

Workshop on “ETHICS AND CLINICAL TRIALS”

Organized by

Institute Ethics Committee & Clinical Trial Review Committee



AIIMS Bibinagar, Hyderabad

on 8th and 9th of February, 2024

at AIIMS Auditorium

We, from IEC and CTRC AIIMS Bibinagar, Hyderabad cordially invite you to participate in the **“Ethics and Clinical Trials”** Workshop on **8th & 9th February** at Auditorium, AIIMS Bibinagar, Hyderabad.

Why this Workshop?

Biomedical research and clinical research (including clinical trials) are one of the vital mandates of AIIMS. And in line with its vision statement, AIIMS Bibinagar, since its inception, is promoting scientific research opportunities among all including faculty, residents, nursing officers, and students. Therefore, to support our researchers to undertake biomedical, clinical research or clinical trials in the most scientifically robust and ethically appropriate way this workshop is planned. This Workshop would cover topics related to ethical principles that govern the conduct of research involving human participants (**ICMR Ethical Guidelines, 2017**) and also the principles of conduct of clinical trials (**The New Drugs and Clinical Trials Rules, 2019**) including **Good Clinical Practice (GCP)**.

***Maximum number of delegates permitted: 75**

***Last date of registration: 6th February 2024**

PATRON

- **Dr. Vikas Bhatia**, Executive Director
AIIMS Bibinagar, Hyderabad

ADVISORS

- **Dr. G. Suryanarayana Raju**, IEC Chairperson
AIIMS Bibinagar, Hyderabad

ADVISORS

- **Prof. (Dr.) Rahul Narang**, Dean (Academics)
AIIMS Bibinagar, Hyderabad
- **Prof. (Dr.) Sangeetha Sampath**, Dean (Research)
AIIMS Bibinagar, Hyderabad
- **Prof. (Dr.) Abhishek Arora**, Medical Superintendent
AIIMS Bibinagar, Hyderabad

Dr. Madhavi Eerike
Associate Professor
Dept. of Pharmacology
AIIMS Bibinagar
Member Secretary, IEC
Chairperson, CTRC

ORGANIZING COMMITTEE
Members of IEC and CTRC
AIIMS Bibinagar

Dr. Gerard Marshall Raj
Assistant Professor
Dept. of Pharmacology
AIIMS Bibinagar
Member Secretary, CTRC

Workshop on
“ETHICS AND CLINICAL TRIALS”
Inauguration – Program Schedule
8th February 2024 (Thursday)

Welcome address **Dr. Madhavi Eerike**, Member Secretary, IEC, AIIMS Bibinagar

Address by MS **Prof. (Dr.) Abhishek Arora**, Medical Superintendent, AIIMS Bibinagar

Address by Dean (Research) **Prof. (Dr.) Sangeetha Sampath**, Dean (Research), AIIMS Bibinagar

Address by Dean (Academics) **Prof. (Dr.) Rahul Narang**, Dean (Academics), AIIMS Bibinagar

Address by IEC Chairperson **Prof. (Dr.) G. Suryanarayana Raju**, IEC Chairperson, AIIMS Bibinagar

Special Address by Executive Director **Prof. (Dr.) Vikas Bhatia**, Executive Director, AIIMS Bibinagar

Keynote Address **Prof. (Dr.) Y K Gupta**, President, AIIMS Bhopal & AIIMS Vijaypur, Jammu
Former Dean (Academics) & Head, Dept of Pharmacology, AIIMS, New Delhi

Vote of thanks **Dr. Gerard Marshall Raj**, Member Secretary, CTCRC, AIIMS Bibinagar

**10:15 –
10:45 a.m.**

Scientific Program

8th February 2024 (Thursday)

Time	Program/ Activity	Speaker
9:30 – 10:15 a.m.	ICMR Bioethical guidelines	Prof. (Dr.) Sneha Ambwani Prof & Head, Dept. of Pharmacology, AIIMS Jodhpur
10:15 – 10:45 a.m.	Inauguration	Dignitaries
10:45 – 11:00 a.m.	Tea Break	
11:00 – 11:45 a.m.	GCP principles in clinical trials – Ensuring quality and compliance	Prof. (Dr.) Y K Gupta, President, AIIMS Bhopal & AIIMS Vijaypur, Jammu Former Dean (Academics) & Head, Dept. of Pharmacology, AIIMS, New Delhi
11:45 – 12:45 p.m.	Ethics Committee composition, functions and review procedures	Prof. (Dr.) Suryanarayana Raju Chairperson, IEC, AIIMS Bibinagar Former Dean of Research and Projects, Senior Prof & Head, Dept. of Surgical Oncology, NIMS, Hyderabad Former Member, MARB, National Medical Commission
12:45 – 1:30 pm.	Ethical guidelines for clinical trials on AYUSH products	Dr. V G Hudder Associate Professor, Dept. of Kayachikitsa (Internal Medicine), All India Institute of Ayurvedha (under Ministry of AYUSH)
1:30 – 2:00 p.m.	Lunch Break	
2:00 – 3:00 p.m.	SAE reporting and compensation	Prof. (Dr.) Jayanthi M Dept. of Pharmacology, JIPMER, Puducherry
3:00 – 3:45 p.m.	Informed consent	Dr. Madhavi Eerike Associate Professor, Dept. of Pharmacology, AIIMS Bibinagar
3:45 – 4:00 p.m.	Tea Break	
4:00 – 4:30 p.m.	Open house/ Quiz	

Scientific Program

9th February 2024 (Friday)

Time	Program/ Activity	Speaker
10:00 – 11:00 a.m.	Conduct of investigator- initiated clinical trials	Dr. Aparna Mukherjee Scientist E, Clinical trial unit, ICMR-HQ, New Delhi
11:00 – 11:15 a.m.	Tea Break	
11:15 – 12:15 p.m.	Randomization, Blinding, Allocation concealment	Prof. (Dr.) Melvin George Dept. of Clinical Pharmacology SRM Medical College & Hospital, Tamilnadu
12:15 – 1:15 p.m.	Adaptive trial design	Prof. (Dr.) Denis Xavier Professor and Head, Dept. of Pharmacology St. John's Medical College Ex-Vice Dean (PG) Head, Division of Clinical Research and Training St. John's Research Institute
1:15 – 2:00 p.m.	Lunch Break	
2:00 – 2:45 p.m.	Technological advancements in clinical trials	Dr. Saibal Das Scientist D, ICMR- Centre for Ageing and Mental Health, Kolkata
2:45 – 3:30 p.m.	Good data and record management practices in clinical research	Dr. Gerard Marshall Raj Asst. Professor, Dept. of Pharmacology, AIIMS Bibinagar
3:30 – 3:45 p.m.	Tea Break	
3:45 – 4:15 p.m.	Open house/Quiz	

Registration is free

But mandatory for receiving participation certificate

Registration link

<https://forms.gle/zckAJBoWhnXgLvfG6>

Registration

QR code



For Contact

Dr. Madhavi Eerike

dr.madhavieerike@gmail.com

9941476332

Dr. Gerard Marshall Raj

drgmr1111@gmail.com

9245124616

