

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow



# Standard Operating Procedure (SOP)

for

**Departmental Research Committee  
Institutional Research Committee and Research Sub-Committee and  
Investigators for Intramural Projects**



2015

**Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow**



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**Departmental Research Committee**

**Institutional Research Committee and Research Sub-Committee and**

**Investigators for Intramural Projects**

2015



# संजय गाँधी स्नातकोत्तर आयुर्विज्ञान संस्थान

रायबरेली रोड, लखनऊ – २२६०१४ (यू० पी०) भारत

**Sanjay Gandhi Postgraduate Institute of Medical Sciences**

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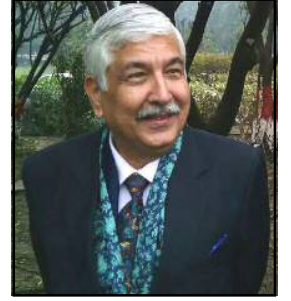
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## Forward

The objective of the Standard Operating Procedure (SOP) is to put in place an effective & consistent Scientific Review mechanism for health & Biomedical Research for all the proposals submitted by the Principal Investigator of this Institute.

The Primary responsibility is to ensure that Research performed at this Institute within the existing frame work is of appropriate scientific quality and high standard.

The Institute has been promoting research activities in biomedical sciences, since it inception i.e. from year 1988. The Research proposal generated at this Institute need to have the approval by the Research Committee before being submitted to Institutional Ethics Committee for ethical clearance. The Research Committee has been functioning from 1988. It has been realized that there should be a Standard Operating Procedure (SOP) for Research Committee as well as for Investigator.


In this endeavor, the Standard Operating Procedure (SOP) document for Departmental Research Committee, Institutional Research/Research-sub-committee & for Principal Investigator, has been prepared for smooth functioning of the Research Committee & reduce the time taken for critical review of the proposals. This document will also helps the investigators to prepare the proposals with certain requirements and submission of the annual and final reports on prescribed formats.

However, the SOPs should be revised and up dated as and when such a need arises.

I would like to thanks the Members of the Institutional Research Committee & Research Cell, for their help in preparing the Standard Operating Procedure (SOP).

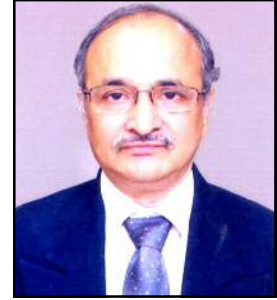
I hope the Research committee members, Principal Investigators & Researchers will find them user friendly.

Any suggestions to improve them are most welcome.

  
(Prof. Rakesh Kapoor)  
Director

**Dr. Ramnath Misra MD, FRCP (London)**  
**Dean**  
**Professor and Head Clinical Immunology**

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Lucknow-226014 INDIA



## Forward

It is with great pleasure and satisfaction that we have established the Standard Operating Procedures (SOP's) for the Departmental Research Committee, Institutional Research/Research sub-committee & for Principal Investigators.

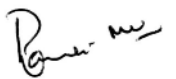
The Standard Operating Procedures, by definition is a detailed written instruction to achieve uniformity and maintain standards in the performance of the specific functions.

Since the Research activities has been started for more than two decades in this Institute, therefore, it was thought that SOP's may be developed for Departmental Research Committee, Institutional Research/Research sub-committee & for Principal Investigators to smooth line the activities & responsibilities.

The development of the SOP's document started in the month of February, 2015 and just within four months, it has been prepared by the Research Cell and approved by the 67<sup>th</sup> Research Committee meeting held on 9<sup>th</sup> May, 2015, for its implementations.

I wish to thanks, all the Research Committee members of this Institute for their valuable contributions, without which this great achievement would not have been achieved.

As a living document, the SOP's will be reviewed from time to time in the future and SGPGIMS will endeavor to ensure the full participation of all stakeholders.

  
**(Dr. R. N. Misra)**  
**Dean**

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# Standard Operating Procedures (SOP) for Departmental Research Committee

## 1. Scope

Departmental Research Committee, has been constituted vide office order no. PGI/DIR/RC/545/2014 dated: 09.06.2014 for all Academic Departments to discuss all the projects requiring ethics/research cell/administrative approval (any type of project & funding) for scientific evaluation submitted by the investigators.

## 2. Constitution

- |   |                  |
|---|------------------|
| 1. Head of the Department                                     | Chairman         |
| 2. All the faculty members                                    | Members          |
| 3. Other faculty members from different Department (optional) | Co-opted members |

## 3. Frequency of DRC

The Departmental Research Committee will meet at least every two months in the Department and earlier if needed. The minutes of the DRC will be sent to Research Cell within two weeks along with a copy of the research projects discussed.

## 4. Quorum Requirements

At least 50% of members of the DRC including regular HOD, should be present during the meeting and all should sign on the proceedings.

## 5. Procedure

The DRC will forward all the projects to Research/Ethics committee as required, if the project is approved. (Apart from a copy of DRC minutes & project to Research Cell as mentioned above). If the project is not approved, it should be sent to Research Cell along with DRC minutes. The final decision will be taken by the Research Committee/Research Sub-committee of the Institute, whose decision will be final. If no project to be discussed in DRC, a note stating, it will be sent to the Research Cell by HOD.

## **Format for Departmental Research Committee Meeting**

1. Title of the Research Project
2. Name of Principal Investigator
3. Name of Co-investigator (if any)
4. Date of Departmental Research Committee meeting
5. Specific Comments (on scientific merit/ethics related issues only)
6. Recommendations – Accepted/Modifications/Rejected
7. Reasons for Modifications/Rejections if any

**(Signature of Regular HOD)  
Chairman**

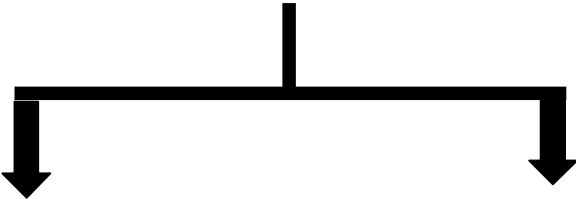
**(Signature of Members)**

**Flow Chart for Departmental Research Committee**

**Principal Investigator**



**Departmental Research Committee**



**Research Committee/  
Research Sub-Committee**

**Ethics Committee**



# Standard Operating Procedures (SOP) for Institutional Research Committee

## 1. Scope

The scope of the committee to put in place an effective and consistent scientific review mechanism for health & biomedical research for all the proposals submitted by the investigators in their area of research interest.

## 2. Functions of Research Committee (RC)

The Research Committee of SGPGIMS, has the overall responsibility for reviewing, approving and monitoring of all the research projects undertaken by the investigators and discuss all the issues related to the research.

The objective of the committee is to review the scientific merit, rationale of the study and feasibility, scientific design and methodology, data quality, safety & progress of each health and biomedical proposals for the welfare of human participants.

## 3. Composition of Research Committee

The Research Committee of the Institute shall be multi-disciplinary and multi-institutional in composition.

The number of committee shall be kept small (10-14 members) as a large committee makes it difficult in reaching consensus and in having the presence of all the members. At least 25% shall be external members in the committee, preferably from the local institutions, to ensure the fare scientific evaluation of the protocols submitted by the investigators.

The Director, SGPGIMS, shall constitute the Research Committee and forward it to Academic Board of the institute for its approval as per the following:

The Chairperson of the committee shall be the Director of Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow. The Member Secretary, drawn from the Institute itself, shall conduct the business of the committee. Other members will be mix of medical and non-medical scientific and non-scientific persons including external members to reflect the different view points.

The composition may be as follows:

- |  |                           |
|--|---------------------------|
| 1. Director  | Chairperson               |
| 2. Dean  | Member & Vice-Chairperson |
| 3. Faculty Incharge Research   | Member Secretary          |
| 4. Two Clinicians from Medical discipline                                      | Member                    |
| 5. Two Clinicians from Surgical discipline                                     | Member                    |
| 6. One Clinical from Radiation sciences  | Member                    |
| 7. One Clinical from Laboratory sciences                                       | Member                    |
| 8. One Non-Clinician from basic sciences                                       | Member                    |
| 9. One faculty member from Dept. of Biostatistics                              | Member                    |
| 10. Three external medical/non-medical members from Local/outside institutions | Member                    |

The Research Committee should have majority of members involved in medical research for long duration. They could be drawn from the Institute as well as from the outside Govt. /Private Institutions any where in the country. There should be adequate representation of age, gender etc.

#### **4. Duration of Committee**

The duration of committee shall be for the period of three years.

#### **5. Membership Duration and Responsibilities**

1. The duration of the membership shall be three years
2. There will be no bar on the members serving for more than one term but it is desirable to have around two third fresh members.
3. A member can be replaced in the event of long term non availability (three consecutive meetings). Authority to replace the member shall be with the Director, SGPGI.
4. The member should maintain confidentiality during the meeting and sign a confidentiality form at the start of their term.
5. Each members of the committee will submit a declaration to maintain the confidentiality of documents submitted to them during their membership period.
6. Conflict of interest if any shall be declared by members of the Research Committee at the beginning of every meeting.

#### **6. Quorum Requirements**

A minimum of 8 members including at least two outside members will be required for the quorum. All decisions should be taken in the meeting and not by the circulation of project proposals.

#### **7. Offices/Conduct of Meeting**

The Chairperson will conduct all the meetings of the Research Committee. If for reasons beyond control, the Chairperson is not available, then the Dean will conduct the meeting. The Member Secretary will be responsible for organizing the meeting, maintaining the records and communicating with all concerned. He/She will prepare the minutes of the meetings and get them approved by the Chairperson. All the decisions will be communicated to investigators by the Research Cell. The minutes should be circulated by the Research Cell within two weeks to all the members for their information.

#### **8. Independent Consultants**

Research Committee may call upon subject experts as special invitee for the review of selected research protocols. These experts may be from the outside of the institute and have sufficient expertise on the concern research proposals submitted to them. They will not take part in the decision making process.

#### **9. Application Procedure**

1. All the proposals should be submitted in the prescribed application format, the copies of which should be available with the Research Cell and Institute's website.
2. All relevant documents should be enclosed with the proposal as per the check list.

3. The required number of hard copies along with CD of the proposal with application & documents in prescribed format duly signed by the PI and Co-investigators/collaborators should be forwarded by the Head of the Department.
4. The Research Cell will acknowledge the receipt.
5. The date of meeting will be intimated to the Principal Investigators who shall be available for the presentation of their proposal for the Research Committee meeting.
6. The decision of Research Committee will be communicated in writing within two weeks by the Research Cell, if the revision is to be made, the revised proposal should be submitted by the PI within stipulated period of time as recommended by the Research Committee.

## **10. Review Procedure**

1. The Research committee shall be held 4 times in a year as per the following schedule:
  - i. Second week of September and November (Feb./May/Sept./Nov.)
  - ii. Second week of February and May

The last date for receiving the proposals will be 30<sup>th</sup> July for its submission to the Research Committee meeting scheduled to be held in the month of August, similarly, the last date for the receiving the proposals will be 31<sup>st</sup> January for its submission to the Research Committee meeting scheduled to be held in the month of February. (i.e. it will be the last day of the preceding month in which the meeting is scheduled)

### **For Old Projects**

1. There will be annual review by the Research committee for the new projects sanctioned to the Investigators with the following elements to review
  - i. To review the progress of the project in terms of sample size target by the investigator
  - ii. The procurement of consumables and utilization of budget
  - iii. Any deviation from the methodology as proposed in the original project

The subsequent review of the project will be conducted after two years to review the completion of the project and its outcome.

If any reasons, the Research Committee are not able to meet, the progress report can be reviewed by a sub-committee of Dean, Faculty I/c Research and three members of the Research Committee.

### **For New Projects**

1. The agenda & proposals should be send to the members at least two weeks in advance. The decision will be taken by consensus and through a procedure described in the point no. 13.
2. The Principal Investigator should present the proposal before the Research Committee & the Co-investigator should be present for any clarification regarding the project. Residents/Students should not be allowed to present the proposal. I case, PI is not available during the meeting, he/she can authorize one of the Co-investigator to present the proposal before the committee.
3. Independent consultants/experts may be invited as a Special Invitee to offer their opinion on specific research proposals.

4. The decisions of the meeting shall be recorded in the minute's book and shall be confirmed during the next meeting with the signatures of the Chairperson at each page.

## 11. Element of Review

1. Rationale of study
2. Scientific design & methodology
3. Relevance of sample size and its statistical correlation
4. Experimental details and its feasibility
5. Conduct of study
6. Procedure for selection of subjects including inclusion & exclusion criteria
7. Outcome of the proposal
8. Facilities & infrastructure
9. Plans for data analysis & reporting
10. Relevance of budget estimation

## 12. Decisions Making

1. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the Chairperson prior to the review of the application & recorded in the minutes.
2. Only members will make the decision. The decisions shall be taken in absence of the Principal Investigators & Co-investigators.
3. In case, if the member has submitted the project as Principal Investigator/Co-PI, he/she should be outside of the Committee Room during the decision making process and shall not give the marks to his/her project.
4. The decision of the Research Committee may be to approve the project or reject or to revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.

## 13. Procedure for decision making for the project (Intramural)

- |   |   |
|---|---|
| <ul style="list-style-type: none"><li>• Research question</li><li>• Design of the project</li><li>• Methodology</li><li>• Relevance</li></ul> | } Out of 10 in each area<br>Maximum marks = 40<br>Minimum marks = 0 |
|---|---|

After cumulating the marks given by members, the percentage may be drawn. Below 50% the project will not be considered for Intramural funding.

In case, there is funding available only for one project and there are two or more projects at a same percentage point then the preference will be given to the Junior Faculty Members.

## 14. Communicating the decision

1. Decisions will be communicated to the Principal Investigators by the Research Cell in writing.
2. Suggestions for modifications and reasons for rejection should be communicated to the Principal Investigators & their HOD's.

## **15. Follow up the procedures**

1. Six monthly report should be submitted by the Principal Investigator on prescribed format to the Research Cell after just completion of six months. If PI false to submit the six monthly report in time, the expenditure of grant may be stopped by the competent authority of the Institute.
2. Annual report should be send by the Principal Investigator at the end of one year on prescribed format for its review.
3. The final report should be submitted to the PI within two weeks of the expiry of the project to the Research Cell for its submission to the Research Committee for final review.
4. If any amendment/deviation is done by the Principal Investigator during the currency of the project, it should be reported to the Research Cell for its placement to the Research Committee.
5. The Principal Investigator should submit the copy of the manuscript/acceptance/publication of the research paper in the indexed journal derived from the same project.

## **16. Record keeping and archiving**

1. Curriculum vitae (CV) of all members of the Research Committee
2. Minutes of all the meetings duly signed by the Chairperson
3. Copy of all the correspondence with members, investigators etc.
4. Copy of all the existing relevant documents of the Institutional norms
5. Copy of all the reports (six monthly, annual and final)
6. Copy of manuscript, accepted/published reprints of the research papers

## **17. Updating Research Committee Members**

1. All the relevant information's, regarding the research activities derived from the various statutory bodies should be brought to the attention of the members of the Research Committee by the Member Secretary.
2. If any changes are done in any formats or procedure, it should be brought to the knowledge of members, investigators and co-investigators and should be available in the Institute's website.

# **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow**

## **SECRECY UNDERTAKING BY MEMBER OF THE RESEARCH COMMITTEE**

**Name:**

**Designation:**

**Address:**

I understand that as a Member of the Research Committee I may receive documents containing confidential or privileged information about research activities related to the study.

I agree not to disclose or discuss such information or minutes of the meeting with persons not entitled to have them. I also agree either to return all documents marked CONFIDENTIAL /PRIVILEGED to Member Secretary or destroy them after perusal.

**Date**

**Signature**

## ONE PAGE CV FOR MEMBERS OF THE RESEARCH COMMITTEE

<b>Last Name</b>	<b>First Name</b>	<b>Middle Initial</b>
<b>Date of Birth (mm/dd/yy):</b>		<b>Sex:</b>
<b>Professional Mailing Address (Include institution name)</b>		
<b>Telephone (Office):</b>		<b>Mobile Number:</b>
<b>Telephone (Residence):</b>		<b>E-Mail:</b>
<b>Academic Qualifications (Most current qualification first)</b>		
<b>Degree/Certificate</b>	<b>Year</b>	<b>Institution, Country</b>
<b>Professional Experience:</b>		
<b>Month and Year</b>	<b>Title</b>	<b>Institution/Company, Country</b>
<b>Signature:</b>		<b>Date:</b>
<b>(Signature Required)</b>		

# Standard Operating Procedures (SOP) for Research Sub-Committee

## 1. Scope

The Research sub-committee as constituted by the Institute for the purpose to review the ongoing activities of the Intramural projects viz; Annual Reports & Final Reports presented by the Principal Investigators. Only internal members of the Research Committee will be eligible for becoming the member of the Research sub-Committee.

## 2. Function of the Research sub-committee

The Research sub-committee of the Institute has the overall the responsibility for reviewing all the research projects undertaken by the Investigators. The objective of the committee to review critically the ongoing status of the projects and also provide opinion to the PI, if the PI is facing difficulty while executing the project work.

## 3. Composition of Research sub-committee

The Research sub-committee of the Institute shall be a multi-disciplinary in composition.

The number of committee members should be kept small (total five). As a large committee makes its difficult to meet and reaching consensus. All the members will be internal in the committee.

Director, SGPGI, shall constitute Research sub-committee on the recommendation of the Faculty I/c Research.

The Chairperson of the above committee shall be Dean of SGPGIMS, Lucknow.

The Faculty I/c Research shall be the Member Secretary of the above committee.

Other members will be mixed Medical, Surgical & Non-Medical scientific persons.

The composition may be as follows:

- |  |                  |
|--|------------------|
| 1. Dean, SGPGI.  | Chairperson      |
| 2. One clinician from Medical Discipline                 | Member           |
| 3. One non-clinician from Medical/non-Medical Discipline | Member           |
| 4. One Clinician from Surgical Discipline                | Member           |
| 5. Faculty I/c Research                                  | Member Secretary |

## 4. Duration of the Research sub-committee

The Duration of Research sub-committee shall be for the period of three years.

## 5. Membership Duration and Responsibilities of the Research sub-committee

1. The duration of the membership shall be three years.



2. There will be no bar on the members serving for more than one term, but it is desirable to have around two third fresh members.
3. A member can be replaced in the event of long term non-availability (three consecutive meetings). Authority to replaced the members shall be with the Director, SGPGIMS.
4. Conflict of interest if any, shall be declared by the members of the Research sub-committee at the beginning every meeting.

## **6. Quorum Requirements**

A minimum of 4 members including at least one Clinician & non-clinician members will be required for the quorum. All decisions should be taken in the meeting and not by the circulation of project reports.

## **7. Offices/Conduct of Meeting**

The Chairperson will conduct all the meetings of the Research sub-Committee. If the permanent Dean who is the Chairperson of the above committee, is not available, the acting Dean will conduct the above meeting. The Member Secretary will be responsible for organizing the meeting, maintaining the records and communicating with all concerned. He/She will prepare the minutes of the meetings and get them approved by the Chairperson. All the decisions will be communicated to investigators by the Research Cell. The minutes should be circulated by the Research Cell within two weeks to all the members for their information.

## **8. Application Procedure**

1. All the reports should be submitted in the prescribed format, the copies of which should be available with the Research Cell and Institute's website.
2. All the relevant documents should be enclosed with the reports as per the check list.
3. The required number of hard copies along with CD of the reports with supporting documents viz: copy of the publication, abstracts, conference presentation documents etc.
4. The Research Cell will acknowledge the receipt.
5. The date of meeting will be intimated to the Principal Investigators who shall be available for the presentation of their reports for the Research sub-Committee meeting.
6. The decision of Research sub-Committee will be communicated in writing within two weeks by the Research Cell, if the Research sub-committee recommends for extension/termination of the project, the same shall be communicated to the Principal Investigators after the minutes are approved by the Director, SGPGI.

## **9. Review Procedure**

1. The Research sub-committee shall be held as per the need/if Research Committee can not be held due to some unavoidable circumstances.
  - i. Second week of May
  - ii. Second week of November
2. The Research sub-committee will review the annual/final reports of the ongoing projects sanctioned earlier to the investigators with the following elements to review:

- i. To review the progress of the project in terms of sample size target by the investigator.
  - ii. Appropriate methodology adopted by the investigator as per the sanctioned protocol design.
  - iii. The status of procurement of consumables and utilization of budget.
3. The Agenda & reports should be send to the members at least two weeks in advance. The decision should be taken by consensus.
  4. The decisions of the meeting shall be recorded in the minutes book and shall be confirmed during the next meeting with the signatures of the Chairperson at each page.

## **10.Element of Review**

1. The appropriate implementation of project as per the methodology sanctioned in the project
2. Sample size target by the investigator during the one year of its implementation in the annual report and total sample size target by the investigator during the completion of the project
3. Experimental details during the conduct of the study
4. Outcome of the study after completing its duration
5. To assess the generation of extramural project based on the work conducted by the investigator after completion of the project
6. Quality of publication resulted from the project
7. Utilization of budget during annual and final year

## **11.Decisions Making**

1. A member shall withdraw from the meeting during the decision procedure concerning as application where a conflict of interest arises. This shall be indicated to the Chairperson prior to the review of the application & recorded in the minutes.
2. Only members will take the decision. The decisions shall be taken in absence of the Principal Investigators & Co-investigators.

## **12.Communicating the decision**

1. Decisions will e communicated to the Principal Investigators by the Research Cell in writing.
2. Suggestions for modifications and reasons for rejection should be communicated to the Principal Investigators.

# Standard Operating Procedures (SOP) for Principal Investigators regarding Intramural Projects

## 1. Scope

The project should be developed with well defined objectives that can be completed in 24 months (two years). These are specifically meant to generate pilot data or innovative technology development. These projects will help the investigators to generate extramural grant on larger sample size.

## 2. Period for submission of project

The projects proposal will be invited from all the Faculty Members twice in a year in the month of November and May for two years duration. The Research Committee will review the projects in February and September each year. The Principal Investigator's are encouraged to submit project even before the invitation is sent so that they can be taken in the upcoming Research Committee Meeting.

## 3. Number of copies

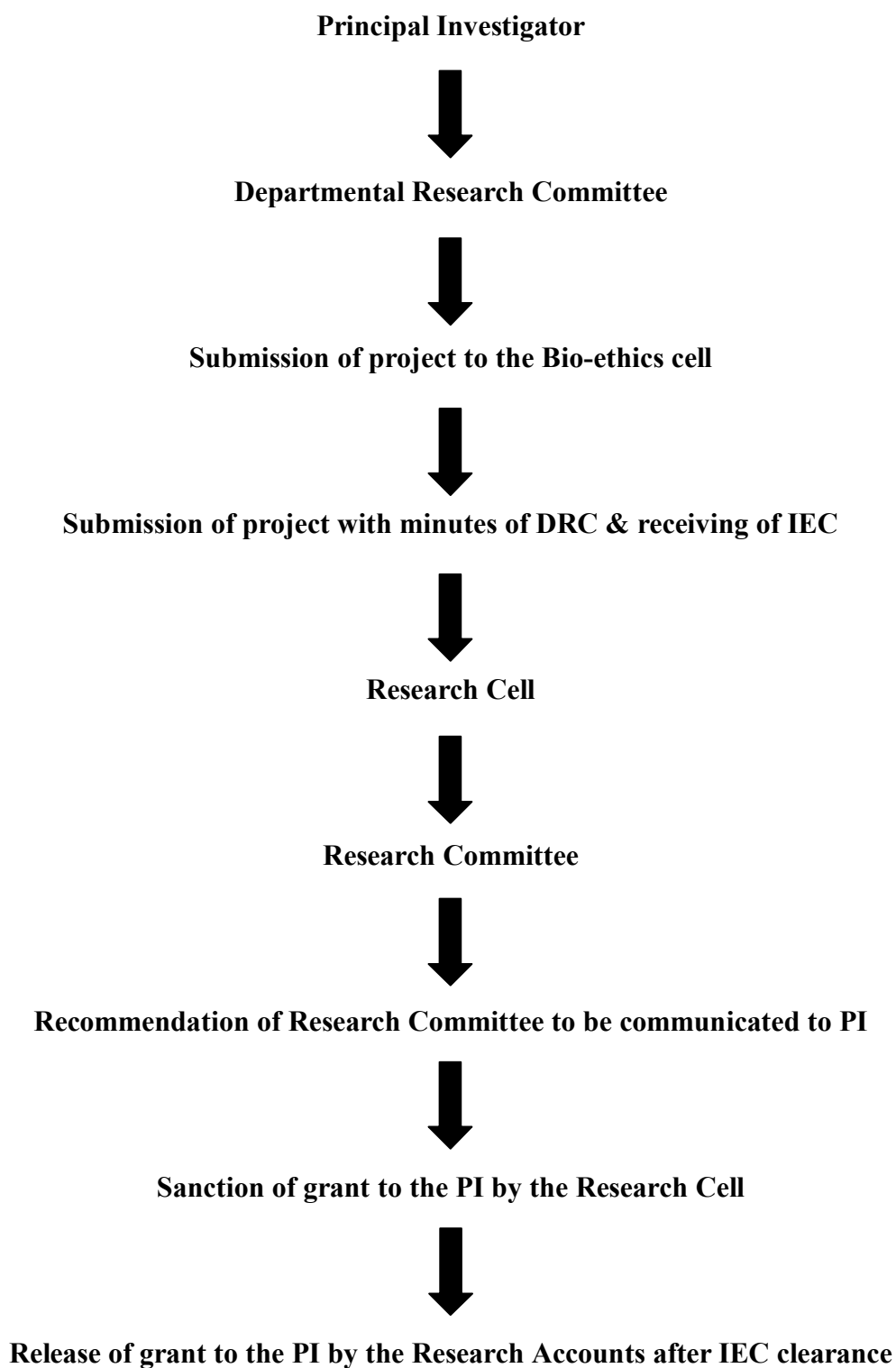
14 hard copies & a soft copy on CD should be submitted by the Principal Investigator to the Research Cell.

## 4. Procedure for application of intramural funding

1. Faculty member should apply for only one intramural project.
2. The project should be discussed in the Departmental Research Committee meeting and the 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 project 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 the project shall not exceed 24 months (two year).
5. The budget shall not exceed 3 lacs. Under exceptional circumstances the budget for Rs. 5 lacs maximum may be considered by the committee for outstanding, innovative projects with their proper budget justification.
6. The budget should be given in detail with full justifications of all the items on a separate sheet. **Please do not tailor the budget to make it around 5 lacs. There is no provision for staff in the intramural projects. Contingency should not be asked separately.**
7. The projects which are funded by the Institute, the funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural projects.
8. **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
9. Senior Residents, Pool Officers and PhD students, Research Associates or Paramedical staff, Scientists working in projects can not be co-investigators. (Only faculty members of this institute shall be Principal Investigators or co-investigators).
10. 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.

11. If the project involves direct intervention or interaction with patients, the Principal Investigators 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 concerning Department where the samples are collected.
12. For faculty member approaching superannuation, the remaining service period of Principal Investigator should be longer than the duration of project at the time of submission.
13. At any given period of time, no faculty member should have >2 intramural projects running. Third project will be considered only when at least one of the currently running two projects has been completed and reviewed in the Research Committee or and Principal Investigator has submitted manuscript/acceptance/published paper from the project.
14. The intramural project **should not** be send to the extramural funding agency simultaneously.
15. Statistical inputs from the Department of Biostatistics & Health Informatics may be taken, if needed.
16. 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.
17. The grant for new intramural project will be released when the PI will provide the ethical clearance of the concerning project to the Research Cell.
18. All the presentations for the new projects should be made before the committee and the PI should present the project consisting of 8 slides.
19. The PI should send the project as per the prescribed format with each section should start on a new page and all the points should be addressed.
20. 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 Research Committee.
21. Till such time that institute develops a mechanism for provision of insurance cover for the trial subjects no drug/device/procedural trials will be allowed either for 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.
22. 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 Gazatte 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, SGPGI.
23. 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.
24. Out sourcing 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.

## **Flow chart for submission of projects by the Principal Investigators**



# Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow

## Intramural Research Project Receipt form to be submitted in Duplicate

Type of submission:	New	Revised
Title of the project:		
Name of Principal Investigator & Department:		

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

Sl. No.	Mandatory Document	Yes	No	Not Applicable	Page No.
1.	Project proposal as per the prescribed format				
2.	Minutes of the Departmental Research Committee Meeting				
3.	Institutional Ethics Committee Receipt for submission				
4.	Institutional Animal Ethics Committee Receipt for submission				
5.	Undertaking by the Principal Investigator				
6.	C.V. of New or Investigator outside the SGPGI				

### Documents submitted

a) Complete

b) Incomplete, will submit on

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Receivers Name:

Signature & Date (with stamp)

Project submitted by Name & Signature:

# Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow

## Format for submission of Intramural Project

### PART-1: GENERAL INFORMATION

Project Title:

Investigators:

Name	Department	Signature
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Principal Investigator

Co-investigator

Co-investigator 1

Co-investigator 2

Total Cost (Rs):

Project summary including clearly state objectives (Not Exceed 250 words):

Key words (at least 5)

Copy of the Departmental Research Committee Recommendation

Copy of the Ethics committee submission certificate

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

### PART-2: TECHNICAL DETAILS

Rationale of the study supported by cited literature (Should state the Hypothesis/Key questions being addressed)

The relevance and expected outcome of the proposed study

Preliminary work done so far

Specific objectives (in bulleted form)

Work plan methodology/experimental design to accomplish the stated aim including the sample size (Patient/Control/Volunteers) and source of volunteers/Control

Inclusion/Exclusion criteria

**PART-3: BUDGET PARTICULARS (on separate sheet) (All items should be listed with cost)**

Budget should not include salary for research staff/purchase of equipment

**PART-4: BRIEF BIODATA OF PRINCIPAL INVESTIGATORS**

Name:

Designation:

Professional Experience and Training relevant to the project

Publications (Numbers only)

Books:

Research Papers (Only indexed, not abstract)

National

International

Patents:.....

(Please Specify):.....

Selected peer-reviewed publication in last 5 years (Maximum 5)

**PART- 5 (A): DETAILS OF PREVIOUS INTRAMURAL PROJECTS**

S. No.	TITLE	DURATION	BUDGET	COMPLETED/ NOT COMPLETED	FINAL COMPLET ION REPORT SUBMITT ED	MANUSCRIPT SUBMITTED/ PAPER PUBLISHED GIVE DETAILS	DETAIL OF ABSTRACT PRESENTED AT CONFERE CE/ DETAIL OF PUBLICATIO NS	EXTRAMURA L PROJECT GENERATED FROM THE INTRAMURAL PROJECT YES/NO IF YES GIVE DETAILS

**PART-5(B): DETAILS OF EXTRAMURAL PROJECTS**

S. No.	TITLE	DURATION	BUDGET	NAME OF FUNDING AGENCY	ONGOING/ COMPLETED



# **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow**

## **UNDERTAKING BY THE PRINCIPAL INVESTIGATOR**

### **1. TITLE OF THE PROJECT**

### **2. NAME, DESIGNATION AND DEPARTMENT OF THE PRINCIPAL INVESTIGATOR**

### **3. OTHER INVESTIGATORS OF THE RESEARCH PROJECT**

### **4. NAME AND ADDRESS OF ANY OTHER MEDICAL COLLEGE, HOSPITAL OR INSTITUTION WHERE PARTS OF THE STUDY WILL BE DONE**

### **5. NUMBER OF ONGOING PROJECTS IN WHICH YOY ARE PI.**

1. I confirm that I will initiate the study only after obtaining the ethical clearance from the Institute.
2. I will not implement any deviation from the approved protocol without prior consent of the Research/Research sub-committee and also informed simultaneously to the Institute Ethics Committee
3. I confirm that the Co-investigators of the study team have been informed about their obligations and are qualified to meet them
4. I will personally supervise the study and ensure that requirement of obtaining informed consent and other ethical requirements as per the SOP of the IEC.
5. I will inform the IEC for any unexpected or serious adverse event at the earliest as per the guidelines of the SOP of the SGPGI.
6. I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.
7. I will submit the six monthly report on prescribed format after the completion of six months and also I will submit the annual report after one year on prescribed format for its review by the Research/Research sub-committee
8. I will submit the final report of the project on prescribed format along with the copy of the manuscript or copy of the accepted/published research paper in the international journal derived from the said project

Signature of Principal Investigator

Date

## ONE PAGE CV FOR OUTSIDE INVESTIGATORS

<b>Full Name:</b>		
<b>Last Name</b>	<b>First Name</b>	<b>Middle Initial</b>
<b>Date of Birth (mm/dd/yy):</b>		<b>Sex:</b>
<b>Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator)</b>		
<b>Professional Mailing Address (Include institution name)</b>	<b>Study Sited Address (Include institution name)</b>	
<b>Telephone (Office):</b>	<b>Mobile Number:</b>	
<b>Telephone (Residence):</b>	<b>E-Mail:</b>	
<b>Academic Qualifications (Most current qualification first)</b>		
<b>Degree/Certificate</b>	<b>Year</b>	<b>Institution, Country</b>
<b>Current and Previous 4 Relevant Positions Including Academic Appointments (Most current position first)</b>		
<b>Month and Year</b>	<b>Title</b>	<b>Institution/Company, Country</b>
<b>Brief Summary of Research Experience related to the project:</b>		
<b>Signature:</b>	<b>Date:</b>	
<b>(Signature Required)</b>		

## **Standard Operating Procedures (SOP) for submission of Annual Progress Report by the Principal Investigator**

1. The Principal Investigator will submit the annual progress report on prescribed format for research progress and utilization of funds after the expiry of one year from the date of release of grant.
2. The investigator should clearly highlight the target of sample size as per the sanctioned protocol.
3. Any change in the objective or the design of the protocol, the PI should clearly mention in the report.
4. The Principal Investigator should justify in the report that the project will be completed in the remaining one year period of the project.
5. If the PI found that the project is not completed within the sanctioned duration, he should clearly justify for extension of the project with duration.
6. Only Principal Investigator/Co-investigator will present the annual progress report of the project in the Research Committee meeting.

## **Format for Annual Progress Report for Intramural Project**

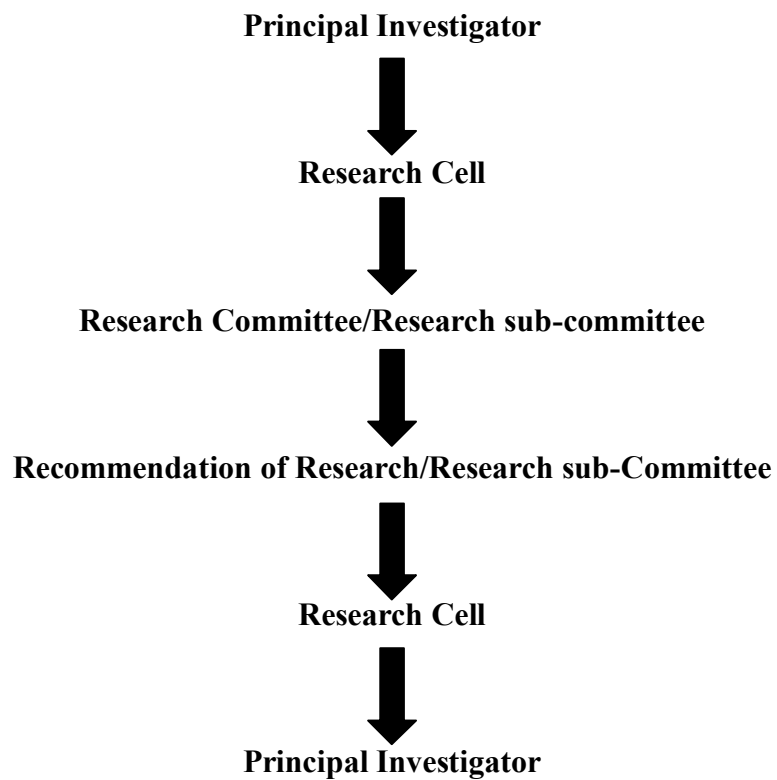
1. Name of Principal Investigator, Co-investigator (if any) and Department
2. Title of the project
3. Total budget sanctioned
4. Amount utilized out of the total budget sanctioned during one year
5. Progress during the one year duration
6. Sample size as per the sanctioned project and how many completed during one year
7. Does the project required extension, if so, give justification
8. Highlight of the work done during the one year
9. Do you think that with the one year duration, progress of the project and after the completion a suitable data will generated for publication out of the project.

Signature of PI

Signature of Co-investigator  
(if any)

Signature of HOD

## **Flow chart for submission of annual progress reports by the Principal Investigators**



## **Standard Operating Procedures (SOP) for submission of Final Progress Report by the Principal Investigator**

1. The Principal Investigator should submit the final report of the project after the completion of the study on the prescribed format for its review before the Research/Research-sub committee
2. The Principal Investigator should highlight in the final report regarding the result & discussion derived from the data obtained from the study
3. The Principal Investigator should submit the data for the study, he/she completed
4. The Principal Investigator should clearly state that whether this project can explored for extramural funding
5. The Principal Investigator should attach the manuscript along with the report or copy of the accepted research/published paper in the international journals

# Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow.

## Intramural Final progress report Receipt form to be submitted in Duplicate

Type of submission:	Annual	Final
Title of the project:		
Name of Principal Investigator & Department:		

### Checklist to assess the project report before submission to the Research sub-Committee for review

Sl. No.	Mandatory Document	Yes	No	Not Applicable	Page No.
1.	Copy of the sanctioned project proposal				
2.	Annual report on prescribed format				
3.	Final report on prescribed format				
4.	Copy of the manuscript				
5.	Copy of published paper in indexed international/national journals with impact factor				
6.	Copy of abstract presented in the international/national conferences				

#### Documents submitted

a) Complete

b) Incomplete, will submit on

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Receivers Name:

Signature & Date (with stamp)

Project submitted by Name & Signature:

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## **Format for Final Progress Report for Intramural Project**

1. Name of Principal/co-investigator & Department
2. Title of the project
3. Total sanctioned budget of the project (Rs.)
4. Total expenditure incurred for the project (Rs.)
5. Duration of the project (D/M/Y)
6. Report for the period: From \_\_\_\_\_ To \_\_\_\_\_
7. Objectives of the project (as stated in the sanctioned project proposal)
8. Experimental details
9. Results & discussion
10. Does this project leads to an extramural project
11. Copy of the manuscript
12. Publication from the project (Name author, title of paper, name of journal, Vol. Page year)
13. Self assessment of the progress

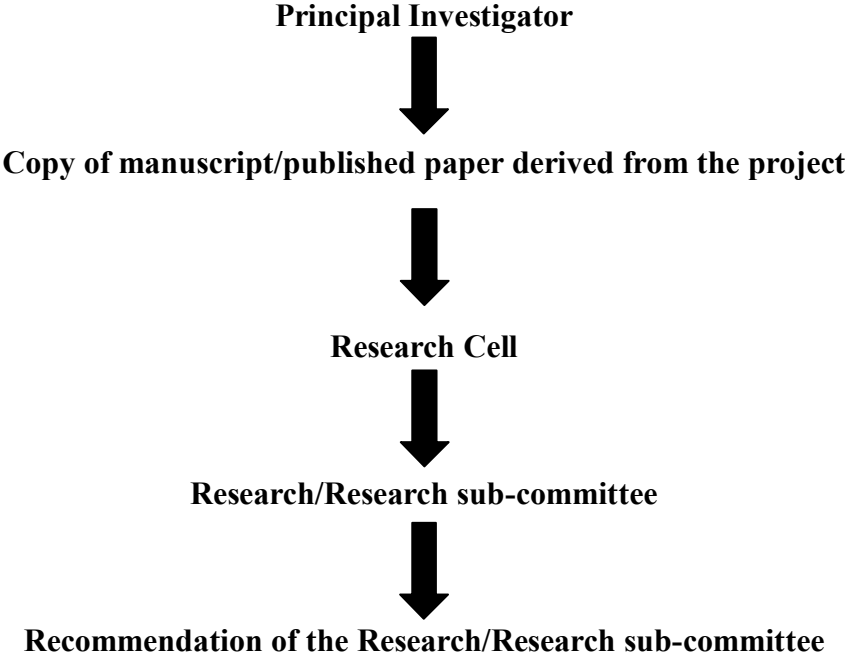
**Signature of  
Principal Investigator**

**Signature of  
Co-investigator (if any)**

**Signature of  
Head of the Department**



**Flow chart for submission of final reports by the Principal Investigators**



# **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow**

## **CONSTITUTION OF RESEARCH COMMITTEE: Three years (2013-2016)**

1. Director, SGPGI	Chairman
2. Dean, SGPGI	Member
3. Dr. C. M. Gupta, Former-Director, CDRI, Lucknow	Member
4. Prof. Shally Awasthi, Dept. of Pediatrics, KGMU, Lucknow	Member
5. Prof. Nuzhat Husain, Director, Ram Manohar Lohia Institute of Medical Sciences, Lucknow	Member
6. Prof. S.K. Yachha, HOD, Ped. Gastroenterology, SGPGI.	Member
7. Prof. Soniya Nityanand, Head, Dept. of Hematology, SGPGI	Member
8. Prof. Ashok Kumar, Dept. of Surgical Gastroenterology, SGPGI	Member
9. Prof. Gaurav Agarwal, Dept. of Endocrine Surgery, SGPGI	Member
10. Prof. M.M. Godbole, Dept. of Molecular Medicine & Biotechnology, SGPGI.	Member
11. Prof. K.N. Prasad, Dept. of Microbiology, SGPGI	Member
12. Prof. Sunil Jain, Dept. of Radiodiagnosis, SGPGI	Member
13. Dr. Uttam Singh, Dept. of Biostatistics & Health Informatics, SGPGI	Member
14. Faculty Incharge Research, SGPGI.	Member Secretary

## Notes

Standard Operating Procedure (SOP) is also available on Institute website  
[www.sgpgi.ac.in](http://www.sgpgi.ac.in)

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