NEIGRIHMS

NORTH EASTERN INDIRA GANDHI REGIONAL INSTITUTE OF HEALTH & MEDICAL SCIENCE, SHILLONG

(An Autonomous Institute, Ministry of Health and Family Welfare, Government of India)
Director's Block, Mawdiangdiang, Shillong – 7930018 Meghalaya
www.neigrihms.gov.in

DEPARTMENT OF MEDICAL EDUCATION

NEIGR/MEU/2013/64 Dated: 20th August 2015

Circular

Department of Medical Education NEIGRIHMS is conducting

"**International workshop on Harmonization-Good clinical practice & Ethical prospective of Bio-medical Research"**

At NEIGRIHMS, Shillong on 29th August 2015 supported by AUM Clinical Research Management Organization (AUM CRMO), Guwahati

Aims of workshop: To provide Practical benefit & hands on practice to potential investigator of Bio-medical Research @NEIGRIHMS (Faculty, Senior Resident Doctors & Post Graduate Scholars & Member of IEC).

Dates and duration of the workshop: 29th August 2015 at 10:00 AM – 1:00 PM (Saturday) (Half Day) at LT- 1

Registration: Registration is mandatory but complimentary for Workshop. Please Contact the office of the Coordinator, Department of Medical Education for Registration & more details.

Module: Workshop will be conducted in the Lecture Theatre - I with Pre-Test & Evaluation by Post-Test.

Eligibility of this workshop: Faculty members, Senior Resident Doctors & Post Graduate Scholars & Member of IEC. Potential investigator of Bio-medical Research

Certificate: Successful completion of this workshop will be awarded by Certificate of Participation.

Circular is issued after approval from the competent authority.

Course Coordinator
Dr. Md. Yunus
Additional Professor, Anesthesiology & Critical care
Coordinator, Medical Education Unit
NEIGRIHMS
Email: drmdyunus@hotmail.com , meuneigrihms@hotmail.com
Cell No: 09436706438, 09774334284

Copy to: - 1) PA to Director for information to Director

2) PA to Dean for information to Dean & Notification & participation of Faculty, PG Student & SRD

3) Chairman, IEC, NEIGRIHMS for information

4) PA to Principal & Member Secretary of IEC, NEIGRIHMS for information

5) Members of IEC, NEIGRIHMS for information

6) Sub-Dean (Research) for information & circulation

7) PA to Deputy Director for information to Deputy Director

8) All HOD & In charge of the Department for information & Circulation

9) All Faculty Members for information & Circulation

10) Principal, Nursing College for information & circulation to their Faculty & potential investigator of Bio-medical research

11) Ms. Pynhun Sutnga, DPA for uploading in the Institute Website

12) Office copy

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Certificate: Successful completion of this workshop will be awarded by Certificate of Participation.

It is requested to all Head of Department/ In charge to nominate Faculty members/ Post Graduate students/Post Doctors and Senior Resident Doctors for this workshop course.

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Course Coordinator

Dr. Md. Yunus

Additional Professor, Anesthesiology & Critical care
Coordinator, Medical Education Unit
Sub-Dean (Research), NEIGRIHMS
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12) All Notice Boards

13) Office copy

DEPARTMENT OF MEDICAL EDUCATION

International workshop on Harmonization-Good clinical practice & Ethical prospective of Bio-medical Research

Date: 29th August 2015(Saturday)

Venue: Lecture Theatre – 1

Time: 10 AM – 2: 30 PM

Supported by: AUM Clinical Research Management Organization (AUM CRMO), Guwahati

NEIGRIHMS

SCIENTIFIC PROGRAMME

Time & Duration	Topics	Speakers
9:30 AM to 10:00 AM	Complimentary Registration	
10:00 AM to 10:10 AM	Introduction of IEC, NEIGRIHMS	**Dr. Md. Yunus**
10:10 AM to 10:30 AM	Challenges in applying for grants of Biomedical Projects	**Dr. P. K. Bhattacharya**
10:30 AM to 10:40 AM	Address by	**Dean, NEIGRIHMS, Principal (IEC, Secretary) NEIGRIHMS & Chairman of MEU**
10:40 AM to 10:50 AM	Introductory Note on ELS	**Mr. Rajeev Singha from Excel Life Sciences**
10:50 AM to 11:05 AM	Pre Assessment on ICH GCP	ELS
11:05 AM to 11:15 AM	**Tea & Coffee break**	
11:15 AM to 11:35 AM	ICH GCP – Overview and Clinical Research History	ELS
11:35 AM to 12:00 PM	Drug development and Clinical trial phases	ELS
12:00 PM to 12:15 PM	Principles of ICH GCP	ELS
12:15 PM to 12:30 PM	ICH GCP – Ethics Committee (Role and responsibilities of EC)	ELS
12:30 PM to 12:40 PM	ICH GCP – Sponsor (Role and responsibilities of Sponsor)	ELS
12:40 PM to 1:00 PM	ICH CGP – Investigator (Role and responsibilities of Investigator)	ELS
1:00 PM to 1:10 PM	**Tea & Coffee break**	
1:10 PM to 1:25 PM	ICH GCP – Essential documents Protocol & IB Informed Consent and Audio Visual Consent	ELS
1:25 PM to 1:55 PM	Schedule Y – Amendments (Introduction to Schedule Y, Compensation Guidelines, SAE Reporting Timelines)	ELS
1:55 PM to 2:05 PM	Post Assessment on ICH GCP	ELS
2:05 PM to 2:15	Training Feedback	ELS