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 PRINCIPAL INVESTIGATOR 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**
Principal Investigator				
Co-PI's				

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

Sponsor Information : 1. Indian a) Government ☐ b) Private ☐	Central ☐	State ☐	Institutional ☐
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 / contrasts?	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.

PARTICIPANT INFORMED CONSENT FORM

Patient Identification Number (PIN) for this study:_____

(Title of the project)

Name of Principal investigator:……...…….…….

Designation…….., Department…….……,

Tel.No(s)…….email ID……..…….……

The contents of the information sheet dated…… that was provided have been read carefully by me/ explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks/ benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw from the study at anytime, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from UPUMS, Saifai. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

---------- Date:
(Signatures /Left Thumb Impression) Place:

Name of Participant:_____Son/Daughter/spouse of:_____

Complete postal address:_____

This is to certify that the above consent has been obtained in my presence.

---------- Date:
Signatures of the Principal Investigator Place:

1) Witness–1 (Subject's relative)	**2)Witness–2**
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Signature	Signature
Name:	Name:
Address:	Address:

NB: Three copies should be made, one each for (1) Patient (2) Researcher (3) Institution

(Investigators are advised to prepare the translation in simple understandable Hindi on their own)

Its MANDATORY TO PREPARE THIS (ACCORDING TO YOUR RESEARCH PROTOCOL)
IN BOTH THE LANGUAGES

सहभागी सुचित सहमति प्रपत्र

इस जांच के लिए सहभागी पहचान नम्बर.....

अनुसंधान शीर्षक .....

मुख्य अन्वेषक का नाम.....

पद .....

फोन नं0.....

मैने दिनांक ..... के सूचना पत्र में दिये गये सभी तथ्यों को पढ़ लिया है। मुझे समझ आने वाली भाषा में विस्तारपूर्वक बता दिया गया है और मैने तथ्यों को भलीभाँति समझ लिया है। मै पुष्टि करता/करती हूँ कि मुझे प्रश्न पूछने का अवसर दिया गया है।

मुझे अध्ययन की प्रकृति, उद्देष्य तथा इसके सम्भावित लाभ/जोखिमों और अध्ययन की सम्भावित अवधि एवं अन्य प्रासंगिक जानकारी के बारे में विस्तारपूर्वक समझा दिया गया है। मैं समझता हूँ कि इस अध्ययन में मेरी भागेदारी स्वैच्छिक है और इस अध्ययन से किसी भी समय बिना कोई कारण बताए, बिना मेरी चिकित्सा देखभाल या कानूनी अधिकारों के प्रभावित हुए मै अपना नाम वापस ले सकता/सकती हूँ।

मै समझता/समझती हूँ कि इस अनुसन्धान में मेरी सहभागिता से मेरे बारे में एकत्र जानकारी और चिकित्सा नोटों को यूपीयूएमएस, सैफई अस्पताल के जिम्मेदार लोगो द्वारा देखा जायेगा। मै इन व्यक्तियों को अपने रिकार्ड देखने की अनुमति प्रदान करता/करती हूँ।

मैं उपर्युक्त अध्ययन में भाग लेने के लिये अपनी सहमत प्रदान करता/करती हूँ।

सहभागी के हस्ताक्षर/बाएं अंगूठे का निशान दिनांक स्थान

सहभागी का नाम

पिता/पति का नाम

पूरा पता

यह प्रमाणित किया जाता है कि उपर्युक्त सहमति मेरी उपस्थति में ली गई है

मुख्य अन्वेषक के हस्ताक्षर दिनांक स्थान

1. गवाह के हस्ताक्षर (रिश्तेदार)
   नाम
   पता

2) गवाह के हस्ताक्षर
   नाम
   पता

Its MANDATORY TO PREPARE THIS (ACCORDING TO YOUR RESEARCH PROTOCOL) IN BOTH THE LANGUAGES

PATIENT INFORMATION SHEET

The project must be accompanied by the Participant information sheet addressed to the patient or participant or parent/ guardian, in case of minor. While formulating the participant information sheet, the investigator must provide the subjects with the following information in **English and Hindi, in a simple layman's language which can be understood by them, in a narrative form, directed to the participant/ LAR, covering all the points**:

1. Study Title
2. Aims and methods of the research study
3. Expected duration of participation
4. The benefits to be expected from the research to the participant or to others
5. Any risk or discomfort to the participant associated with the study
6. Maintenance of confidentiality of records
7. Provision of free treatment for research related injury
8. Compensation of subjects for disability or death resulting from such injury
9. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would be entitled otherwise
10. Amount of blood sample (quantity in tea spoon full) to be taken
11. Costs and source of investigations, disposables, implants and drugs/ contrast media
12. Telephone number/ contact number of Principle investigator and Co-Investigator at the top of each page
13. In case of a drug trial:
    a. The chemical name of the drug, date of its manufacturing and batch number must be mentioned
    b. Initial bioequivalence study of the drug/ references should be provided
14. Self-certification should be given that the translation to vernacular language is correct

Its MANDATORY TO PREPARE THIS (ACCORDING TO YOUR RESEARCH PROTOCOL)
IN BOTH THE LANGUAGES

रोगी सूचना पत्र

नाबालिग के मामले में परियोजना रोगी या प्रतिभागी या अभिभावक / अभिभावक को संबोधित प्रतिभागी सूचना पत्र के साथ होना चाहिए। प्रतिभागी सूचना पत्र तैयार करते समय, जांचकर्ता को निम्नलिखित सामान्य जानकारी वाले विषयों को अंग्रेजी और हिंदी में एक साधारण आम आदमी की भाषा में प्रदान करना होगा जिसे उनके द्वारा समझा जा सकता हैए एक कथा रूप में, प्रतिभागी / एलएआर को निर्देशित किया गया, जिसमें सभी बिंदु शामिल हैं।

1. अध्ययन शीर्षक
2. अनुसंधान अध्ययन के लक्ष्य और तरीके
3. भागीदारी की अपेक्षित अवधि
4. अनुसंधान से प्रतिभागी या दूसरों के लिए अपेक्षित लाभ
5. अध्ययन से जुड़े प्रतिभागी को कोई जोखिम या असुविधा
6. अभिलेखों की गोपनीयता का रख-रखाव
7. अनुसंधान से संबंधित चोट के लिए नि शुल्क उपचार की व्यवस्था
8. ऐसी चोट से होने वाली विकलांगता या मृत्यु के लिए विषयों का मुआवजा
9. किसी भी समय जुर्माना या लाभ के नुकसान के बिना व्यक्तिगत रूप से भाग लेने और अनुसंधान से वापस लेने के लिए स्वतंत्रता, जिसके लिए विषय अन्यथा हकदार होगा
10. रक्त नमूना की मात्रा (चाय चम्मच में मात्रा पूर्ण) लेने के लिए
11. जांच, निपटान, प्रत्यारोपण और दवाओं / विपरीत मीडिया की लागत और स्रोत
12. प्रत्येक पृष्ठ के शीर्ष पर सिद्धांत जांचकर्ता और सह.जांचकर्ता का टेलीफोन नंबर / संपर्क संख्या
13. दवा परीक्षण के मामले में:
    ए) दवा का रासायनिक नामए इसके विनिर्माण और बैच संख्या की तारीख का उल्लेख किया जाना चाहिए
    ख) दवा / संदर्भों का प्रारंभिक बायोइक्विलेंस अध्ययन प्रदान किया जाना चाहिए

14 आत्म-प्रमाणीकरण दिया जाना चाहिए कि स्थानीय भाषा का अनुवाद सही है

Its MANDATORY TO PREPARE THIS (ACCORDING TO YOUR RESEARCH PROTOCOL)
IN BOTH THE LANGUAGES

UNDERTAKING

Annexure – 1A

IEC-UPUMS, Saifai Serial No and Date: …….

Title of the Proposal: …….

…….

I,……..... (Name of PI), ……

..... (Designation)…… (Dept.) do hereby solemnly state and affirm that the above mentioned project shall be done in accordance with the guidelines of ICMR and GCP.

……

(Signature of Principal Investigator)

Date: ……

UNDERTAKING

Annexure – 1B

IEC-UPUMS, Saifai Serial No and Date: …….

Title of the Proposal: ……

……

I,…….. (Name of PI), ……

..... (Designation)…… (Dept.) do hereby solemnly state and affirm as under.

2. The above mentioned project shall be done in accordance with ICMR and GCP Guidelines.

3. ……
(Name and Address of the Institute/Sponsor/Individual)
will be responsible in case of any adverse event caused due to deviation in above mentioned guidelines.

…… ……..

Signature of the Individual/ Head of the Institute/ Sponsor with Seal

(Signature of Principal Investigator)

Name and Mobile No. of the person to be contacted in case of adverse event.

1. .
2. .
3. .
4. .
5. .

UNDERTAKING

Annexure – 1C

IEC- UPUMS, Saifai Serial No and Date: …….

Title of the Proposal: …….

…….

I, ……..... (Name of PI), ……
..... (Designation)…… (Dept.) do hereby solemnly state and affirm as under:

We are taking …… (ml) of Blood to conduct the below mentioned test in

accordance with the stated project/research.

A. .
B. .
C. .
D. .
E. .

1. Once all the necessary tests are done and completed, the left over blood samples are trashed in biohazard bins which are specially tagged for incineration process and then the leftover Blood are disposed-off in a very controlled and regulated manner.

……
(Signature of Principal Investigator)

Date: ……