# Dean Research Section

## IGIMS,Patna

## Roles & Responsibilty

Indira Gandhi Institute of Medical Sciences (IGIMS), Patna (India) is a University established under State Act in 1983. It is the only super specialist institute of Bihar. The institute provides education in medicine and conducts health and medicinal research. It got affiliation of medical college from MCI in September 2011. It has 100 MBBS seat.

**Research** has been major thrust area at the super speciality medical institutes like AIIMS, New Delhi, PGIMS. Chandigarh, SGPGI, Lucknow, JIPMER etc.

**OBJECTIVE:**

Objective of the Indira Gandhi Institute of Medical Sciences as per **IGIMS Act 1984,** was to;

i) to establish clinical research centre,

ii) to develop community health research centre with special emphasis on reproductive biology and population control,

iii) to develop research and training in basic sciences .

The above objectives somehow could not take up the mandate in true spirit and lagged behind from SGPGI, Lucknow which was also established at the same time.

To make the research environment vibrant, it is imperative to establish a Research Advisory Committee, on the pattern of AIIMS, New Delhi or SGPGI,Lucknow or any Institute of eminence in the country.

One of the administrative functions of the Dean Research Cell will be to coordinate the activities of extramural research projects funded by various national/international agencies like ICMR, DST, DBT, CSIR, Ministry of Health & F.W., WHO, Gate Foundation etc. besides, generating its' own intra-mural projects.

The administrative hierarchy of the Research Section shall include Dean (Research), Associate & Sub-Dean (Research) & Registrar.

Dean: **Dr.Prabhat Kumar Sinha, MS**

( It will include dean research committee comprising of faculty members of the IGIMS)

Associate Dean & Sub-Dean:

Registrar

## VISION OF DEAN RESEARCH CELL:

### Clinical research for Post Graduates:

Clinical research may be defined as investigations involving human subjects or the use of patient samples. The scientific practices described here are generally accepted by investigators conducting both multi-center and single-institution clinical studies and help ensure both the quality and integrity of scientific findings in clinical research. The guidelines are not intended to relieve investigators of any ethical obligations that may be imposed by individual Research Advisory Committee / IRB, overseeing the rights of study subjects in clinical research.

A major component of clinical research consists of either prospective clinical trials or retrospective studies based on medical or administrative records. Of these two types of studies, prospective trials contain fewer chances for investigator bias and for lost or incomplete data than do retrospective studies, and are to be preferred whenever they are feasible. Some phenomena, however, such as rare diseases or diseases requiring exceptionally long follow-up, can only be studied from a case series assembled from medical records. These guidelines address issues that arise in both types of studies.

### I. Experimental Design

Successful clinical studies acknowledge the complexity of conducting scientific research with human subjects, and are based both on the principles of experimental design and on respect for the rights of study subjects. Experiments in human subjects generally have highly variable outcomes, and efficient designs that lead to unbiased conclusions are critical.

**Recommendations:**

1. Each study, whether it be observations on one or more patients, a randomized trial, or a population based study, should have clearly articulated research objectives that can be achieved from a successful execution of the study design.

2. Whenever some aspects of a study involve clinical or scientific specialties outside the expertise of the investigator, drafts of the protocol or research plan should be circulated to specialists in those areas for review and comment. IGIMS department heads can take the help of experts of the concerned fields of other institutes.

3. Every prospective or retrospective clinical study should have a written protocol or research plan that states the goals of the study, provides a background and rationale for the study, specifies the criteria for inclusion or exclusion of cases, outlines the methods and timings of follow-up, gives a precise definition of the types of anticipated outcome measures, and gives the details of the statistical design. The study design should minimize the possibility for investigator bias in the interpretation of the results. The design specification may range from a description of anticipated measurements in an exploratory study to a precise specification of the number of cases that will be registered in a phase randomized trial (With DCGI). In the case of prospective trials, the protocol should describe in detail how patients are to be treated or managed. Any substantial changes to the conduct of the study, including modifications of the sample size, eligibility criteria, or treatment regimens, should be reflected in amendments made to the protocol or research plan and approved by co-investigators and the Research Cell Committee of the institute.

4. In randomized clinical trials, the sequence of treatment assignments should be prepared by a statistician or other experienced investigator associated with the trial and kept confidential. In no instance should an investigator treating patients on the trial know the sequence of potential treatment assignments.

5. Clinical studies all require approval of local Institutional Review Boards/ Research Advisory Committee of IGIMS. Every prospective clinical study should contain an Informed Consent form that explains in clear, non-technical terms the possible risks and benefits for subjects participating in the trial.

An essential component of postgraduate (PG) training is initiating the students towards biomedical research and inculcating in them the ability to define lacunae in the present knowledge and how to frame researchable questions. A postgraduate medical student of the Indira Gandhi Institute of Medical Sciences is required to be conversant with various regulatory requirements, ethical issues and international standards of planning, conducting and publishing research. A vast majority of students who join PG courses (MD/MS/DM/MCh/PhD) have little knowledge, exposure or training in these aspects. As a part of an essential requirement, each PG student is expected to conduct research and to develop protocol for the project to be undertaken for the course.

Over the years, the standard of research among PG students has fallen short of the expectations. The Research Section of the institute will help in establishing a vibrant environment conducive for research. Important recommendations of the various committees are to start a series of courses in research methodologies which would educate our students on important aspects of research. The curriculum of these courses will be so designed as to expose them to basic aspects of ethics, biostatistics, cell biology and all other areas not covered by departmental academic activities. The courses will be conducted by in-house faculty of the institute but in areas where expertise or enthusiasm does not exist, experts from outside like AIIMS, ICMR institutes and experts could also be involved. The courses will be interactive in nature.

**Implementation:** A 5-day course should be organized every month in each academic session to accommodate all DM, Mch or MD students who take admission in the academic sessions . There will be an exit examination at the end of the course which will be mandatory for each student to pass.

Each department will be obliged to send all newly admitted students to attend the course as a part of the mandatory requirement for them before submission of the thesis protocol. The academic section will be requested to make a department wise schedule for all the students.

Regular feedback from and evaluation of the course/faculty by the participants will be done to bring in further improvements for courses in future.

## FOUNDATION COURSES: Students and Faculty are encouraged to undertake short courses for sensitizing themselves for conducting Research.

- **Epidemiology** - This course covers the basic principles and methods of epidemiology, including disease (outcome) measures, measures of association, study design options, bias, confounding, and effect modification.
- The Epidemiological program provides instruction in the epidemiological and bio statistical methods used in observational clinical research. Training in the oral and written presentation of clinical research to be provided
- **Biostatistics** - This course addresses how to organize, summarize, and display quantitative data; the use of statistical software (Epi-Info/Stata); measures of variability, and confidence intervals; and interpreting tests of significance. The course also provides an understanding of the basic principles and uses of linear and logistic regression models for clinical research.

- The Clinical Trials program provide instruction in the conduct, implementation, and analysis of clinical trials, with a focus on the methods of study design, ethics, recruitment, and bio statistical considerations that are used in designing and analyzing clinical trials.

**After completing this program, residents/tutors/faculty will be able to:**

1. Perform both observational and experimental clinical research using the methods introduced in this program
2. Plan and implement one or more clinical research projects
3. Analyze, interpret, and present clinical research data
4. Asking the right research question, generating a hypothesis.

5. Study designs: Designing studies appropriate to the research question
6. Inclusion and exclusion of study subjects (patients and controls)
7. Study Tools: Questionnaire, clinical data, investigations etc.
8. Defining outcome measures and conclusions
9. Basic Biostatistics for sample size calculation and hypothesis testing
10. Issues: randomization, blinding, concealment, bias, confounders, risk factor, correlation etc.
11. Ethical issues including consent taking in conducting research
12. Good Clinical Practice
13. Data management
14. Presentation of results
15. Guidelines for reporting: CONSORT, STROBE, PRISMA etc.
16. Literature search
17. Scientific misconduct including plagiarism(Authors who present the words, data, or ideas of others with the implication that they are their own, without attribution in a form appropriate for the medium of presentation, are committing theft of intellectual property and may be guilty of plagiarism and thus of research misconduct.)
18. Thesis/dissertation: Step by step
19. Writing a paper

The Research Section will offer all necessary assistance in the smooth conduct of such courses.

**RESEARCH PRESENTATION BY THE FACULTY**

The institute will organize periodic research presentations by its faculty on the third Friday of every month. The presentation will be voluntary. The faculty member making the presentation generally shoul focus on his/her research carried out in the recent past on a specific topic of interest. This will act as an important platform for scientific interaction, generating new ideas and for fostering inter-departmental collaborative research.

The responsibility of conducting this activity will be on Research Section The faculty members will be requested to present their studies in a manner that it is relevant and of interest to most members of other disciplines. It is also important to frame researchable questions for the future so that translational value of the studies can be highlighted and new collaborative groups made. With the ever growing specialties and super specialties, most faculty members may not be aware of the strengths of their colleagues, technical capabilities and academic brilliance.

The monthly Research Presentations will provide the right environment and forum for our faculty to discuss new ideas and forge collaborations between basic scientists and clinicians. This will go a long way in enhancing the overall research environment. The Research Section earnestly appeals to all faculty members to join hands with renewed enthusiasm and vigor to make this monthly activity a useful exercise.

## EXTRAMURAL RESEARCH PROJECTS

For any vibrant medical institute extramural funding constitutes the major chunk of the research grants. The overall administrative aspects of the projects are managed by the Dean Research Section right from its inception.

**Standard Operating Procedures for applying for extramural funding:** If a faculty/scientist of IGIMS, Patna wants to apply for funding for a research project, it is mandatory for a project proposal to be routed through the Research Section for the first stage of vetting in accordance with the procedural aspects being followed at the Institute. After the requisite scrutiny of the project as regards the budget, staff and their salary structure, provision of co-investigator and establishment charges etc., the Research Section forwards the proposal to the funding agency. It is mandatory to have a Co-Investigator, preferably from the same department as that of the Project Investigator.

No faculty member/scientist of IGIMS will able to claim the status of a Principal Investigator or Co-Investigator of a project either at IGIMS or any other external Institution if the project has not been registered in the Research Section, IGIMS. In case any faculty member/scientist is associated with any collaborative research project

outside IGIMS, permission for the same would have to be sought before the initiation of the project.

**How to obtain operative approval/project code number?**

Once the project is sanctioned by the funding agency, operative approval from the competent authority at IGIMS, is required and thereafter a "Project Code Number" is allotted by the Research Section which should be cited in all correspondence related to that project.

The Project Investigator (PI) should not start the work of the project or employ staff without the operative approval of the competent authority. Operative approval would not be granted without ethical clearance from the Institute Ethical Committee.

For any research project to be initiated at IGIMS, the following clearances are required as appropriate. These requirements are also applicable to international projects:

1.) Institute Ethics Committee (This should be registered with DCGI, Ministry of Health Govt.of India, as per new rule )
2.) Animal Ethics Committee
3.) Bio-Safety Committee
4.) Radiation Safety Committee
5.) Health Ministry Screening Committee of ICMR
6.) Clinical Trial Registry of India
7.) Institute Committee for Stem Cell Research & Therapy
8.) DCGI Approval

## II. Data Management and Trial Monitoring

Complete and accurate data are an essential part of the record of any clinical research. Since serious problems can occur when data are missing or are not consistent with source medical records, each study should include a plan for the keeping of accurate and well documented data not subject to loss through computer failure or insecure storage.

**Recommendations:**

1. In prospective trials, data should be abstracted from source medical records as the trial proceeds, using data collection forms designed at the outset of the study. Data collection forms should also be used in retrospective record studies.

2. The criteria for the evaluation of study subjects (including the classification of outcome and any treatment side effects) should be specified in the protocol or research plan.

3. Interim review of the data from an ongoing trial should make use of statistical methods that guard against increased false-positive or false-negative reporting rates caused by inappropriate conclusions from preliminary analyses.

4. For research involving primary data collection, the principal investigator should retain original data for as long as practically possible, but never for less than five years from the first major publication or from the completion of an unpublished study. All data should be kept in the research unit responsible for conducting the study. Copies of computer programs and the results from statistical calculations used in research involving nationally gathered survey data should also be kept by research units for a minimum of five years from publication based on these results. After notification to responsible departmental officials, principal investigators may make copies of original data or computer programs for personal use or when moving to another research unit or institution.

5. If primary data are kept on a computer file, backup files should be maintained, preferably at a second site, to prevent loss from computer failure.

## III. Scientific Reporting

Writing a manuscript reporting the results of a clinical study is a complex and demanding task. Unclear or ambiguous reports reduce the value of a study and may lead to a discrediting of the research.

**Recommendations:**

1. The statistical analysis used in reporting the results should coincide with the planned analysis used to design the study. Reasons should be given in the manuscript for any different analyses that are used.

2. All cases registered in a clinical trial or records reviewed in a retrospective study must be accounted for in any manuscript reporting the results. Any case not used in the analysis of outcome data should be identified (by case number) and the reason for exclusion noted.