Rajendra Institute of Medical Sciences, Ranchi

organizes

Short Term Fellowship Program in Good Clinical Practice

supported by Department of Health Research, New Delhi

MODULE 1 : 17TH APRIL - 29TH APRIL

MODULE 2 : 15TH MAY - 27TH MAY

MODULE 3 : 12TH JUNE - 24TH JUNE

LIMITED SEATS AVAILABLE

Venue: 3rd Floor Research & Administration Hall, Administrative Block, RIMS, Ranchi

Invitation

Ministry of Health and Family Welfare
Government of India

Dear Friends,

Greetings from Rajendra Institute of Medical Sciences, Ranchi

It gives me a great pleasure and honor to invite you to Short Term Fellowship Program in Good Clinical Practice, to be held in RIMS, Ranchi from 17/04/2023 to 24/06/2023. Eminent faculty will provide candidates a platform for interaction and exchange of views on good clinical practice. The fellowship program will strengthen your understanding of clinical research process including ethical aspects and date integrity. Looking forward to welcoming you to Ranchi and experience our amazing hospitality.

Best Regards,

Prof. Dr. Kameshwar Prasad
Principal Investigator,
DHR, Project, RIMS
-Cum-
Director & CEO, RIMS, Ranchi

List of Mentors: -

Dr. Arpita Rai,
Co-Investigator, DHR PROJECT,
Assoc. Professor, Dental College, RIMS

Dr. S B Singh,
Co-Investigator, DHR PROJECT,
Assoc. Professor, PSM, RIMS

Dr. S N Dwivedi,
Ex. Professor, Biostatistics AIIMS, New Delhi

Prof. Santanu K Tripathi
Dean (Academic) &HOD, Pharmacology Netaji Subhas Medical College and Hospital, Amhara, Bihta, Patna.

Dr. Satish Chandra
Ex-Dean, RIMS

Dr. P K. Bhattacharya
Dean (Research), RIMS

Dr. Sandhya Kumari
Professor, Anatomy, RIMS

Dr. Bhoopendra Singh
Professor FMT, RIMS

Dr. Anupa Prasad
Assoc. Professor, Genetics &Genomics

Dr. Lakhan Manjhi
Assoc. Professor, Pharmacology, RIMS

Dr. Archana Kumari
Assoc. Professor, Obs & Gynae, RIMS

Dr. Amit Kumar
Assoc. Professor, Lab Medicine, RIMS

Dr. Dewesh
Assoc. Prof. PSM, RIMS

Dr. Amit Vasant Mahuli,
Assoc. Professor, Dental College, RIMS

Dr. Ganesh Chauhan
Assoc. Professor, Genetics &Genomics

Introduction to Department of Health Research (DHR):

Department of Health Research (DHR) was created as a separate Department within the Ministry of Health & Family Welfare by an amendment to the Government of India (Allocation of Business) Rules, 1961 on 17th Sept, 2007. The Department of Health Research was formally launched on 5th October 2007 by the Minister for Science & Technology and Earth Sciences in a function presided by the Minister for Health & Family Welfare, in the presence, inter-alia, of the Minister of State for Health & Family Welfare. The Department became functional from November 2008 with the appointment of first Secretary of the Department. The aim of the DHR is to bring modern health technologies to the people through research and innovations related to diagnosis, treatment methods and vaccines for prevention; to translate them into products and processes and, in synergy with concerned organizations, introduce these innovations into public health system. https://dhr.gov.in/about-us/about-department

Introduction to Rajendra Institute of Medical Sciences(RIMS), Ranchi:

The Rajendra Institute of Medical Sciences (RIMS) is a premier medical institute located at Ranchi, the capital of Jharkhand. The Institute is an autonomous body established in 2002 under an Act of Jharkhand state Assembly. The Institute started as Rajendra Medical College in the year 1960 and was named after Dr. Rajendra Prasad, the first President of India. The Medical College Hospital came into existence in February 1965 and has excelled ever since. The Motto of the Institute is "SARVE SANTU NIRAMAYA". RIMS Ranchi has a 263 acre and spacious campus. It has a more than 2100 bedded multi- speciality hospital with State of the Art equipment. The institute is a tertiary care centre that has the excellent infrastructure for patient care as well opportunity to acquire knowledge and skills from experienced faculty. The Institute also has a 100 bedded Trauma Centre, the first of its kind in Eastern India with most modern equipment. Under PMSSY scheme, a 240 bedded Super Specialty block was established to provide care for the patients in the field of Oncology, Neurology, Cardiology, Urology, Paediatric Surgery and Cardio-thoracic Surgery. The Dental College, RIMS, Ranchi was founded in the year 2017 and is the first autonomous Dental College under Government of Jharkhand. RIMS conducts teaching programs in medical, dental and para-medical courses. Besides undergraduate courses, RIMS also offers post - graduate courses, PhD and super-specialty courses offered in various disciplines. RIMS also runs a College of Nursing and is affiliated to Ranchi University.

https://www.rimsranchi.ac.in/

About The Project: – Short Term Fellowship Program in Good Clinical Practice (GCP)

RIMS, Ranchi has received funding under the Support to Institute for imparting training (Human Resource Development for Health Research) scheme of DHR to conduct short term fellowship in Good Clinical Practice for 3 years (2022-24). The first fellowship was conducted between April to June 2022 and 31 successful candidates were awarded fellowship.

Good Clinical Practice is a set of guidelines for biomedical studies which encompasses the design, conduct, termination, audit analysis, reporting and documentation of the studies involving human subjects. The guideline seeks to establish two cardinal principles: protection of the rights of human subjects and authenticity of biomedical data generated. These guidelines have been evolved with consideration of WHO, ICH, USFDA and European GCP guidelines as well as the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research. They should be followed for carrying out all biomedical research in India at all stages of drug development, whether prior or subsequent to product registration in India.

This Good Clinical Practice (GCP) training is designed to prepare medical/dental college faculty, PhD scholars and post-graduate students in the conduct of clinical trials with human participants. This 6-week training will be based on International Council on Harmonization Good Clinical Practice (ICH-GCP) Principles.

Objectives: –

1. To provide an overview and practical advice on the application and implementation of internationally accepted principles for GCP and clinical research in human subjects.
2. To provide a reference tool for participants by providing the necessary background and insight into the reasons for the requirements of GCP and their efficient application.
3. To get a comprehensive understanding of the clinical research process

Criteria of Selection:

We seek **interested post graduates, PhD students and faculties working in medical/dental colleges from across India.** The training will be free of cost for the participants. However, it will follow a strict selection criterion. An elementary knowledge of research methodology would be preferred; however, the workshop does not entail any theoretical background of textual knowledge. Applicants will be required to provide the following by email rims.dhrproject@gmail.com by 25th February 2023:

- Application form for expression of interest – Appendix 1
  - ❖ A concept proposal related to the clinical trial as per the attached format. The ideas/ interventions can be drug molecules, therapeutics, vaccine candidates, biological, nutritional products, diagnostics, or community based interventions and others. The concept notes will be peer-reviewed by the Advisory Committee for Clinical Research, RIMS, and Ranchi. The following criteria will be used to evaluate proposals - Novelty, applicability and Justification for research. Appendix 2
  - ❖ Brief Curriculum Vitae / resume highlighting relevant skills, experience, and training.

The list of selected candidates will be updated on RIMS website.

Tentative Program

Week 1: -Overview of the clinical research process and clinical trial

- Overview of the clinical research process
- Formulating research question: PICO and its variation; Criteria for good research question
- Study Design
- Sample Size
- Randomization process and blinding
- Selecting endpoint/response variables
- Baseline assessment of study participants
- Confounders in clinical trial
- Internal vs external validity in clinical trial
- Reporting and interpretation of RCT (CONSORT checklist)

Week 2: -Systematic Review & meta-analysis

- Statistical methods used in interim monitoring
- Analysis of RCT
- Issues related to data analysis
- Survival analysis
- Search strategy
- Data extraction
- GRADE:
- Fundamentals of GRADE
- GRADE: Rating the certainty of evidence, Sub Group Analysis
- Network Meta-Analysis: Overview
- GRADE: Guideline Development overview, Strong Vs Weak Recommendation.

Week 3: -Ethics in clinical research, Research misconduct

- Ethics committee/Institutional Review Board (composition, membership & responsibilities)
- Investigator's responsibilities to Ethics committee
- Criteria for ethical approval of research
- Informed consent
- Documentation requirements in informed consent
- HIPAA rights, Privacy and Enforcement
- Confidentiality of Clinical Trial Participant Records
- Exceptions to Confidentiality Requirements
- Identifying Research Misconduct & Possible Penalties for Research Misconduct
- Investigating allegations & Responding to Allegation of Research Misconduct
- Safeguard for Informants & accused Person
- Protection from conflict of interest
- Publication bias, suppression and delays in reporting
- Conflict of interest & publication

Week 4: -Regulatory issues, Research protocol & documentation. Roles and responsibilities

- Regulatory bodies – CDSCO, CTRI, DHR
- Acts and rules pertaining to clinical trials
- Content of research protocol
- Protocol Amendment & Violation
- Documentation requirement for sponsored trial
- Regulatory issues pertaining to new drugs, investigational new drugs & subsequent new drugs, vaccine, medical devices and diagnostics, biologics.
- General &Specific responsibilities of sponsor, General &Specific responsibilities of Principal investigator
- Role and responsibilities of research site staff
- Multi-centric clinical trial, Global Clinical Trial, Clinical Trial with Commentary& alternative medicine
- Visit to Research lab at RIMS, Ranchi

Week 5: - Conduction of trial, patient safety/ adverse event, Health Related Quality of Life

- Site Selection & Site initiation
- Recruitment & Recruitment Strategies
- Retention & Retention strategies
- Assessment of Harm/adverse event
- Classification of Adverse Events
- Analysing Adverse Event, Reporting of Harm, Regulatory Considerations
- Health Related Quality of Life (HRQL): overview, Methodological and design Issues, Selection of HRQL Instruments
- Study closeout: Termination Procedures, transfer of post-trial Care and Post Study Follow up, Data & Records Dissemination of Results.
- Visit to Central Medical Record Department & Training centre

Week 6: - Quality Control

- Problems in data collection, Minimizing Poor Quality Data, Electronic Source Data
- Monitoring board/committee structure, Monitoring board/Committee functions, Monitoring Visit Procedures
- Quality Monitoring of Data, Procedures and Drug Handling.
- Various types of audit in clinical trials
    1. Clinical Trials Audit Observations and study of Critical observations
    2. Breach reports and Compliance guidelines
- Competency Assessment
- **Research Protocol Presentation by Fellows**

Last Date of Application: 25th Feb 2023

Certification:

Upon completion of the training, certificates will be provided to the fellows. The trainees should fulfill the following conditions for being eligible for certification:

a) A minimum attendance of 85%

b) Submission of pre and post training assessment.

c) Scoring a minimum of 75% marks in training end competency assessment. (In case a fellow fails to achieve 75% marks in the competency assessment, he can give two further attempts for the competency exam in online or offline mode at an interval of one month)

d) Submission of Ad-hoc research proposal (ICMR format) based on the concept note submitted at the time of selection.

e) Presentation of the Ad-hoc research proposal.

Other Terms and Conditions: -

1 There is no Registration fee for the candidate.

2. No TA DA will be provided by the host Institute.

3. No accommodation facility will be provided by the host Institute. Guest house on self paid basis may be provided subject to availability. Please contact Miss Anita Kumari, Project Assistant (Contact no-8809197830)

4. No Application will be accepted after the last date.

5. Decision made by the Director RIMS will be final.

Appendix 1 – Application form for expression of interest

SHORT TERM FELLOWSHIP PROGRAM IN GOOD CLINICAL PRACTICES

1. Name :

2. Contact Details (Mobile No & Email Id) :

3. Age/Gender:

4. Name of the Institution:

5. State :

6. Present Designation/Last Post Held :

7. Have you attended any workshop/training program related to GCP? Yes / No

8. Are you involved in any clinical trial? Yes / No

9. If you are involved what was your role?

10. Tick reasons for interests in this training program:

- ☐ To Gain Knowledge about GCP
- ☐ To enhance your knowledge about this concept
- ☐ Developing new Prowess
- ☐ Having Fun While Learning
- ☐ Network with like-minded researchers

Appendix 2 – Format for concept note

1. **Title of the proposed research project:** – should be concise and yet sufficiently descriptive and informative. Title may include study design such as randomized controlled trial.

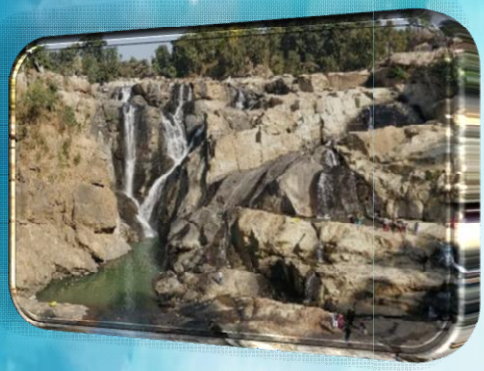
2. **Rationale not more than 350 words:** –Describe the current knowledge available on the subject area, critical gaps in knowledge, its relevance and application to local, national and international context and the research questions which this project aims to address.

3. **Brief outline of the project:**

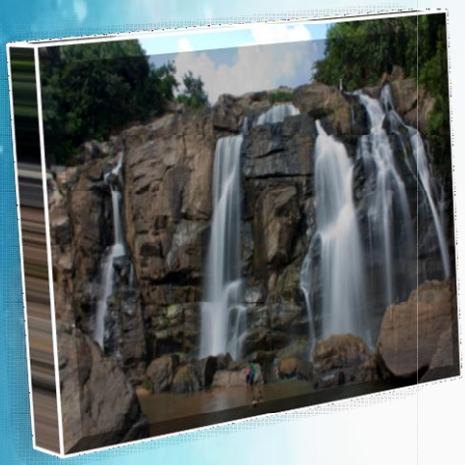
Glimpses of Previous Year (2022)

Discover Ranchi

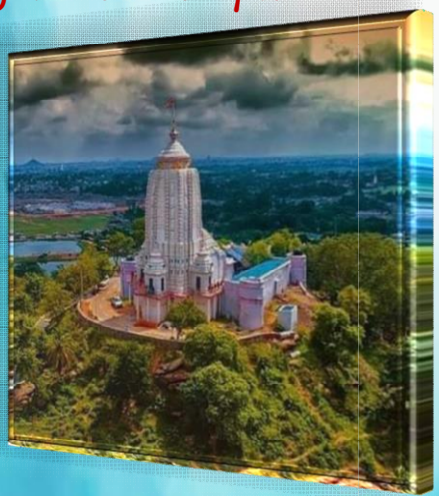
1. Dassam Fall



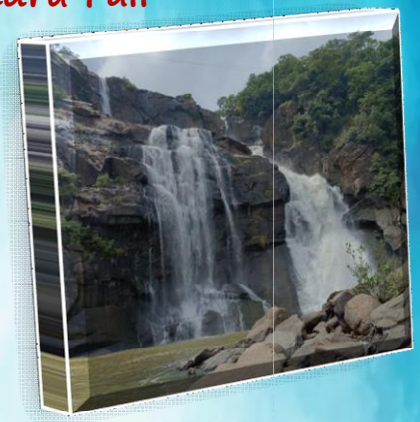
2. Johnna Fall



3. Jagarnath Temple



4. Hundru Fall



5. Surehwar Mahadev Temple

6. Rajrappa Temple