

PROTOCOL WRITING FOR A RESEARCH GRANT



Siddhartha Laskar

Professor

Department of Radiation Oncology

Member Secretary, Institutional Review Board

Tata Memorial Hospital, Mumbai

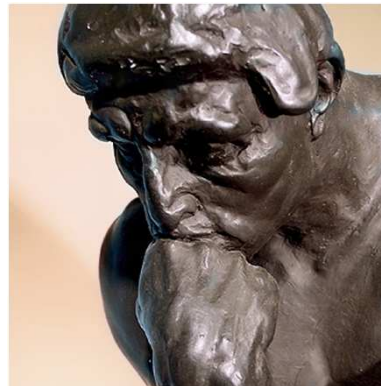
INDIA

(laskars2000@yahoo.com , www.tmc.gov)

APPLICATION DEVELOPMENT STRATEGY



Plan

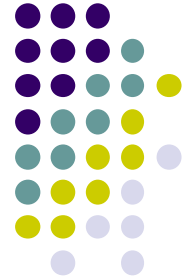


Think



Write

COMPONENTS OF A SUCCESSFUL GRANT APPLICATION



-
- Strong Idea
 - Strong Science
 - Strong Application



FORMULATING A RESEARCH QUESTION

Identify a Broad Area of Interest:

literature searches, discussions with colleagues, policy makers and the community

Then ask yourself a series of questions:

- Is this idea stimulating and important enough?
- Does this idea have long-term potential to be expanded?
- What is the focus of my department, institution, and profession, and how do their goals fit with my topic of interest?
- Does the idea reflect contemporary thinking in the field?
- Will the idea contribute by contesting contemporary thinking in the field?
- What areas need further exploration?
- Could my study fill a gap or lead to greater understanding?
- Has a great deal of research already been conducted in this topic area?
- Is the timing right for this question to be answered?
- Which funding agencies would be interested in funding this study?
- Most importantly, will my study have a significant impact on the field?



FORMULATING A HYPOTHESIS

Hypotheses: Predictions about the nature and direction of the relationship between two or more variables. A well-thought-out and focused research question leads directly into hypotheses.

Ideally, a hypotheses should:

- Give insight into a research question.
- Be testable and measurable by the proposed research methodology.
- Spring logically from the experience of the researchers.

Make sure that you:

- Provide a rationale for your hypotheses explaining how they were derived and why they are strong?
- Provide alternative possibilities for the hypotheses that could be tested and explain why you choose the ones you did over others?



EVALUATE YOUR RESOURCES

By asking yourself these questions:

- What is my level of expertise, interest and comfort with this topic?
- Do I have the necessary skills or knowledge to carry out my idea?
- Do I have the time to complete the tasks that will be required?
- Am I willing and able to commit the time to a project?
- Do I have the resources needed to complete the project?
- Are others available to serve as collaborators to complement my level of expertise?



Write an abstract or Concept paper that reflects your current thinking.

This will help you narrow your topic and force you to describe your idea systematically. This abstract can also be used to obtain feedback from colleagues and potential funding agencies.

Discuss your ideas and establish whether the idea fits the priorities of the funding agency you are targeting.

Begin to reshape your ideas based on these conversations and a further review of the literature.

A good research question should be narrow enough to address specific issues

AIMS AND OBJECTIVES



An aim is a broad statement of desired outcomes while **objectives** are the steps you are going to take to test your hypotheses or answer your research question.

Make sure that each hypothesis is matched with a specific objective.

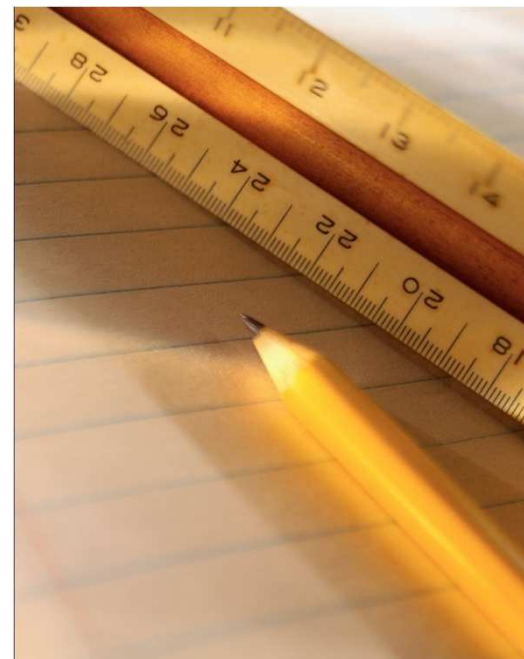
Objectives must be measurable, highly focused and feasible, given the time and money you are requesting in the grant.

Be realistic about what you can accomplish in the duration of the grant and within the projected budget.

OBJECTIVES



- S – Specific
- M – Measurable outcomes
- A – Achievable, attainable
- R – Realistic
- T – Time-bound, achievable
in a specified time period





PROJECT TEAM

The **goal of this section is to demonstrate the experience and competence** of the applicant or project team to perform the tasks of the proposed project. Use this section to show reviewers that, based on your past successes with similar research, the project team is capable of carrying out this work.

If you have limited experience, **complement your experience by teaming-up with a collaborator** to enhance your expertise in certain areas.

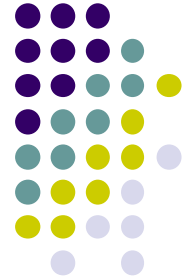
Ask yourself the following questions when deciding on a project team:

- How willing am I to work with others to shape, develop, and implement this idea?
- Am I willing to be flexible and see different sides of a question?
- Am I willing to let go of or modify an important idea to fit the interests of others?

RESEARCH PROJECT INVESTIGATOR STRUCTURE



- Principal Investigator: Oversees entire project, especially its scientific integrity
- Co-investigator: Contributes to a discrete area of expertise
- Project co-ordinator: Day-to-day management of the study
- Interviewers: Assessment of participants
- Interventionist: Implements experimental protocol in intervention studies
- Data coder/cleaner: Coding, data capture, checking for accuracy of data entry
- Data base manager: Establishes and maintains data files
- Statistician: Assists in determining statistical analysis

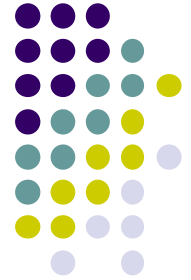


THE PRINCIPAL INVESTIGATOR (PI)

What makes a good PI? These are some general criteria:

- Recent publications in peer-reviewed journals related to the proposed research area
- Prior supervision of research team members
- Prior position as a key member of a research team
- Receipt of prior funding for grants/contracts in the proposed research area
- Preferably a doctoral degree but sometimes a Masters degree with proven research experience in the proposed area.

COLLABORATORS

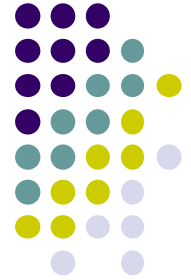


Suggestions of ways in which to find possible collaborators:

- ***Network yourself*** Start attending major conferences in your field.
- ***Contact other researchers*** in your organisation, nationally or internationally.

When deciding on a collaborator it is advisable to choose people:

- who can ***add to your expertise***, not copy it
- who are ***not too busy*** to help you when you need help
- who are ***willing to agree to disagree yet you get along*** with and will ***enjoy working with***



Collaborators can also serve as mentors

Some of the benefits of having a mentor:

- Having access to experienced researchers, especially in your field.
- Assistance in developing and exploring research ideas, hypotheses, etc.
- Sharing of personal and professional experiences while writing and submitting a research grant proposal.
- Receiving relevant and up-to-date information about new research methods.
- Establishing collaborative associations with peers.
- Constructive feedback on research proposals and throughout the research process.



SHORT DESCRIPTION OF THE PROJECT (ABSTRACT)

This section should include information:

- The purpose of the research
- The importance of the research
- The background and feasibility of your project
- A brief description of target population, hypotheses, and methodology
- A brief description of methodology and expected results
- A description of the contributions your research will make to the field
- Health outcomes.

BACKGROUND



Make certain that your background ***discussion remains focussed*** on the issues your research will address. At the end of each topic, point out to the reader how your proposed findings will help resolve important issues in the field.

The background section should contain:

- Information on ***scope of the problem*** i.e. why it is important.
- A critical ***review of the relevant literature***, including highlights of ongoing research and gaps in knowledge.
- An ***explanation of why this study needs to be done***, and why this research is relevant and necessary for the target population.
- A ***well-grounded theoretical basis*** for your study or project.
- The ***long-term implications of this research***, including contributions to the existing pool of knowledge.

METHODOLOGY



Make sure that the study you describe corresponds with the specific objectives you listed earlier in the proposal. Make sure that the underlying science and methods are sound, feasible, & complete.

Give details of:

- The design of the study (e.g. descriptive, comparative, longitudinal, case-control, quasi-experimental, randomised) and explain why that design was chosen.
- The procedures for training of researchers or interviewers.
- Access to specialised facilities or equipment where applicable.
- Data collection procedures.
- Procedures for handling of participants and confidentiality issues.
- Procedures and approval for working with animals where applicable.
- Possible hazards to research personnel and study subjects.
- Timeline for tasks to be completed during the project period.

ICH GCP GUIDELINE SUMMARY



1) Glossary

Common language for investigators/sponsors/ethics committees

2) Principles of Good Clinical Practice

13 Tenets of ICH GCP

3) Requirements for IRB/IEC

Roles responsibilities and composition

4) Responsibilities of the investigator

5) Responsibilities of the sponsor

6) Requirements for clinical trial protocol and protocol amendments

7) Responsibility of the sponsor in the development of investigator's brochure

8) Essential documents

PRINCIPLES OF ICH GCP



1. PROVISIONS AND PREREQUISITES FOR A CLINICAL TRIAL

- 1.1 Justification for the trial
- 1.2 Ethical principles
- 1.3 Supporting data for the investigational product
- 1.4 Investigator and site(s) of investigation
- 1.5 Regulatory requirements

2. THE PROTOCOL

3. PROTECTION OF TRIAL SUBJECTS

- 3.1 Declaration of Helsinki
- 3.2 Ethics committee
- 3.3 Informed consent
- 3.4 Confidentiality



4. RESPONSIBILITIES OF THE INVESTIGATOR

- 4.1 Medical care of trial subjects
- 4.2 Qualifications
- 4.3 Selection of trial subjects
- 4.4 Compliance with the protocol
- 4.5 Information for subjects and informed consent
- 4.6 The investigational product
- 4.7 The trial site
- 4.8 Notification of the trial or submission to the DRA
- 4.9 Review by an ethics committee
- 4.10 Serious adverse events or reactions
- 4.11 Financing
- 4.12 Monitoring, auditing and inspection
- 4.13 Record-keeping and handling of data
- 4.14 Handling of and accountability for pharmaceutical products
- 4.15 Termination of trial
- 4.16 Final report



5. RESPONSIBILITIES OF THE SPONSOR

- 5.1 Selection of the Investigator(s)
- 5.2 Delegation of responsibilities
- 5.3 Compliance with the protocol and procedures
- 5.4 Product information
- 5.5 Safety information
- 5.6 Investigational product
- 5.7 Trial management and handling of data
- 5.8 Standard operating procedures
- 5.9 Compensation for subjects and investigators
- 5.10 Monitoring
- 5.11 Quality assurance
- 5.12 Study reports
- 5.13 Handling of adverse events
- 5.14 Termination of trial



6. RESPONSIBILITIES OF THE MONITOR

- 6.1 Qualifications
- 6.2 Assessment of the trial site
- 6.3 Staff education and compliance
- 6.4 Data management
- 6.5 Case-report forms
- 6.6 Investigational product
- 6.7 Communication
- 6.8 Notification of the trial or submission to the regulatory authority
- 6.9 Reports

7. MONITORING OF SAFETY

- 7.1 Handling and recording adverse events
- 7.2 Reporting adverse events

8. RECORD-KEEPING AND HANDLING OF DATA

- 8.1 Responsibilities of the investigator
- 8.2 Responsibilities of the sponsor and the monitor
- 8.3 Archiving of data



9. STATISTICS AND CALCULATIONS

- 9.1 Experimental design
- 9.2 Randomization and blinding
- 9.3 Statistical analysis

10. HANDLING OF AND ACCOUNTABILITY FOR PHARMACEUTICAL PRODUCTS

- 10.1 Supply and storage
- 10.2 Investigational labelling and packaging
- 10.3 Responsibilities of the investigator
- 10.4 Responsibilities of the sponsor and the monitor

11. ROLE OF THE DRUG REGULATORY AUTHORITY

- 11.1 General responsibilities
- 11.2 On-site inspections

12. QUALITY ASSURANCE FOR THE CONDUCT OF A CLINICAL TRIAL

INDIAN GCP GUIDELINES



- Released in Dec 2001 (Developed by CDCSO and endorsed by DCGI)
- Based on ICH GCP, WHO, USFDA, European GCP, ICMR
- Revised Schedule Y (Jan 2005)
- Gazette Notification in Jan 2013



STATISTICAL CONSIDERATIONS

Ensure that the following have been fully considered in your methodology section:

- The inclusion and non-inclusion criteria for subjects or participants.
- The source of recruitment of subjects or participants is clearly indicated.
- The nature of the control group, if any, indicating whether it will be simultaneously studied or whether it will be a historical reference group.
- What data will be collected and the frequency of data collection.
- The research instruments and data collection forms. Include a copy of each instrument in an appendix. Include details of previous reliability and validity data.
- The sample size.
- Data analysis and evaluation.

BUDGET



- Clearly define the heads under which the budget has been allocated with defined timelines in the life history of the study
- Include all other sources of funding for the proposed study.
- Provide justification for all categories of funds requested.
- Reviewers can recommend budget cuts when they think that expenses are overly high or unwarranted.
- The budget must accurately reflect the plan for data collection, data analysis, and data write-up.
- Demonstrate that you can complete a good small project for a relatively smaller amount of money and establish a good track record before applying for larger research grants.



OUTCOMES OF YOUR STUDY

Consider the following questions:

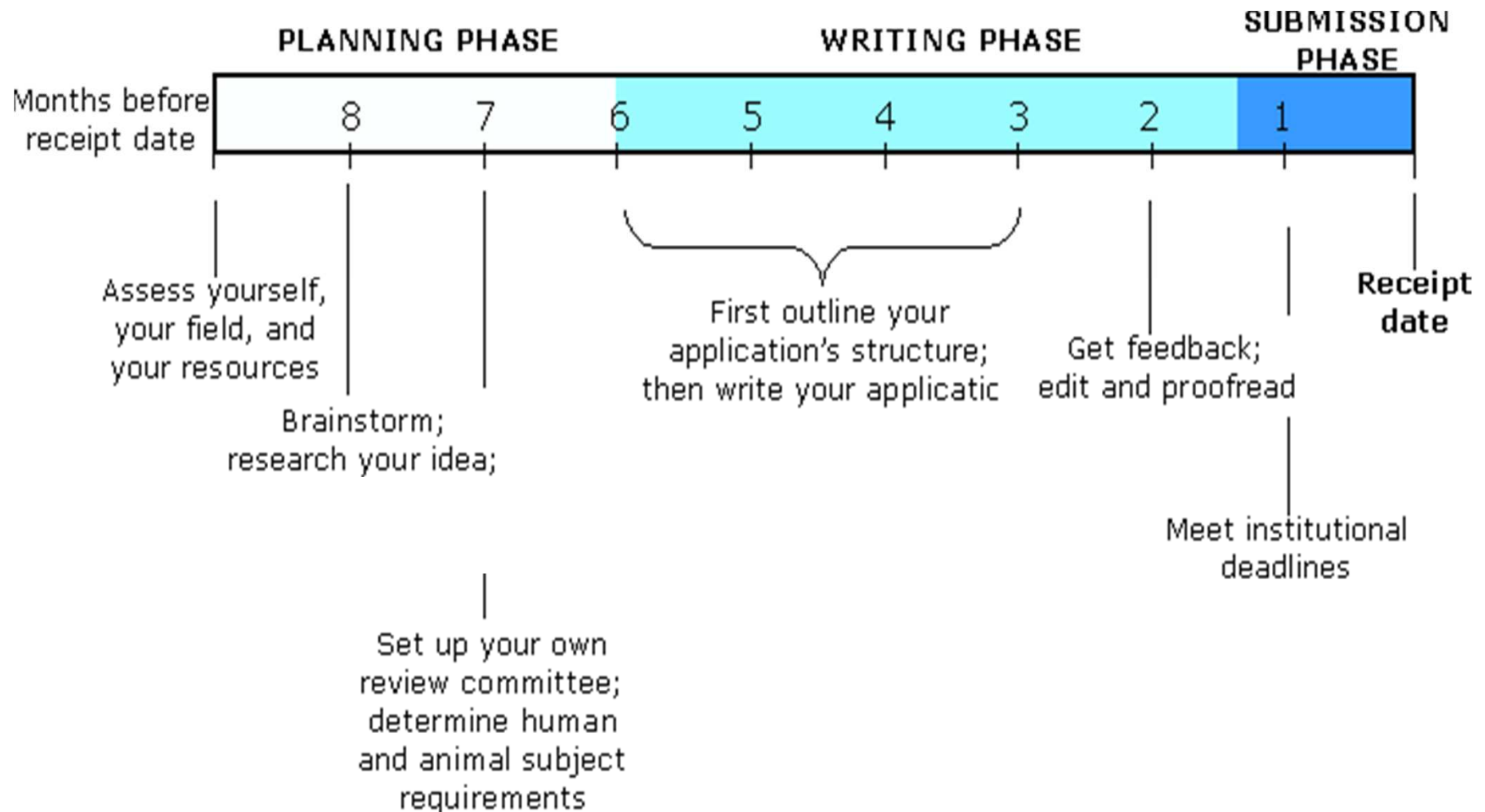
- Why are you doing this research?
- What are the long-term implications?
- Who will benefit from these findings and who might be deprived or harmed as a result of the study?
- What will happen with the research findings?
- What is the ultimate application or use of the research?



APPROVALS

- Ensure that your proposal has the necessary ethics and institutional approval before submitting to the funding agency.
- Incomplete proposals could be returned to you and will delay the review of your proposal.
- Approvals from national regulatory bodies & local regulations

PRE-SUBMISSION PLANNING TIMELINE

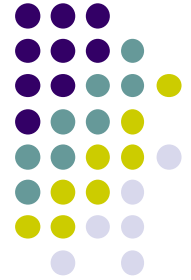




MULTIPLE PRINCIPAL INVESTIGATORS

- Single PI model does not always work well for multi-disciplinary, collaborative research
- Recognize contributions of all contributors
- A complex issue – Talk to all stakeholders & funding agency

GOOD GRANTSMANSHIP

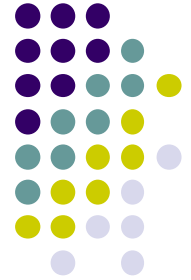


- Show your draft application to a colleague
- Show your draft application to a colleague who does not already know what you intend to do
- Show your draft application to a colleague who is not your best friend
- Your draft reviewers need to understand
 - What you intend to do
 - Why you believe it is important to do
 - Exactly how you are going to do it
- If they don't get it, you must revise your application
- Leave enough time to make revisions

ALIGNMENT OF APPLICATION FORMAT WITH SCORED REVIEW CRITERIA



SCORED REVIEW CRITERIA	APPLICATION
Significance	Research Strategy a. Significance
Investigator(s)	Biosketch Personal Statement
Innovation	Research Strategy b. Innovation
Approach	Research Strategy c. Approach
Environment	Resources Environment



GOOD PRESENTATION

- Be realistic ... not overly ambitious
- Discuss potential problem areas
- Discuss possible solutions

Explain rationale for your decisions

- Be explicit
- Reviewers cannot read your mind ...

Don't assume they know what you intend

HALLMARKS OF A GOOD GRANT APPLICATION



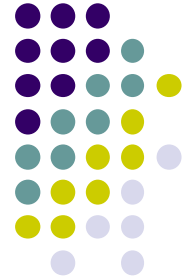
- Strong significance to an important problem in public health: High MPACT
 - High degree of novelty and innovation
- Strong track record by a well qualified applicant
- Clear rationale
- Relevant and supportive preliminary data
- Clear and focused approach that provides unambiguous results
- Careful attention to details
 - Layout, Fonts, Clarity of data, Error bars, Spelling, etc

COMMON REASONS CITED FOR A WEAK APPLICATION



- Lack of or weak impact
- Significance not obvious or weak
 - Too ambitious, lacking focus
 - Unclear or flawed hypothesis
 - Feasibility unsupported
 - Unrealistic Budget
- Poor writing
- Approach flawed
- Applicant track record weak or lacking appropriate expertise

SUCCESSFUL WRITERS



- Research skills
- Sales capabilities
- Written and oral communication skills
- Ingenuity and flexibility
- Administrative capabilities (from leadership to accounting)
- Human relations skills
- Persistence, dedication, patience, and the capacity for hard work
- Political acumen
- Integrity

BUDGET STRATEGY



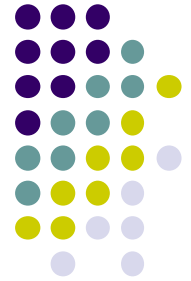
- Ask for what you need to do the work – not the max that you can
- Justify requests that are significant or out of the ordinary
- Reviewers emphasize project quality over budget
- Follow sponsor and institutional guidelines and policies
- When in doubt, ask!

TOP 10 REASONS FOR AN UNSUCCESSFUL PROPOSAL

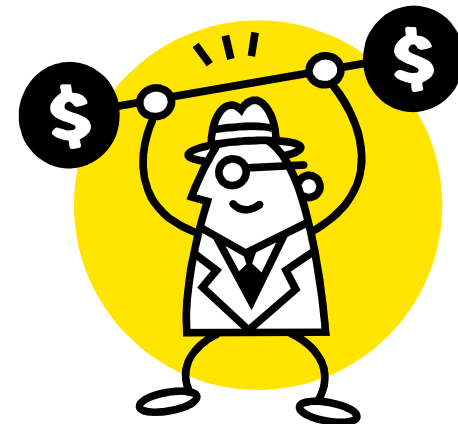


1. Project doesn't address agency priorities
2. Guidelines not followed
3. Not a compelling idea
4. Ideas not clearly presented
5. Methodology appears to be flawed
6. Overuse of jargon
7. Overly ambitious
8. Narrative and budget don't correspond
9. Sloppy presentation
10. The work has already been done

IF YOUR PROPOSAL IS REJECTED...



- Don't give up!
- Get reviews
- Talk to agency contact
- Re-evaluate, revise and resubmit
- Look for other potential funders



INDIAN COUNCIL OF MEDICAL RESEARCH (ICMR)



Thrust Areas of Research

Learn about terms and conditions of all schemes supported by ICMR.

Grant Schemes

Studentships

Short Term Research Studentship

Fellowships/ Associateships

Ad-hoc Research Schemes

Research Fellowships/ Associateships

Junior Research Fellowships

Post Doctoral Research

ICMR Postdoctoral Research Fellowship

Talent Search Schemes

ICMR Talent Search Scheme for MD/MS-PhD Programme

MD/MS/DW/MCH Thesis

Financial Assistance to MD/MS/DW/MCH Thesis

Others

Centres for Advanced Research

Task-Force Projects

International Travel by Non-ICMR Scientists

Emeritus

Emeritus Medical Scientist Scheme

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New Schemes

New Scheme "Medical Innovation fund"

International Collaboration

Fellowship Programme under Indo-German Science Centre for Infectious Diseases

Guidance for International Collaboration

ICMR International Fellowship Programme for Indian Biomedical Scientists

ICMR International Fellowship Programme for Biomedical Scientists from Developing Countries

An Overview of International Collaborative Project Biomedical Research

Consideration of International Collaborative Projects by HMSC

Search Research Projects

ICMR Grants/Schemes

Final Reports of Extramural Projects

List of Extramural Research Projects Sanctioned

April 2007 - March 2009

April 2002 - March 2007 (10th Plan)

April 1997 - March 2001 (9th Plan)

List of Extramural Research Fellowships Sanctioned

April 2007 - March 2009

April 2002 - March 2007 (10th Plan)

April 1997 - March 2001 (9th Plan)

Graphical Analysis of Extramural Research Grants

2010 - 2011

2008 - 2009

2007 - 2008

2002 - 2007 (10th Five Year Plan)

2006 - 2007



- ▶ Charter
- ▶ Societal Development
- ▶ Patent Facilitating Cell
- ▶ Project Performa Downloads
- ▶ Events
- ▶ Women & Development
- ▶ Call for Proposals
- ▶ Right to Information
- ▶ Vacancies
- ▶ News Clippings
- ▶ BTIS NET
- ▶ Tenders/Circulars
- ▶ Biosafety
- ▶ Related Link
- ▶ Discussion Forum
- ▶ Databases
- ▶ Guidelines for Students
- ▶ SBIRI
- ▶ BIRAC / BIPP
- ▶ Archives

Department of Biotechnology,
Ministry of Science and Technology,
Government of India

DBT Launches Online Project Submission- eProMIS

Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India provides financial assistance to Research and Development projects. Moving forward w.e.f. 1st September, 2011 DBT has introduced eProMIS a web portal (<http://dbtepromis.nic.in> or <http://dbtepromis.gov.in>) in order to enable online projects submission. Key Features of the eProMIS are online registration for new investigators, tracking the current status of the project, online availability of user manual, various forms etc., online access to proposals for review & evaluation and reduced time lag, paper work at various stages of processing. This system will facilitate complete monitoring and project management.

Online project submissions are now being accepted. All project Investigations are requested to submit their proposal online through eProMIS. For any assistance in this regard contact at epromis.dbt@nic.in.

Note: The Project Investigator (PI) should submit at least five hard copies printed out after submission of their proposal online in eProMIS to the department. The hard copies should be exactly similar to soft copy submitted in eProMIS in their contents.



C

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Scientific & Engineering Research

- Mission on Nano Science and Technology (Nano Mission)
- Fund for Improvement of S&T Infrastructure in Universities and other Higher Educational Institutions (FIST)
- Sophisticated Analytical Instrument Facilities (SAIFs)
- Human Resource Development and Nurturing Young Talent.
 - Swarnajayanti Fellowships
- Women Scientists Programs
- Kishore Vaigyanik Protsahan Yojana
- Innovation in Science Pursuit for Inspired Research (INSPIRE) programme
- National Science & Technology Management Information System (NSTMIS)
- SERB Constitution Notification **new**

Scientific & Engineering
Research

Technology Development

S&T and Socio Economic
Development

International S&T
Cooperation

Women Scientists Programs

Visit SERB (www.serb.gov.in) for more programmes and schemes



Department of Science & Technology

Ministry of Science & Technology

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विज्ञान और प्रौद्योगिकी मंत्रालय

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Instrumentation Development Programme

Instrumentation is one of the major areas of Science & Technology which makes a great impact on vital sectors of national activities such as education, scientific research, industry, agriculture, medicine and health etc. The Department of Science & Technology (DST) has been promoting the area of Instrumentation through its Instrumentation Development Programme (IDP).

Objectives

The programme focuses on strengthening indigenous capability for research, design, development and production of instruments in the country leading to fulfillment of the following objectives: -:

- Indigenous development and production of instruments,
- Continuous updating of the technology of instruments to keep pace with technology improvements taking place globally, and
- Innovations in the area of instrumentation.

INDIAN RESEARCH FUNDING AGENCIES



- A one point source to know all about Indian government websites at all levels an <http://www.goidirectory.nic.in/exe.htm>
- Council for Scientific and Industrial Research <http://www.csir.nic.in>
- Defence Research Development Organisation <http://www.drdo.nic.in>
- Department of Biotechnology, Govt. of India <http://www.dbtindia.nic.in>
- Department of Ocean Development <http://www.dod.nic.in>
- Department of Science and Technology, Govt. of India <http://www.dst.gov.in>
- Format of summary sheet for new project proposals involving foreign collaboratio <http://www.icmr.nic.in/guide/summary.doc>
- Funding schemes of Ministry of Environment and Forests, Govt. of India <http://www.envfor.nic.in/funding/funding.html>
- Indian Council for Medical Research-Guidance for International collaboration for <http://www.icmr.nic.in/guide.htm>
- Indian Council for Social Science Research <http://www.icssr.org>
- Indian Council of Agricultural Research <http://www.icar.org.in>
- Indian Space Research Organisation, Department of Space, Govt. of India.-Researc <http://www.isro.org/respond/index.htm>
- Nanotechweb.org feature articles. <http://www.nanotechweb.org/rss/features.xml>
- The future of Nanotechnology. <http://www.nanotechweb.org/articles/feature/3/8/1/1?rss=2-0>

INTERNATIONAL RESEARCH FUNDING AGENCIES



- Agency for Health Research and Quality-funding opportunity
<http://www.ahrq.gov/fund>
- American Indian Research and Development, Inc - Research Opportunities
<http://www.aigc.com/other-funding-opportunities/research-opportunities.html>
- Columbia University Medical Center Research funding
<http://www.cumc.columbia.edu/research/funding.html>
- Defence Advance Research Project Agency (DARPA)
<http://www.aipa.mil>
- Engineering and Physical Sciences Research Council (EPSRC)-UK Govt's leading fun
<http://www.epsrc.ac.uk/default.htm>
- European Science Foundation. Funding for all subjects
<http://www.esf.org>
- External funding agencies-funding databases, Social Sciences and Humanities fun
<http://www.research.mala.bc.ca/grants/index.asp?document=external-sources>



Thank You