उ0प्र0 आयुर्विज्ञान विश्वविद्यालय
सैफई, इटावा (उ0प्र0) – 206 130
Uttar Pradesh University of Medical Sciences
Saifai, Etawah (U.P.)– 206 130

No. 02 /962-CD/UPUMS/IRC/2025-26 Date : 01 / 08 /2025

CIRCULAR

Subject-New Research Proposals for intramural grant are invited:

New research proposals are invited from the permanent employee of this University for Intramural Research funded projects. Interested faculty members can submit the proposal as per the given format (attached). **Kindly refer to the SOP for principal investigator for research proposal submission under intramural grant (attached).** The last date for submission of completely filled research proposals is **30 Aug, 2025**. MS Word files of all the forms are being provided, kindly use only MS Word files for filling the forms by typing and no handwritten forms will be accepted.

Kindly submit **single hardcopy and a softcopy** of following documents in given order-

1. Covering letter
2. Recommendation and Minutes of DRC meeting
3. Proposal on prescribed Proforma for intramural funded projects
4. Form for Ethical clearance
5. Patient Information sheet (Both English and Hindi)
6. Patient informed consent Form (Both English and Hindi)
7. Case Proforma as per study

"Guidelines, SOPs, and Proformas for research activities of UPUMS, Saifai-2023" is available on the website of the Institute.

Softcopy of all the documents is to be sent as single PDF file on **researchcell.upums@gmail.com**

For any query kindly contact in Room No. 333, Admin Block 2nd Floor Research cell.

Enclosures: (Also available on the website of the Institute and sent on email of all HOD's as 03 PDF documents and 02 MS Word Files)

1. SOP for intramural funded projects. (01 PDF file)
2. Proforma for intramural funded projects. (both PDF and MS Word File)
3. Form for ethical clearance (both PDF and MS Word File)

(Dr. Savita Agarwal)
Faculty In-charge
Research Cell

Copy to following for information and necessary compliance:

1. All Deans (Medical, Dental, Pharmacy, Paramedical and Nursing by email)
2. Finance Officer.
3. All Members of the IRC.
4. All HOD's by email.
5. Medical Superintendent.
6. Member Secretary IEC.
7. I/c CAC to upload this circular on University Website.
8. PPS for perusal of Hon'ble Vice Chancellor.
9. P.S. to Registrar.
10. Notice Board.

(Dr. Savita Agarwal)
Faculty In-charge
Research Cell

Uttar Pradesh University of Medical Sciences, Saifai

9.5 Standard Operating Procedure (SOP) for Principal Investigator for Research Proposal Submission

Scope

The project should be developed with well-defined objectives that can be completed in 12 months (one year) and maximum extended up to 2 years. These are specifically meant to generate pilot data or innovative technology development. These projects will help the investigators to generate extramural grants on a larger sample size.

Period for submission of project

The project proposal will be invited from all the Faculty Members twice a year in the month of February and August. The Research Committee will review the projects in March and September each year. The Principal Investigators are encouraged to submit the project even before the invitation is sent so that they can be taken in the upcoming Research Committee Meeting.

Number of copies

14 hard copies & a soft copy should be submitted by the Principal Investigator to the Research Cell.

Procedure for application of intramural funding

1. Faculty members should apply for only one intramural project.
2. The project should be discussed in the Departmental Research Committee meeting and a copy of the minutes should be attached with the project proposal prior to the submission to the Research Cell for its placement in the Research Committee.
3. The projects which are submitted by the Principal Investigator for intramural funding, the PI should attach the proof of submission to the Institutional Human Ethics/Animal Ethics committee prior to the submission to the Research Cell.
4. The duration of each project is ordinarily limited to 12 months period after sanction of the intramural grant, and can be extended maximum for another one year, if needed.
5. The budget shall not ordinarily exceed Rs. 5 lakhs. Under exceptional circumstances, the budget for Rs. 7 lakhs maximum may be considered by the committee only for outstanding, innovative projects after due sanction by the Hon'ble Vice-Chancellor.
6. The budget should be given in detail with full justification for all items in a separate sheet under various heads. **Please do not tailor the budget to make it around 5 lakhs. Contingency should not be asked separately.**
7. The funds will be utilized only for the purchase consumables: chemicals, kits, disposables, travel expenses for field-based studies, etc. All items covered under the Learning Resource Allowance Scheme will not be allowed under this scheme. Stationary (office and computer), photocopying will not be allowed. Expenditure for attending conferences for presenting the paper of the approved projects will not be

allowed.

8. Funding will not be utilized purchase of any permanent items like instruments, machines, equipment, computer, books etc. which are not of consumable nature.
9. For the field based /community-based study, data collectors can be hired on a daily basis. The minimum wages and other monetary benefits will be decided as per the guidelines of the central and state labour employment act.
10. Senior and Junior Residents, PhD students, Research Associates, Undergraduate and Postgraduate students, and Paramedical staff cannot be co-investigators. PhD projects will not be allowed to utilize this intramural funding. Registration of Ph.D. students will not be allowed under this scheme and employment staff will not be allowed.
11. Collaborative projects involving more than one department should be discussed with all participants. Only those actually involved in the work should be co-investigators. The co-investigator from outside the institute may be approved by the Research Committee depending upon the need & merit of the project. His/her one-page CV should be attached.
12. If the project involves direct intervention or interaction with patients, the Principal Investigator should be a clinical faculty member, similarly, if the project involves Research work on human subjects with no direct intervention, then the co-investigator should be from the concerned Department where the samples are collected.
13. For faculty members approaching superannuation, the remaining service period of the Principal Investigator should be longer than the duration of the project at the time of submission.
14. At any given period of time, no faculty member should have more than TWO intramural projects running. The third project will be considered only when at least one of the currently running two projects has been completed and reviewed by the Research Committee or and Principal Investigator has submitted a manuscript/acceptance / published paper from the project.
15. The intramural project **should not** be sent to the extramural funding agency simultaneously.
16. Statistical inputs from the Expert (Biostatistician) may be taken if needed.
17. For those faculty members who have already completed two or more intramural projects, further projects will be sanctioned only if they have published a paper in an indexed journal from at least one of the last two completed projects or have generated an extramural research grant from the inputs derived from the intramural project.
18. The grant for a new intramural project will be released when the PI will provide the ethical clearance of the concerning project to the Research Cell.
19. All the presentations for the new projects should be made before the Research Committee and the PI should present the project consisting of 10-12 slides.
20. The PI should send the project per the prescribed format with each section starting on a new page and all the points should be addressed.
21. If a faculty wants to use his/her intramural project for funding a DM/M.Ch. project, the student may be a Co-investigator after approval of the Research Committee.
22. Till such time that the institute develops a mechanism for the provision of insurance cover for the trial subjects, no drug/device/procedural trials will be allowed either for the intramural project, independent projects, DM/M.Ch./MD projects, or for investigator-initiated trials. It is allowed only when there is a provision of sufficient insurance cover for compensation of trial subjects, for e.g. in extramural/drug/device trials funded by industries.
23. If an investigator conducts a drug/device/procedural trial and if any problem arises for the compensation to the subjects as per the DCGI guidelines and Gazette of India, the institute will not be responsible in any manner. This will be applicable even if the project has been cleared by the Institutional Ethics Committee, UPUMS, Saifai.

24. No projects will be allowed to go through the IEC/signatures for higher authorities of the institute unless the minutes of the Departmental Research Committee are attached thereof.
25. Outsourcing of any investigations will not be permitted from intramural projects. If there is a strong justification, it has to be discussed in the Research Committee meeting of the Institute and will have to be approved explicitly.
26. For all the projects, there should be at least one co-investigator in each project preferably from the same department and there should be an undertaking by the co-investigator that he/she will take the responsibility to complete the project and financial matters related to it. In case PI is unable to complete the project due to unavoidable circumstances (resignation, superannuation etc.).

27. All the investigators are requested to provide a copy of the published papers/submitted manuscript or a write-up explaining why the paper has not been published for all previous closed/completed intramural projects.

Dr. Usha Shukla
Dean (Medical Faculty)
U.P. University of Medical Sciences
Saifai-20

Uttar Pradesh University of Medical Sciences, Saifai

Intramural Research Project Receipt form to be submitted in Duplicate

1. Title of the project:

2. Type of Submission: a. New b. Revised

3. Name of PI and Department:

Checklist to assess the project before submission to the Research Committee for review

S.No	Mandatory Documents	Yes	No	Not Applicable	Page nos.
1	Project Proposal as per the prescribed format				
2	Minutes of the Departmental Research Committee				
3	Institutional Ethics Committee receipt for submission				
4	Institutional Animal Ethics Committee receipt for submission				
5	Undertaking by the PI				
6	CV of new or co-investigator(s) outside UPUMS, Saifai.				

Documents submitted
a) Complete
b) Incomplete, will submit on:_____

Receivers Name:
Signature & Date (with stamp)
Project submitted by Name & Signature:

Uttar Pradesh University of Medical Sciences, Saifai

PROFORMA FOR PROJECT PROPOSAL RESEARCH GRANT
PART (I): GENERAL INFORMATION

1. Project Title:

2. a. Broad Area: Basic/Translation/Clinical/Systems research /Community/ Education / Behavioral
   b. Specific Area:
   c. Key words (maximum three)
3. Duration:

4. Total Cost:
5. Principal/Co-Investigator(s)

Investigators	Name	Designation	Department	Signature
PI				
Co-PI				
Co-PI				
Co-PI				
Co-PI				

6. Project Summary (maximum 500 words) (Attach separate sheet):

7. Copy of the Departmental Research Committee Recommendation

8. Copy of the Ethics committee submission certificate

(Head of the Department will be responsible for periodic monitoring of the project)

9. Is radio tagged material proposed to be used in the project either for clinical trials or experimental purposes? If so, clearance from Nuclear Medicine Committee, Bhabha Atomic Research Centre, Mumbai, indicating should be attached.

10. Projects involving recombinant DNA/Genetic engineering work should be examined and certificate by the Institutional Biosafety Committee (IBSC) to be enclosed. Guidelines for constitution of IBSC can be obtained from Secretary, Department of Biotechnology, CGO Complex, Lodhi Road, New Delhi-110003.

11. Documents of the institutional ethics committee (IEC) should be enclosed. Guidelines for IEC for animal experiments should follow CPCSEA requirements and for human studies should follow ICMR guidelines.

12. PI and Co-PIs should ensure that that there is no financial conflict of interest by the investigators.

PART II: TECHNICAL DETAILS OF PROJECT

(Project proposal to be submitted in the format mentioned as below. The total pages should be within ten A4 papers in 1.5 space, letter size 11, Times New Roman)

1. Introduction

2.1 Origin of the proposal

2.2
(a) Rationale of the study supported by cited literature
(b) Hypothesis
(c) Research questions.

2.3 Current status of research and development in the subject
(a) International Status
(b) National status

2.4 The relevance and expected outcome of the proposed study

2.5 Preliminary work done if any. (New ideas are welcome.)

3. Specific objectives

4. Work Plan: should not exceed **three pages**
4.1 Detailed methodology including study design and outcome measures
4.2 Data analysis plan

5. Timelines:

Activities	Duration

Part III: Budgets Particulars

Budget requirements (with detailed break-up and full justification):
i) Personnel
ii) Contingencies
iii) Expenditure on scientists / technicians (Period, duration & number)

iv) Format of Budget

S.No	Sanctioned Heads	Expected Budget
1.	Salaries	NA
2.	Supplies & materials	
3.	Contingencies (should NOT exceed more than 10% of total Cost)	
4.	Travel	NA
5.	Overhead Expenses	NA
6.	Total Budget	

v) Justification (for each item):

For tests available in hospital (Through HIMS)

S No.	Name of test/ investigation	Hospital Tariff/ rate	No. of tests required	Estimated Cost
	Total Cost			

For tests not available in hospital (Consumables e.g. Testing kits etc)

Sl No.	Item	Pack Size	Quantity	Estimated Cost/Unit	Total Cost
Total Cost					

Part IV: BRIEF BIODATA OF PRINCIPAL INVESTIGATOR/Co-PIs

1. Updated CV including List of Publications for last 5 years and honors /awards of the Principal Investigator /Co-Investigators (Attach Separate sheets)

2. List of current projects being handled including source and amount of funding

PART – 4(A): PROFORMA OF DETAILS OF PREVIOUS INTRAMURAL PROJECTS

S.No.	Title of the project	Duration	Budget	Complete/Not Complete	Final Completion Report Submitted	Manuscript Published /submitted (Provide details)	Abstract Presentedat Conference

PART – 4(B): PROFORMA OF DETAILS OF PREVIOUS EXTRAMURAL PROJECTS

S.No.	Title of the project	Duration	Budget	Complete/Not Complete	Name of Funding Agency

PART – 4(C): CV OF OUTSIDE CO-INVESTIGATOR(S)

Last Name	Middle Name	First Name
Date of Birth(dd/mm/yyyy):		Sex:
Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator)		
Permanent Mailing Address: (Include institution name)	Study Sited Address (Include institution name)	
Telephone (Office):		Mobile No:
Telephone (Residence):		E-mail:
Academic Qualification (Most Current Qualification First)		
Degree/Certificate	Year	Institution, Country
Current and Previous 4 Relevant Positions Including Academic Appointments (Most current position first)		
Month and Year	Title	Institution/Company,Country
Brief Summary of Research Experience related to the project:		
Signature	Date:	

PART V: DECLARATION AND ATTESTATION

i. I/We have read the terms and conditions for UPUMS Intramural Research Grant. All necessary departmental facilities will be provided if the research project is approved for financial assistance.

ii. I/We agree to submit within one month from the date of termination of the project, the final report and a list of articles, both expendable and non-expendable, left on the closure of the project.

iii. I/We agree to submit statement of accounts for the project to the Director Finance, UPUMS, Saifai for official audit before the end of financial year.

iv. It is further certified that the equipment(s) required for the project will not be purchased from the funds provided by UPUMS, Saifai for another project(s) in the department.

v. ***I/We agree to submit (online) all the raw data (along with descriptions) generated from the project to the UPUMS Data Repository within one month from the date of completion / termination of the project.***

Signature of the:

a) Principal Investigator _____

b) Co-Investigator(s) _____

c) Head of the Department _____

Date:

INTRAMURAL RESEARCH FORM

SECTION – 'A'

Name of the Principal Investigator: ……

Designation:…… **Department**……

Date of Joining DD MM YYYY **Date of Retirement** DD MM YYYY

Title of the Proposal: ……

……

……

Study Design ……(Any other)

Duration of Study…… (Kindly attach Gnatt Chart)

Fund Required: Rs……(In words) ……

Details of Co – Investigator (within Institute)

Sl. No.	**Name** Designation Department	**Contact Details** Mobile Number Email Id	Role and Responsibilities allotted	**Signature**

Details of Co – Investigator (from outside the Institute)(Prior approval of Research Cell should be obtained)

Sl. No.	Name Designation Department	Institute	Contact Details Mobile Number Email Id	Role and Responsibilities allotted

SECTION – 'B'

DETAILS OF PREVIOUS/ONGOING INTRAMURAL PROJECTS:

Title of the Previous study: ……

……

……

Date of Study approved with IEC no.: …… (attach IEC Approval Letter) Date of Completion: …… (Submit Completion Certificate) Amount Granted: Rs. …… (in words)…… Details of Publications made: ……

(SELF DECLARATION)

I…… (Name) …… (Designation)

…… (Department) do hereby affirm the following:

1. I will strictly abide by the rules and guidelines of Research Cell as per SOP.
2. The fund allotted will only be utilised for purchase of items required as per SOP of Intramural funding.
3. I will acknowledge the institute in my publications made under the above-mentioned proposal.
4. I will inform the Research Cell when the Manuscript is accepted / published.
5. No Senior/Junior Residents, PhD Students, Research Associates, Undergraduate or Postgraduate students and Para-Medical staff are Co-Investigator in the above mentioned Proposal.

……

Signature of the Principal Investigator

UNDERTAKING

I……in the Department of ……state that simultaneously the proposal will not be sent for funding to any other agency (extramural funding)

Name and Signature of the Principal Investigator

UNDERTAKING

Dr.. …… is a co-PI from the same department as PI and He/She will take the responsibility to complete the project titled……

……

Name and Signature of the Co-Principal Investigator

Name and Signature of the Principal Investigator

CHECKLIST

Sl. No.	Particulars	Tick
1	IEC Forms	
2	PIS & PICF in Both English and Regional Language	
3	Clearance from Departmental Research Committee. (Attach Minutes)	
4	Detailed Budget (On a separate paper)	
5	An undertaking stating the proposal will not be sent for funding to any other agency (extramural funding)	
6	Undertaking from the Co-PI of same department stating that he/she will take the responsibility to complete the project due to unavoidable circumstances.	
7	CV of all the Investigators	
8	Copy of clinical trial protocol	
9	GANTT Chart	
10	Any Other, if required	

List of Four External Reviewers Suitable For The Evaluation Of The Proposal

S No.	Name of the Reviewer	Designation	Affiliation	Email Address	Mobile Number
1					
2					
3					
4					

Name and Signature of the Principal Investigator

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)

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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

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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

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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

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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: ……