



# **ALL INDIA INSTITUTE OF MEDICAL SCIENCES, MADURAI**

**(An Institute of National Importance under PMSSY Division, Ministry of  
Health and Family Welfare, Government of India)**

## **Standard Operating Procedure (SOP) For Institutional Research Committee (IRC)**

**(VERSION 1, DECEMBER 2023)**

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**ALL INDIA INSTITUTE OF MEDICAL SCIENCES  
MADURAI**

Ramanathapuram campus

**INSTITUTE RESEARCH CELL**

**STANDARD OPERATING PROCEDURES**

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# **All India Institute of Medical Sciences, Madurai**

## **Institute Research Cell**

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## **1. Mission of Institute Research Cell**

- ◆ To develop the standard operating procedures for all activities of Institute Research Cell.
- ◆ To build the capacity of the personal to facilitate collaborative research.
- ◆ To develop and maintain research infrastructure of international standards.
- ◆ To promote a research culture in the institute.

## **2. Objectives / Functions of Research Section**

- ◆ Prepare SOPs for Intramural and Extramural Research projects.
- ◆ Facilitate the faculty, students and scientists to undertake collaborative research. Promoting the research opportunities by facilitating the collaborations with national and international research organisations.
- ◆ Building the capacity of the faculty, students and scientists by training in research methodology and publications procedures.
- ◆ Set up a state-of-the-art multi-disciplinary research laboratory.
- ◆ Developing and implementation of effective administrative, financial and stores management research funds.

### **3. Research Advisory Committee (RAC)**

#### **Formation of RAC:**

The AIIMS Madurai Research Advisory Committee (RAC) has to be constituted by inclusion of external research experts. In reference to the criteria laid by Department of Scientific and Industrial Research (DSIR), the Research Advisory Committee in the institute should have minimum 10 members with at least 40% external experts. As all extra mural funding agencies mandated the requirement of DSIR certificate complying to this requirement is essential for the institute to make a progress in funded research projects. In this regard, a panel of external experts are suggested for Research Advisory Committee.

#### **Functions of Institute Research Committee (IRC – AIIMS Madurai)**

The research proposals generated at AIIMS Madurai need to have the approval of a scientific committee, a part of Institutional research committee before being submitted for an ethics committee for consideration. Under this process AIIMS Madurai Research Committee (IRC AIIMS Madurai) performs mainly the function of consideration of research proposals of faculty and students of AIIMS Madurai for quality improvement and approval. After the approval the proposals are referred to Ethics Committee for consideration until the IEC AIIMS Madurai registration at Department of Health and research (DHR) is completed.

#### **Functions of Research Advisory Committee (RAC-AIIMS Madurai)**

The Research Advisory Committee (RAC) is composed of experts from various kinds of medical institutions and organizations, representing a range of disciplines and streams. The committee's goal is to offer a diverse viewpoint on research that is undertaken and then disseminated to the society. Additionally, to encourage faculty and students to enhance the institution's research endeavours and to attract research grants to support faculty and student research ideas and projects. To offer faculty opportunities for short-term study abroad programs or observer ships, as well as to mentor students and faculty through inter-institute clinical encounters. To encourage inter-departmental, inter-institutional, and intra-institutional research activities; to develop methods for planning and carrying out collaborative research projects spanning many knowledge domains.

#### **Role of External RAC experts**

1. To act as an advisory to guide the research policy in the institute
2. To review the ongoing research activities in the institute and suggest research promotional measures accordingly
3. To participate in the research committee meeting during the evaluation of research proposal
4. To appraise the merit of submitted research projects submitted under intramural grant and recommend the list of awardees

**Tenure of external RAC members**

The external RAC members will be revised 2-3 years once.

**Frequency of External RAC members Visit:**

Direct (in person) participation: Two times in a year on rotation basis among the external experts.

Online participation as applicable.

**Financial Implications for external RAC members:**

The institute has to make arrangements for the travel of external experts (RAC) and their stay. In addition, a fixed emolument of Rs. 5000 / sitting / expert has to be given.

## 4. Institutional Research Committee (IRC)

### Scope

The scope of this SOP is to provide guidelines for the activities related to Institutional Research Committee.

### Functions of Institutional Research Committee (IRC)

The Research Committee shall be responsible for receiving, reviewing, approving and monitoring of all the research projects undertaken by the investigators of AIIMS, Madurai.

### Composition of IRC

The members of Institutional Research Committee (IRC) of the Institute will be selected from multiple disciplines of AIIMS, Madurai (and multi-institutional). The committee shall be made with 10-14 members with at least 25% shall be from external members in the committee) for ensuring the fair scientific evaluation of the research protocols. There should be adequate representation of age, gender etc. The Chairperson of the committee shall be the Director of All India Institute of Medical Sciences, Madurai. There shall be a proper representation of medical and non-medical internal faculty with a strong scientific and research temperament and experience including external members to reflect the different viewpoints.

The composition may be as follows:

S. No	Name	Role
1.	Dr. Mangayarkarasi V	Chairperson
2.	Dr. Ganesh Babu C P	Member
3.	Dr. Asmathulla S	Member
4.	Dr. Kalaiselvi S	Member Secretary
5.	Dr. Vijaya R	Member
6.	Dr. Meyyappa Devan Rajagopal	Member
7.	Dr. Elantamilan	Member

### Duration of Committee

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

### Membership Duration and Responsibilities

1. The duration of the membership shall be of three years.
2. Any members can serve for more than one term but all efforts will be taken to appoint fresh members comprising at least two-third of total 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, AIIMS, Madurai.
4. The member should maintain confidentiality during the meeting and sign a

confidentiality form at the start of their term.

5. Each member 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.

#### **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.

#### **Updating Research Committee Members**

1. All the relevant information, 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.



## 5. Intramural Funded Research Projects at AIIMS, Madurai

The IRC provides funds for research projects submitted by faculty of AIIMS. It is the policy of the Institute to promote research and provide equal opportunity for all interested. The summary of intramural schemes and their timelines are provided in Table 1. Application for intramural projects is to be submitted to the Research section.

Table 1: Summary of Intramural Schemes and Timelines

<b>Scheme</b>	<b>Individual Project</b>	<b>Collaborative Project</b>
Eligibility criteria	Assistant, Associate, Additional Professors, Professors, Scientists	Assistant, Associate, Additional Professors, Professors, Scientists
Grants/funds	Divided & distributed by competent authority as per merit of the project	
Duration	2 Years maximum	2 Years maximum
Announcement date	February	February
Last date for submission	March	March
Mode of submission	1 hard copy & soft copy	1 hard copy & soft copy
Tentative decision	May	May
Last date for availing grant	Within 3 months of intimation of selection of the project. Must have ethical, biosafety and other clearances	

### 5.a. Individual Intramural project

#### **Purpose:**

The emphasis is to support research of individual (at the start of the career of young) investigators. The investigator should publish at least one article in national/international peer reviewed journal from the funded project. The research work done in intramural project can lead to larger projects for extramural funding agency.

#### **Who can apply?**

Permanent staff (Assistant, Associate, Additional Professor, Professors) and scientists can submit their research proposal to the research unit which is forwarded through the Head of the concerned department. Faculty can apply any number of projects. Only one project is awarded for an investigator in a financial year. The same project or part of it should not be submitted for funding to more than one funding agency. The investigators who have been funded earlier can also apply if their previous project is completed and its final report is submitted to the Research cell.

### **How to apply?**

Proposals are invited to the Research Cell every year. Filled applications (vide infra) are to be submitted within the stipulated dates (will be intimated through Notices) either online or direct submission to Research Cell

### **Financial Support:**

The funding will be distributed based on merits of the project. The funding period is one year and can be extended to maximum 2 years on case-to-case basis depending on the review of the first-year annual report.

### **Project presentation:**

The submitted research projects are reviewed by Institutional Research Committee/IRC that reviews projects separately with external expert. The comments/ modifications suggested by the research committee is communicated to the principal investigator (PI) and the changes should be incorporated into the proposal. The applicants are required to make a power point presentation of the research projects before the committee and submit a hard copy of the modified proposal. After recommendation from the committee the projects are sanctioned for funding.

### **Clearances and initiation of the project:**

Applicants will obtain statutory clearances (appointment as permanent faculty) as appropriate to their project. Ethical clearance from Institute ethics committee is obtained and on submission of ethical clearance certificate, a project code is provided by Research Cell to the PI. Other necessary clearance from biosafety committee, biomedical waste management depending on the project is obtained. For submission of any clinical trial-based proposal, the faculty should get approval from Drug Controller General of India (DCGI) or Central Drugs Standard Control Organization (CDSCO).

### **Utilization of Funds:**

The fund provided through Intramural grant, should be utilized only for the purchase of consumables like chemicals, kits, disposables etc. Utilisation of fund for purchase of permanent equipment is not permitted. Stationery, printing, photocopying, postage is not allowed from intramural funds but can be obtained from department resource after approval from Head of Department. Any items covered under learning resource allowance scheme of the faculty should not be procured in intramural project funds. Funds should be spent by 31<sup>st</sup> March, of the year the project was sanctioned for.

For auditing purposes, all project-related purchases must be conducted through the GeM portal or in accordance with other central government regulations. Faculty members who receive Intramural funding are responsible for reporting all income generated from their projects, such as royalties, copyrights, and patents, ensuring these are registered under the name of AIIMS Madurai. They must submit these details for auditing and adhere to the guidelines set by the Research Advisory Committee (RAC).

**Review of research work:**

The PI has to inform the progress to the IRC every year by submitting an annual project report and by making presentation if asked for.

**5.b Interdisciplinary Collaborative Intramural Research Project:****Purpose:**

To promote research that are interdisciplinary and beyond the scope of a single department

**Who can apply?****How to apply?**

Faculty from 2 departments can apply. The applicant/ PI from one department should clearly mention the contribution and distribution of work in the joint project.

**Financial support:**

The funding will be distributed based on merits of the project to the PI. The project is sanctioned for one year and can be extended for one more year after review of the annual progress report.

**Clearances and Initiation of the project:**

Process is same as the early career intramural research grants. The PI of both departments should submit a collaborative research agreement after the grant of the project funds regarding the arrangement of ownership of Intellectual Property Rights (IPR)/ patents if applicable and authorship in publications.

**Utilization of funds:**

The budget for the two PI is sanctioned independently. They get to spend their grant individually. Each year both must submit a combined Utilization Certificate with joined annual progress report. The fund is used for consumables and not for employing staff, purchase of equipment or machinery.

**Role of Research Advisory Committee:**

The selection of project, allocation of fund and related guidelines will be related to the PI by the RAC.

## 6. Extramural Funded Research Projects at AIIMS, Madurai

### **Extramural Research Projects with National Funding Agencies:**

Faculty and Scientists can apply to various international, government national & state level funding agencies (e.g., DBT, DSR, ICMR, DHR, CSIR, DRDO, Ministry of Health & Family Welfare etc.) and non- government funding agencies.

### **Terms and Conditions**

#### **Who can apply?**

Permanent faculty and scientists of the institute can be PI. Permanent staff other than faculty and scientists (Biochemist, physiotherapist, nursing officer, dietician, clinical psychologist, para medical staff) can be co-investigator. Contractual staff can apply for short term projects along with Co-investigator who is a permanent staff and with the approval of funding agency.

#### **How to apply?**

Application for extramural funding can be sent to government and non- government funding agencies and these can be National and International agencies. One hard & soft copy of the project proposal The Research cell acts as a first stage of vetting where the project proposal is scrutinized should be submitted to the Research cell duly forwarded by the Head of the Department to which the applicant belongs. The requirements of the funding agency (declarations, endorsement certificates, undertakings) should be signed by the applicant and forwarded through the Head of the Department / In charge Head.

The Research cell acts as a first stage of vetting where the project proposal is scrutinized with regards to budget, staff and salary structure, establishment/overhead charges and requirements related to co- investigator. The deficiencies if any are brought to the notice of the applicant and completed proposals are approved and signed by the FIC/Dean Research and The Executive Director of AIIMS, Madurai and forwarded to the funding agency.

#### **Co-Investigator requirements:**

It is mandatory to have at least one co- investigator from the same department of the PI or the Institute.

**Budget of the project:** Expenditure can be made only under the budget heads sanctioned by the funding agency. Any item not included in budget head will not be allowed. The budget subheads include:

1. Staff – designation, number, period of employment, salary.
2. Contingency for recurring expenses.
3. Travel.
4. Supply & material consumables.
5. Equipment (non-recurring)
6. Overhead charges.
7. Other provisions- conferences, training, workshops.

The PI should clearly mention all items required for the project in the proposed budget.

**Staff & salary under the project:**

The PI should mention the nomenclature of the project staff with eligibility criteria, age limits and salaries as per revised RR (vide infra- annexure) and to be concurred by the funding agency as well. Recruitment of staff is as per Institution norms and will be advertised in website/newspaper and will be taken care by the Institution

**Provision of administrative/Overhead charges:**

Each project should have provision of administrative charges in the project and institute will not allocate separate budget for its expenditure. All expenses of salaries to the staff of Research Cell are to be met under this grant.

**Ethical clearance:**

The following clearances should be obtained-

- a. Institutional Ethics Committee
- b. Institutional Animal Ethics Committee
- c. Biosafety Committee
- d. Institutional Committee for stem cell research
- e. Serious adverse events Committee

The clearances should be obtained in time to submit to the funding agency

**Status of Project / Principal Investigator:**

It is mandatory for the PI to register in the Research Cell and must obtain a code without which he/she cannot claim to be the PI. Faculty, scientists involved in outside Collaborative Research one should register with the Research Cell.

**How to obtain operative approval / Project Code number?**

Once the project is approved by the funding agency operative approval must be obtained from FIC/Dean Research Cell. The faculty/scientist should submit a request letter to obtain the Project code number along with project proposal, ethical clearance certificates, sanction order from funding agency. If the applicant feels ethical clearance is not required then waiver should be sought during operative approval. Once the approval is obtained and Project code number is provided the project can be initiated and this "Project Code Number" is utilised for all further communications.

**Duration of the project:**

This is as approved by the funding agency and further extension if required is sought 3 months before the completion of the project from the funding agency.

**Down gradation or upgradation of approved project post:**

If the PI wants to downgrade or upgrade a post or convert into an equivalent pay scale post, justification for the same needs to be submitted to the funding agency and approval has to be obtained and forwarded to the Research Cell for necessary action, along with necessary

financial approvals for reduced/extra grant of salary. The downgraded/ upgraded post will be treated as fresh contract appointment.

**Outsourcing:**

Outsourcing of services e.g., hiring external professionals or consultants for secretarial work, survey is allowed under the project, subject to approval existing in the project and approval of allocation of funds.

**Addition of new Co-Investigator:**

After registering and getting operative approval, if the PI wants to add a new Co- investigator, he needs to get approval from the funding agency and must intimate the same to the Research cell with proper documents.

**Status of superannuated faculty member:**

Superannuated faculty member will not be able to remain as PI. If the superannuation is before the completion of the project the superannuated member should appoint a co-investigator as PI from the same department or from the institution. There should be one co-investigator from the same department or from the institution in all extramural funded projects. The administrative and Some projects may have co-investigators from other departments in the institute. This practice is discouraged unless a PI is absolutely unavailable in the same department. In this case when the financial powers will lie with the new PI. The superannuated member can continue to be Co- investigator till the completion of the project, even if he joins another institution. The superannuated member cannot claim lab/office space at AIIMS Madurai.

Some projects may have co-investigators from other departments in the institute. This practice is discouraged unless a PI is absolutely unavailable in the same department. In this case when the PI resigns or retires before the completion of the project, he/she should indicate which co-investigator becomes the next project in charge and which department he/she belongs to. The acceptance of the new PI should be simultaneously attached. The status of handover of the existing laboratory in the department, equipment, machinery, students, research staff should be clearly stated by the superannuated PI and along with the acceptance from HOD. If there are PhD students their transfer must be attached and approved by Dean (Academics). If the new PI was not associated with the project earlier, permission for the same should be obtained from the funding agency and must be shared with the Research cell.

**Faculty who has superannuated and re-employed by The Govt. of India/Ministry of Health and Family welfare on contract basis:**

He/she can continue as PI/Co- investigator on their ongoing projects. No approval of funding agency is required.

**Ongoing research project where a faculty member moves to a new AIIMS permanently or for an extended period of deputation:**

Projects are awarded depending on the research capabilities of the applicant faculty member and the availability of resources and infrastructure available at the parent institution. At the time of grant approval an undertaking/ MoU is signed with the funding agency wherein one of the clauses relates to the parent institution guaranteeing the availability of infrastructure and facilities for conduct of research. For operative/administrative and financial aspects of the project also the parent institute provides a guarantee/undertaking.

It is essential that the signatory PI is a permanent faculty of the Institute and is available during the tenancy of the research project. If otherwise the co- investigator in the department can be the new PI who takes charge of the administrative and financial aspects of the project and the previous PI becomes the co-investigator. Due concurrence from the co-investigator and funding agency is obtained for this arrangement.

**Signing of Memorandum of understanding/ Memorandum of agreement:**

Memorandum of understanding (MoU) is a nonbinding agreement between two or more parties outlining the terms and details of an understanding including the requirements and responsibilities of each party. MoU is the first stage towards moving to a formal contract.

Memorandum of Agreement (MoA) is a written document describing a cooperative relationship between two parties wishing to work together on a project or to achieve an agreed upon objective. MoA serves as a legal document and describes the terms and details of the partnership agreement. If a MoU/MoA is to be signed under a research project the PI should ensure the exact collaborative work, terms and conditions finalized between all the parties involved are to be mentioned in the document. MoU/MoA will be approved and signed by FiC/Dean Research only vetting by the Legal counsel of AIIMS with non-government funded projects. With government funding agencies such as DBT, DST, ICMR there is no such requirements.

**Honorarium:**

Research is mandatory activity for faculty or scientists working in AIIMS, Madurai. There is no justification for remuneration by way of honorarium for PI or co-investigator for this purpose from the project funds.

**Submission of Annual report:**

A copy of the annual report submitted to the funding agency is to be submitted to the Research cell also.

**Submission of Final report:**

On completion of the research project the PI should submit the final report of the research project directly to the funding agency and a copy thereof to the Research cell. The PI should also inform if any policy or programmatic change have been made in the concerned field based on the report.

**Multi – Institution projects:**

Transfer of funds to other institutions from AIIMS as part of multi- institution projects is based on approved budget from the funding agency and permission for the transfer must be taken from competent authority (FiC/Dean, Research/FA). The overheads (space for project staff, training, laboratory, transport if not covered by extramural fund, use of library, infrastructure and manpower support with approval of competent authority) will be charged on the budget of AIIMS and not on the total budget of extramural grant reference

**Finance allocation:**

Financial transactions and allocation of funds for Extramural project will be dealt with the Financial Advisor

**Publication Charges:**

Publication charges can be obtained from the research funds if permission is accepted, otherwise to be obtained from Learning Resource Allowance provided for individual faculty/scientists. The institution does not have any provision to pay for such charges from its funds.

**Procurement of materials:**

PI will request kits, consumables etc should be purchased through GEM portal/ local purchase through GFR rules as per institutional norms and should be obtained from stores through indent forms. Imprest account can be opened as per approval of FA for the petty items.



## **7. Review process by IRC / Research Protocol Review Meetings**

### **Scope**

This SOP provide guidelines for the process of research protocol review and instructions for principal investigators.

### **Responsibility**

Institute research cell (IRC) shall frame Research Advisory Committee (RAC) for the review of the research protocols. Member secretary and members of the RAC are responsible for organizing the review meeting as per this SOP.

### **Conduct of Review Meeting**

The Member Secretary will organize the review meetings, maintain 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 the principal investigator.

### **Frequency of Review meetings:**

The research protocol review meeting will be conducted four times in a year as per the following schedule (Feb / May / August / November) on every second week. The principal investigator (PI) shall submit their research protocols to IRC and responsible for prompt submission before the submission date. In the event of unavailability of PI, he or she may assign the responsibility to the Co-PI. IRC will receive the proposals till last working day of the preceding month before the scheduled month.

### **Quorum Requirements**

A minimum of 50% members including at least one outside member will be required for the quorum. All decisions should be taken in the meeting and not by the circulation of project proposals.

### **Independent Consultants**

The chairperson or his nominated IRC 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.

## **Review Procedure**

### **◆ For Old Projects**

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 sent to the members at least two weeks in advance. The decision will be taken by consensus and through a procedure.
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. In case, PI is not available during the meeting, he/she can authorize one of the Co-investigators 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.

### **Elements 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
11. Plagiarism Checking (Plagiarism Sub-Committee)

### **Decision- 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.

### **Procedure for decision making for the project (Intramural)**

<input type="checkbox"/> Research question	Out of 10 in each area
<input type="checkbox"/> Design of the project	Maximum marks = 40
<input type="checkbox"/> Methodology	Minimum marks = 0
<input type="checkbox"/> Relevance	

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.

### **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.

### **Follow up the procedures**

1. Six monthly reports should be submitted by the Principal Investigator on prescribed format to the Research Cell after just completion of six months. If PI fails 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 sent 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.

## **8. Plagiarism Scrutinization Committee (PSC)**

### **Instructions for Manuscript submission Declaration Form**

- a) Download and fill the “PSC Requisition form” (download from website)
- b) Prepare the manuscript as suggested in “Proforma to PSC” (download from website). Rename the manuscript as Name the manuscript as ‘Name – department – manuscript.
- c) Download the “Declaration form for PSC” and print it. Fill it and place signatures as necessary. Scan the document and save it in pdf format. Rename the pdf file as ‘Name – department – declaration form)
- d) Submit the following documents to: (email)
  1. PSC Requisition form
  2. Proforma to PSC
  3. Declaration form for PSC
- e) For queries contact: Member Secretary, IRC, AIIMS, Madurai.

### **Proforma for Manuscript submission to PSC**

PSC request the principal investigator to submit their manuscript in the following subtitles.

***(Do not include images, figures, data tables, and references)***

- a) Candidate Name:
- b) Thesis Title:
- c) Introduction:
- d) Review of literature:
- e) Methodology:
- f) Results: (Do not include data tables.)
- g) Discussion:
- h) Conclusion:
- i) Summary:

**All India Institute of Medical Sciences, Madurai**  
**Institute Research Cell – Plagiarism Scrutiny Committee (PSC)**  
**PSC Requisition Form**

- a) Name of the Principal Investigator:
- b) Category (Faculty, MBBS, MD, MS, MSc, PhD, Nursing etc)
- c) Department:
- d) Year of Course Completion (YYYY)\*
- e) Name of the Guide (Include Dr. / Mr. / Ms.):
- f) Contact details of Principal Investigator (Email & Mobile No):
- g) Title of Thesis / Dissertation / Project (as approved by IRC, AIIMS, Madurai)
- h) Requisition:

I, Dr / Mr / Ms ..... hereby submit my research proposal for scrutinization of plagiarism. I kindly request you to check and provide the plagiarism scrutinization report.

**Signature of Principle Investigator**

**Signature of Guide**

**Date:**

**Date:**

**All India Institute of Medical Sciences, Madurai**  
**Institute Research Cell – Plagiarism Scrutiny Committee (PSC)**

**Proforma for Manuscript submission to PSC**

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- a) Candidate Name:
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- e) Methodology:
- f) Results: (Do not include data tables.)
- g) Discussion:
- h) Conclusion:
- i) Summary:

**All India Institute of Medical Sciences, Madurai**  
**Institute Research Cell – Plagiarism Scrutiny Committee (PSC)**  
**Declaration Form**

**a) DECLARATION OF USE / NON-USE OF COPYRIGHTED CONTENT**

I, Dr / Mr / Ms ..... hereby declare that I have used / not used copyrighted content in my research proposal.

In case where I had used, I will submit the copy of permission obtained to use the copyrighted content for my research project.

**Signature of Principle Investigator**

**Signature of Guide**

**Date:**

**Date:**

**b) DECLARATION OF NON-MODIFICATION OF TEXT AFTER ISSUE OF PSC CERTIFICATE**

I, Dr / Mr / Ms ..... hereby declare that I had submitted the final version of my research proposal to Plagiarism Scrutiny Committee (PSC) for its approval.

I will obtain permission from PSC if my proposal needs any change in its text content.

**Signature of Principle Investigator**

**Signature of Guide**

**Date:**

**Date:**



## **9. Protocol for Submission of Research Proposals to IRC**

### **Check-list for Submission research proposal to IRC, AIIMS, Madurai.**

(Please put tick in the box if available)

1. Covering letter to IRC
2. General Information of the proposal
3. Technical details of the proposal with following subtitles:
4. References in Vancouver style
5. Proforma (Please check copyright, if it is standard tool or scale)
6. Consent form – bilingual (As per given template)
7. Time lines (like Ghant chart)
8. Soft copy sent by email to: IRC email

## Covering Letter

To,  
Faculty In-charge (Research),  
AIIMS Madurai.

Respected Madam / Sir,

Please find the attached research proposal titled

---

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\_\_\_\_\_ ' for review by the Institute Research Cell of AIIMS, Madurai.

Thanking you,

Signature:

Name:

Academic position:

Department:

Email id:

Mobile number:

## General Information

Title of the Proposal :

Principle Investigator Name :

Department :

Designation :

Duration of the course (year) :

Date of Submission :

Signature of the PI :

Signature of Guide

Signature of Co-Guide

Signature of  
Head of the Department

## **Technical details of the Proposal**

**Title of Research work:**

**Introduction:**

**Aim and Objectives:**

**Primary**

**Secondary**

**Review of Literature:**

**Materials and Methods:**

**Study setting:**

**Study Period:**

**Study design:**

**Study subjects:**

**Sample size:**

**Methodology:**

**Data collection:** Proforma attached

**Analysis Plan:**

**Ethical consideration:**

**Implications of the Study:**

**Acknowledgement:**

**References:**

**Proforma / Case Sheet**

1. Name :

2. Hospital no :

3. Date of admission :

4. Age :

5. Sex :

6. History :

7. Other investigation:

8. Other data :



**RESEARCH PROPOSAL FORMAT FOR AIIMS MADURAI  
RESEARCH CELL**

**Section 1 (For Research Cell)**

**Part A: Investigator Details**

<b>1.</b>	<b>Project title</b>		
<b>2.</b>	<b>Principal investigator</b> (Name, Designation & Department)		
	Email ID (PI)		
	Mobile (PI)		
	<b>Ongoing projects with the PI (either PI or Co-investigator)</b>		
	<b>Ongoing funded projects as PI</b>		
<b>3.</b>	<b>Coinvestigators</b> (Name, Designation, Department)  (Add rows if needed)  (Please attach a one-page CV for PI. Number mentioned here are illustrative only. Use single row for each Co-Investigators)	Name, designation, email id and contact number	Department (and institution name, if not JIPMER)
<b>Co-investigators from AIIMS Madurai</b>			
Investigator 1		Department	
Investigator 1		Department	
<b>Co-investigators from AIIMS Madurai</b>			
Investigator 1		Department	
Investigator 1		Department	

4.	<b>Responsibilities of the collaborating institutions (national and international)</b> <b>[Applicable for multicentric projects]</b> (Please include letter of support and one-page CV of investigators outside the institute)	<i>Oversight:</i> <i>Lead coordination:</i> <i>Data collection and data entry:</i> <i>Data analysis:</i> <i>Source of Funding:</i>	
	<b>Name of two external experts with whom this protocol can be shared for technical evaluation</b> (Name of the expert, affiliation, contact number and email id)		
5.	<b>Details in case of inter-institutional projects</b>		
	<b>Name of the coordinating institution</b>		
	<b>Is a copy of the protocol submitted to the coordinating center enclosed?</b>		
6.	<b>Duration of study</b>		
7.	<b>Type of Study</b>	<input type="checkbox"/> International	<input type="checkbox"/> National
			<input type="checkbox"/> Inter-institutional <input type="checkbox"/> Intra-institutional
8.	<b>Funding Agency (name)</b>		
	<b>Overall project amount</b>		
	<b>Funding approved?</b> <input type="checkbox"/> Yes (attach sanction letter) <input type="checkbox"/> Submitted <input type="checkbox"/> No		
9.	<b>Detailed budget</b> (Under different Heads as it is submitted to funding agency with justification)		



## Part B: Project details for technical evaluation

<b>Project title</b>																													
<b>Project Summary (Not a layman summary)</b> <b>Should be confined to one single page</b>																													
<b>1. Introduction</b> (may contain background, rationale, novelty and implications, as applicable)																													
<b>2. Research question (s)</b>	1. (a) 2. (b) 3. (c) 4. (d)																												
<b>3. Aims and objectives</b>																													
Primary	1.																												
Secondary	2.																												
<b>4. Brief review of literature: (organize in different section if it caters to different objectives)</b>																													
<b>5. Study design / type</b> (Choose more than one option if applicable)	<table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> Basic Sciences</td> <td><input type="checkbox"/> Epidemiological</td> </tr> <tr> <td><input type="checkbox"/> Public Health</td> <td><input type="checkbox"/> Clinical</td> </tr> <tr> <td><input type="checkbox"/> Socio-behavioral</td> <td><input type="checkbox"/> Implementation Research</td> </tr> </table> <table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> Descriptive</td> <td><input type="checkbox"/> Longitudinal</td> <td><input type="checkbox"/> Cross-sectional</td> </tr> <tr> <td><input type="checkbox"/> Cross-sectional analytical</td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> Case control</td> <td><input type="checkbox"/> Cohort</td> <td></td> </tr> <tr> <td><input type="checkbox"/> RCT</td> <td><input type="checkbox"/> Diagnostic validity</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Systematic review</td> <td><input type="checkbox"/> Meta-analysis</td> <td></td> </tr> </table> <table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> Qualitative</td> <td><input type="checkbox"/> Quantitative</td> </tr> <tr> <td><input type="checkbox"/> Mixed Method</td> <td></td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Any other (please specify)</td> </tr> </table>		<input type="checkbox"/> Basic Sciences	<input type="checkbox"/> Epidemiological	<input type="checkbox"/> Public Health	<input type="checkbox"/> Clinical	<input type="checkbox"/> Socio-behavioral	<input type="checkbox"/> Implementation Research	<input type="checkbox"/> Descriptive	<input type="checkbox"/> Longitudinal	<input type="checkbox"/> Cross-sectional	<input type="checkbox"/> Cross-sectional analytical			<input type="checkbox"/> Case control	<input type="checkbox"/> Cohort		<input type="checkbox"/> RCT	<input type="checkbox"/> Diagnostic validity		<input type="checkbox"/> Systematic review	<input type="checkbox"/> Meta-analysis		<input type="checkbox"/> Qualitative	<input type="checkbox"/> Quantitative	<input type="checkbox"/> Mixed Method		<input type="checkbox"/> Any other (please specify)	
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<input type="checkbox"/> Qualitative	<input type="checkbox"/> Quantitative																												
<input type="checkbox"/> Mixed Method																													
<input type="checkbox"/> Any other (please specify)																													

6.	Study methods (this template applicable only to human studies)	
7.	<b>Study participants</b>	
	a. Number of Study groups (Number, names and definitions)	One group
	b. Study participants (Inclusion and exclusion criteria– for each group)	
	c. Source of subjects / Study setting	
	d. Is sampling involved? If yes, please indicate the population, sample size and sampling method	
	e. Is randomization involved? If yes, details of procedure	NA
	f. Is allocation concealment involved? If yes, details?	NA
	g. Is blinding involved? If yes, methods.	NA
	<b>8. Details of interventions (only for interventional studies [randomized/cluster trials])</b>	
	a. Details of drugs, devices, or invasive /non-invasive procedures for interventional studies	NA
	b. Are the drugs or devices to be used approved for these indications by Drug Controller General of India (DCGI)? (Attach evidence, approval letter for the study or give undertaking – see below -- to get the approval before starting study)	NA
9.	Data safety monitoring plan (if it is a clinical trial)	

<b>10. Procedures</b> (Please provide details of variables to be collected, frequency (if it is a follow up study) study tools, operational definitions and equipment to be used). We encourage you to provide a flow diagram of the study to get better idea.		
	Statistical Analysis Plan	
Withdrawal criteria (Circumstances that could lead to a decision to withdraw the participant from the study)	NA	
Rescue criteria (Measures that will be taken in case of expected adverse outcomes)	NA	
<b>11. Ethical considerations (Please fill the separate Ethics forms in the prescribed template for submission to ethics committee)</b>		
a.	Are all the proposed procedures considered acceptable in routine practice? If not, please provide details.	
b.	Important ethical issues involved that you can identify	
<b>12. Variables (for a, b, list only those that you wish to analyses)</b>		
a.	Study variables	
b.	Confounding/interacting	-
c.	Any other comments	Nil
<b>13.</b>	Plan for statistical analysis, including tests to be used if any. [be specific according to the stated objective]	

<b>14.</b>	<b>Sample Size</b>		
	a.	Assumptions	
	b.	Method used (Manual or software give details of it)	
	c.	Initial estimate	
	d.	Corrected estimate (After considering losses)	
<b>15.</b>	<b>Relevant references (Use Vancouver style)</b>		

## 16. Enclosures

a.	Data collection proforma / Case Record Form	Attached
b.	Questionnaire (s)	Attached
c.	Copy of signed original protocol (only for multicentric studies) (Please refer to item 7 above)	Not applicable
d.	Copy of signed consent letter from coordinator (only for multicentric studies) (Please refer to item 7 above)	Not applicable
e.	Each external collaborators' consent and one-page CV (Please refer to item 3 above)	Not applicable
f.	Others (please specify)	Not applicable

## 17. Undertaking

PI gives undertaking for submission of annual progress report and publications or conference proceedings coming out of the approved study

