राजेन्द्र आयुर्विज्ञान संस्थान
(झारखण्ड सरकार का एक स्वयतशासी संस्थान)
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RAJENDRA INSTITUTE OF MEDICAL SCIENCES
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Ranchi-834009(Jharkhand)
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Memo No 173 RIMS, Ranchi, Dated 12/01/22

Website Advertisement for Short term fellowship program in Good Clinical Practice

1. Applications are invited for **short term fellowship program in Good Clinical Practice** organized by RIMS, Ranchi tentatively in the month of April-May 2022.
2. This Fellowship program is funded by Department of Health Research, Indian Council of Medical Research (DHR, ICMR).
3. Concept notes for a randomized controlled trial in the attached format and biodata from eligible candidates must reach the office of the Director, Administrative Block, RIMS, Ranchi -834009, latest by 25-1-2022 by 5:00 PM. (Through Speed post)
4. A soft copy of the concept note and biodata must be mailed to **email id-rims.dhrproject@gmail.com**.
5. Faculty members/Residents/Ph.D students from RIMS may also apply for the training program.

Sd/-
Prof. (Dr). Kameshwar Prasad,
Director & CEO, RIMS, Ranchi,
-Cum-
PI, DHR Project.

Attachments: -
1. Concept note format.
2. Advertisement copy.
3. Training program schedule.

Note: -For any query contact -
Program coordinator Dr. Arpita Rai, Associate Professor, Dental Institute -cum-Co-Investigator, DHR Project, Contact No- 987174389 Email id-rims.dhrproject@gmail.com

Copy forwarded to Information & necessary action.
1. Dr. SB Singh, Incharge, Website, RIMS, Ranchi.
2. RIMS, Ranchi Notice board for General Information.

12/1/22

Prof.(Dr).Kameshwar Prasad,
Director & CEO, RIMS, Ranchi,
-Cum-
PI, DHR Project.

Concept-Proposal format

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 (up to 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 question which this project aims to address.*

3. ***Novelty/Innovation (up to 100 words):*** *Describe how the proposal challenges and seeks to shift the current research/knowledge/clinical practice paradigms etc. by utilizing novel theoretical concepts ,approaches or methodologies, instrumentation, or interventions etc. Also mention preliminary work done by the applicant if any.*

4. ***Project Description (up to 700 words):*** *Describe study setting, study design, sampling strategy, sample size, feasibility, expected outcomes, inter-department/inter-institutional collaborations if any, timelines, budget.*

5. ***Strength of PI:*** *Describe academic qualifications; nature of employment (permanent/ad-hoc); previous experience of handling research projects and the scientific contributions made from these grants; enumerate 10 recent publications (in Vancouver style).*

SHORT TERM TRAINING PROGRAM IN GOOD CLINICAL PRACTICE

Rajendra Institute of Medical Sciences, Ranchi

Sponsored by Department of Health Research

Course information

Good clinical practice provides a framework of principles which aim to ensure the safety of research participants and the integrity and validity of data. Compliance with GCP provides public assurance that the rights, safety, and well-being of research subjects are protected and respected, consistent with the principles enunciated in the Declaration of Helsinki and other internationally recognized ethical guidelines, and ensures the integrity of clinical research data. The conduct of clinical research is complex and this complexity is compounded by the need to involve a number of different individuals with a variety of expertise, all of who must perform their tasks skilfully and efficiently. This training is important for all staff involved in Clinical Research and ensures an understanding of the principles adopted in research. This 6-week training program aims to provide the researcher with the basic principles of GCP and how these principles can be applied practically in the research setting.

For whom: Faculty members from medical colleges, post-graduate and PhD students interested in clinical research

Pre-requisites: Submission of concept note related to clinical research and brief curriculum vitae expressing the interest in the training. Laptop with internet connectivity is mandatory.

Criteria for evaluation of concept note- Novelty, applicability and justification of research.

Course duration: 6-weeks

Learning mode: Lectures, interactive sessions with case studies, group activity with mentoring for designing the clinical research project

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.

Note:- 1. There is no registration fee for this fellowship program.

2. Paid Guest house is available on 'first -cum- first' serve basis .

3. Breakfast, Lunch & Dinner will be provided from the grant received.

4. No TA will be admissible.

SHORT TERM FELLOWSHIP PROGRAM IN GOOD CLINICAL PRACTICE TENTATIVE SCHEDULE

SN	Week Schedule	Days schedule	Training program						
			09:30–09:45	09:45–11:00	11:00 -11:15	11:15-12:45	12:45-2:00	02:00 – 03:15	03:15 – 05:00
1.	Week 1: Overview of the clinical research process, Research Methodology, History and milestones, Principles of ICH-GCP	Day 1	Registration	Inauguration and Pre-training assessment	Tea break	Plenary lecture: Overview of the clinical research process	Lunch	Identifying gaps in knowledge through systematic review of literature	Group Activity*
		Day2	Previous day briefing	Formulating research question: PICO and its variation; Criteria for good research question		Study design: overview		Types of clinical trials	Group Activity*
		Day 3		Random allocation and blinding		Selecting endpoints/response variables		Placebo effect	Group Activity*
		Day 4		Sample size calculation		Analysis of RCT data		Reporting of RCT: CONSORT checklist	Group Activity*
		Day 5		Introduction, History and Milestones of GCP		Principles of GCP- I		Application of GCP principles in research	Group Activity*
		Day 6		Indian GCP and Schedule Y		New Drugs and Clinical Trials Rules, 2019		Weekly Quiz	Feedback session
	Week 2: Ethics in clinical research, Informed consent, Overview of clinical research regulatory bodies	Day 1		Declaration of Helsinki		Ethics committee/Institutional Review Board		Membership of Ethics committee	Interactive session**
		Day2		Responsibilities of Ethics committee		Investigator's responsibilities to Ethics committee		Criteria for ethical approval of research	Interaction with members of IEC, RIMS
		Day 3	Previous day briefing	Informed consent	Tea break	Documentation requirements in informed consent	Lunch	Special Requirements Concerning Consent	Group Activity*
		Day 4		Confidentiality of Clinical Trial Participant Records		Exceptions to Confidentiality Requirements		HIPAA Rights, Privacy, and Enforcement	Interactive session**
		Day 5		CDSCO		Ctri		ICMR/DHR	Group Activity*
		Day 6		Weekly quiz		Feedback session		Library time	
	Week 3: Research protocol, Documentation and record keeping, Roles	Day 1		Contents of the Research Protocol-I		Contents of the Research Protocol-II		Contents of the Research Protocol-III	Interactive session**
		Day2		Protocol Amendment		Protocol Violation		Special considerations	Group Activity*

SHORT TERM FELLOWSHIP PROGRAM IN GOOD CLINICAL PRACTICE TENTATIVE SCHEDULE

	and responsibilities	Day 3	Previous day briefing	Documentation Requirements in GCP	Tea break	Documentation in sponsored trial	Lunch	Documentation in investigational new drug	Interaction with members of RPC, RIMS
		Day 4		Responsibilities of Sponsor		General responsibilities of Principal Investigator		Specific responsibilities of Principal Investigator	Interactive session**
		Day 5		Responsibilities of research site staff		Roles and responsibilities in multi-site trial		Summary of roles and responsibilities	Group Activity*
		Day 6		Weekly quiz		Feedback session		Visit to Central Medical Record Department and Training Centre	
	Week 4: Research misconduct, Conflict of interest, Investigational new drugs	Day 1		Identifying Research Misconduct		Investigating Allegations of Research Misconduct		Responding to Allegations of Research Misconduct	Group Activity*
		Day2		Safeguards for Informants and Accused Persons		Possible Penalties for Research Misconduct		Summary of research misconduct	Group Activity*
		Day 3	Previous day briefing	Evaluation of conflict of interest	Tea break	Reporting conflict of interest to funding agency	Lunch	Conflict of interest in ethics committee	Interactive session**
		Day 4		Phases of Clinical Trials of Investigational New Drugs		Investigational New Drugs Requirements		Investigational New Drugs Responsibilities	Group Activity*
		Day 5		Clinical trial with complementary and alternative medicine		Investigational new devices		Drug accountability	Interactive session**
		Day 6		Weekly quiz		Feedback session		Visit to Research Labs at RIMS, Ranchi	
	Week 5: Monitoring, Recruitment of patients/retention Patient safety/adverse events	Day 1		Site selection		Site initiation		Monitoring procedures and SOPs	Group Activity*
		Day2		Recruitment		Recruitment Strategies		Advertising for Study Participants	Interactive session**
		Day 3	Previous day briefing	Planning Patient recruitment strategies to assist the monitor	Tea	Retention	Lunch	Retention strategies	Group Activity*
		Day 4		Use of Incentives		Attrition of study patients		Participant Safety & Adverse Events	Interactive session**
		Day 5		Assessing an Adverse Even		Adverse Event Reporting		Adverse Event Follow-up	Group Activity*

SHORT TERM FELLOWSHIP PROGRAM IN GOOD CLINICAL PRACTICE TENTATIVE SCHEDULE

		Day 6		Weekly quiz		Feedback session		Visit to Research Labs at RIMS, Ranchi	
	Week 6: Quality assurance and quality control	Day 1		Introduction to Quality Assurance and Quality Control in Clinical Trials		Quality Certifications, Govt. Regulations, ICH Guidelines and ISO 9000		Quality Management System in Clinical Trials	Group Activity*
		Day2		Monitoring Visit Procedures		Study close out visits		Various types of Audits in Clinical Trails	Interactive session**
		Day 3	Previous day briefing	Clinical Trials Audit observations and study of critical observations	Tea	WHO Risk Based Approach Analysis	Lunch	Breach reports and Compliance guidelines	Interactive session**
		Day 4		Monitoring board		Data Safety		Data quality assessment	Group Activity*
		Day 5		Competency assessment		Research protocol presentation by fellows		Research protocol presentation by fellows	Research protocol presentation by fellows
		Day 6		Research protocol presentation by fellows		Research protocol presentation by fellows		Post-training assessment	Valedictory
2	Relevance in Public Health	This training is important for all staff involved in Clinical Research and ensures an understanding of the principles adopted in research. GCP is widely accepted and expected in all research involving human participants. GCP is not specific to a protocol, but rather is general and applicable to all protocols. Anyone directly involved in the design or conduct, oversight, or management of research involving human participants, including research site staff, back-up staff, contractors, subcontractors, and consultants who perform key study functions, should complete the GCP training.							