



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.

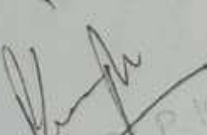
Number of copies

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


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- 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, Saifal.


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Dean (Medical Faculty)
UPUMS, Saifal


Dr. P. K. Singh
Chancellor

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.


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Lucknow-200


Dr. P. K. Singh
Vice-Chancellor

FORMAT OF RESEARCH PLAN

1. **Title of the proposed research project:** should be **concise** and yet sufficiently descriptive and informative. Title may include study design such as randomized controlled trial; an observational study; a case-control study etc
2. **Summary (up to 250 words):** A structured summary should contain the following subheadings: *Background, Novelty, Objectives, Methods, and Expected outcome.*
3. **Keywords:** Six keywords separated by comma which best describe your project may be provided.
4. **Abbreviations:** Only standard abbreviations should be used in the text. List of abbreviations maximum of ten may be given as a list.
5. **Background (up to 500 words):** State the background information to adequately present the problem, mention how the research question addresses the critical barrier(s) in scientific knowledge, technical capability, and/or programmatic/clinical/lab practice and its relevance to local, national and international context.
6. **Literature review (up to 1000 words):** Review to be written cohesively to build justification for the research question to be addressed with reference of key publications in the field. Reference up to 30 in Vancouver style may be provided at the end of literature review.
(References will not be included in the word count)
7. **Novelty/Innovation (up to 250 words):** Describe how the proposal challenges and seeks to shift the current research/knowledge/clinical practice paradigms etc. by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions etc. Mention if there is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions in the proposed study.
8. **Study Objectives:** Define the objectives clearly and in measurable terms; mention as primary and secondary objectives if necessary. Do not write too many objectives.
9. **Methodology (up to 2000 words): Include the following subheads**
 - i. **Study Design:** Proposed study design should be appropriate to fulfill all the objectives; details of study design whether descriptive, analytical, experimental, operational, a combination of these or any other; and adequate description of study population should be provided. Explain the rationale of selection of the research participants and controls (human or laboratory animals), whether chosen randomly, consecutively etc. with inclusion and exclusion criteria, rules for discontinuation, definitions of cases, controls and lost to follow up etc.; in case of Intervention studies a detailed description of Intervention (drug/device/behavioral intervention) should be given. The use of quantitative and qualitative methods may be specified if any.
 - ii. **Sample Size:** Details of sample size and/or power calculation should be described with references where needed. *[Please note: the sample size calculation should provide adequate power to the study to satisfactorily answer all the primary objectives,*

data from pilot studies can also be used for sample size calculation]. Operational definitions for key variables should be presented. A flow chart indicating study design with number of participants should be given where applicable.

iii. Project Implementation Plan: Describe the overall strategy for enrollment of participants including collaboration with other departments where applicable, process of enrollment of participants – how, where and by whom will the participants be enrolled, how and when and where will they be followed up; collection, storage and testing of samples; if new tests are being done describe the process of standardization etc. Describe quality assurance processes to accomplish the study objectives.

iv. Ethics Review: Address review requirements including ethics review [human or animal], approval for use of stem cells, biological etc. and other regulatory reviews/approvals as applicable. Details of obtaining informed consent and its documentation should be described along with risks and benefits to the participants. *[Ethics and other regulatory guidelines related to Bio-medical research are available on ICMR website]*

v. Data collection & statistical analysis plan: Describe the key variables of the study, how will they be measured and unit of measurement. Specify comprehensively the data collection methods and tools are relevant to the study objectives and study design and provide structural components like data entry and analytical platforms to be used for analysis. Present data analysis plan comprehensively mentioning appropriate statistical methods to be used in order to answer/achieve the study objectives.

10. Expected Outcomes (up to 100 words)

11. Limitations of this study (up to 100 words)

12. Timelines: Details of activities to be carried out along with timelines during preparatory phase, data collection, analysis & report writing to be provided.

13. Institutional Support: Mention the efforts made to achieve inter-departmental or inter-institutional collaboration needed for study implementation, details of coordination between clinical, laboratory and data management procedures, mention the institutional resources such as equipment and other physical resources available for use in the project proposed.

14. Budget: Should be appropriate and as per ICMR guidelines available on the website. Justification for staff along with their roles and responsibilities in the project to be provided.

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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	
2.	Supplies & materials	
3.	Travel	
4.	Contingencies	
5.	Overhead Expenses	
6.	Total	

v) Justification (for each item):

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 Presented at 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 Date of Retirement

Title of the Proposal:

.....

Study Design(Any other)

Duration of Study..... (Kindly attach Gnat 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 INTRAMURAL PROJECTS:

Title of the Previous study:

.....

.....

Date of Study approved: (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

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	



RESEARCH CELL
UTTAR PRADESH UNIVERSITY OF MEDICAL SCIENCES, SAIFAI
Intramural Assessment Form

Ref. No. IRC/UPUMS/ /2023/

Date:

*Title of the Proposal: _____

*Name of the PI: _____ *Designation: _____

*Department: _____ *Contact Number: _____

*Email ID: _____

Details of Co-PI:

Sl. No.	Name of the Co-PI	Designation	Department	Role of Co-PI in this Proposal
1				
2				
3				
4				
5				

Details of Previous Research Proposals as PI

Sl. No.	Headings	Number	Completion Report Submitted (Yes/No)
1	Number of Completed Project Proposals		

Details of Ongoing Project Proposals

Sl. No.	IEC Approval No. (Proposal Number)	Date of Last Progress Report submitted (with Dispatch No. form Department)

Signature of the PI

For Office use only

ALLOWED / NOT ALLOWED

Signature of Member Secretary