION TIME: SUBMISSIONS WILL BE RECEIVED ON ALL WORKING DAYS. PROPOSALS RECEIVED TILL specified date WILL BE PROCESSED IN THE COMING INSTITUTION ETHICS COMMITTEE MEETING AND THOSE RECEIVED AFTER WILL BE PROCESSED IN THE NEXT INSTITUTION ETHICS COMMITTEE MEETING. ALL MEETINGS OF INSTITUTION ETHICS COMMITTEE WILL BE HELD Quarterly AS FAR AS POSSIBLE. THE FREQUENCY WILL CHANGE DEPENDING UPON THE NUMBER OF PROPOSALS AND WILL BE UPDATED accordingly.

While submitting replies to queries raised by the IEC, the candidates are advised to mention the IEC reference number/s and also attach a copy of the comments of the IEC Moreover if the approval is required in a particular format, the same may be submitted in a CD/DVD.

Amendment Submission: While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway.

(Kindly read the instructions carefully and do abide by the above.)

FORM TO BE FILLED BY THE Research Scholar (UG/PG/PhD/Super speciality) FOR SUBMISSION TO INSTITUTIONAL ETHICS COMMITTEE (IEC), UPUMS, Saifai

(FOR ATTACHMENT TO EACH COPY OF THE PROPOSAL)

Serial No of IEC Management Office:

TITLE OF THE PROJECT: ……...

……..

	Name, Designation, Department	**Mobile No. Email ID**	**Number of Projects already with Investigator**	**Signature**
Research Scholar (UG/PG/PhD/Super speciality)				
Guide				
Co-Guides				

Name, Mobile Number and Email ID should be clearly written.

Sponsor Information :

1. Indian a) Government ☐ Central ☐ State ☐ Institutional ☐

b) Private ☐

2. International Government ☐ Private ☐ UN agencies ☐

3. Industry National ☐ Multinational ☐

Contact Address of Sponsor:

Total Budget:

Who will bear the cost of investigation / implants drugs / contrast: 1.Patient 2.Project 3. Exempted 4. Other Agencies

1.Type of Study : Cross sectional case control cohort Clinical Trial Review

Participating Centre : Single center Multi-centric Others (Specify)

2. Status of Review: New ☐ Revised ☐

Clinical Trials:

Drug /Vaccines/Device/Herbal Remedies:

i. Does the study involve use of:

Drug ☐ Devices ☐

Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐

ii. Is it approved and marketed

In India ☐ UK & Europe ☐ USA ☐

Other countries, specify ☐

iii. 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 :

iv. 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

4. 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):

5. Subject selection:

ii.	Duration of study :		
iii.	Will subjects from both sexes be recruited	Yes	No
iv.	Inclusion / exclusion criteria given	Yes	No
v.	Type of subjects Volunteers Patients		
vi.	Vulnerable subjects Yes No		

(Tick the appropriate boxes)

pregnant women	☐	children	☐	elderly	☐
Fetus	☐	illiterate	☐	handicapped	☐
Mental	☐	terminally ill	☐	seriously ill	☐

i.	Special group subjects	Yes ☐		No ☐	
(Tick the appropriate boxes)					
captives	☐	institutionalized		employees	☐
students	☐	nurses/dependent		armed	☐
any other	☐	staff		forces	☐

6. Privacy and confidentiality

i.	Study involves -	Direct Identifiers	☐
		Indirect Identifiers/coded	☐
		Completely anonymised	☐

ii.	Confidential handling of data by staff	Yes	No
7. Use of biological/ hazardous materials		Yes	No
ii.	Use of organs or body fluids	Yes	No
iii.	Use of recombinant/gene therapy	Yes	No
If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?		Yes	No
iv.	Use of pre-existing/stored/left over samples	Yes	No
v.	Collection for banking/future research	Yes	No
vi.	Use of ionizing radiation/radioisotopes	Yes	No
If yes, has Bhabha Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?		Yes	No
vii.	Use of Infectious/bio hazardous specimens	Yes	No
viii.	Proper disposal of material	Yes	No
ix.	Will any samples collected from the patients be sent abroad?	Yes	No
If Yes, justify with details of collaborators			

a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No

b) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐

Facility in India inaccessible ☐

Facility available but not being accessed. ☐

If so, reasons…

8. Consent : *Written ☐ Oral ☐ Audio-visual ☐

i. CONSENT FORM : (TICK THE INCLUDED ELEMENTS)

Understandable language		Alternatives To participation	
Statement that study involves research		Confidentiality Of records	
Sponsor of study		Contact information	
Purpose and procedures		Statement that Consent is voluntary	
Risks & Discomforts		Right to withdraw	
Benefits		Consent for future use of biological material	
Compensation for participation		Benefits if any On future commercialization eg. genetic basis for Drug development	
Compensation for study related injury			

*if written consent is not obtained, give reasons.

ii. Who will obtain consent? PI/Co-PI	Nurse/ Counsellor

Research staff	Any other	
9. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
10. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk More than minimum risk High risk	Yes	No
iii. Is there a benefit a) to the subject? Direct Indirect b) Benefit to society		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to : Sponsor Ethics Committee DSMB	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
iv. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long?	Yes	No
12. Is there compensation for participation? **If Yes,** Monetary In kind	Yes	No

13. Is there compensation for injury? **If Yes,** by Sponsor	Yes	No
14. Do you have conflict of interest? **(financial/non-financial) If Yes, specify :**	Yes	No
Conflict of interest for any other investigator(s) (if yes, please explain in brief	1_____Yes 2_____Yes	
15. Participant Information Sheet *(mark √ if yes)*	Attached English version Attached Hindi version	
16. **Participant Informed Consent Form** *(mark √ if yes)*	Attached English version Attached Hindi version	
17. Whether any work on this project has started or not?	*(mark √ if yes, X if no) (Please Separate certificate to this effect).*	
18. In case of clinical trials CTRI status		

CHECKLIST FOR ATTACHED DOCUMENTS

*Covering letter, through proper channel forwarded by Head of Department . . . . . ☐

*Project proposal – 01 Copy . . . . . ☐

*Curriculum Vitae of Investigators . . . . . ☐

*Brief description of proposal . . . . . ☐

*Patient information sheet (PIS) . . . . . ☐

*Patient Informed Consent form (PICF). . . . . ☐

*Soft Copy of the Proposal . . . . . ☐

Investigator's brochure . . . . . ☐

Copy of advertisements/Information brochures . . . . . ☐

Copy of clinical trial protocol and/or questionnaire . . . . . ☐

HMSC/DCGI/DBT/BARC clearance (if required) . . . . . ☐

*Undertaking that the study shall be done in accordance with ICMR and GCP guidelines . . . . . ☐

*Undertaking that Left over blood will be disposed off in controlled & regulated manner (if applicable) ☐

*Undertaking of responsibility in case of adverse event (if applicable) ☐

In case of multi-centric study, IEC clearance of other centres must be provided . . . . . ☐

Definite undertaking as to who will bear the expenditure of injury related to the project . . . . . ☐

If an insurance cover is intended . . . . . ☐

Insurance certificate must be provided (as per ICMR guidelines) . . . . . ☐

Permission to use copyrighted Questionnaire / Proforma . . . . . ☐

Investigator should provide undertaking what they will do with the leftover sample tissue . . . . . ☐

Certificate/undertaking as mentioned in column 17 . . . . . ☐

Others . . . . . ☐

[NOTE: REQUIRED DOCUMENTS MARKED WITH [*] ARE MANDATORY]
Please do not submit without required documentation.