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RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA, BENGALURU
4th T Block, Jayanagar, Bengaluru – 560 041

Date: 07-08-2021

To,
Director and Deans/ Principals
Of all Affiliated colleges of RGUHS.

Dear Sir/Madam,

SUB: Workshop on Sensitization on Regulatory Aspects in clinical trials
on 08-09-2021.

With reference to the above subject, It gives me great pleasure to inform you that Rajiv Gandhi University of Health sciences in collaboration with St. John's Medical College and Research Institute and Indian Society for Clinical Research (ISCR) will be conducting a work shop on sensitization on Regulatory Aspects in clinical trials on 08-09-2021 between 10 AM to 01:00 PM through online platform. You are requested to bring this information to the notice of all the faculty members of your institution. The detailed program of the workshop is enclosed with this mail.

The faculty who wish to participate in the workshop have to register themselves by clicking on the link provided below. The last date for registration to the workshop is 23-08-2021 at 05:00 PM

Link for the participant registration:

<https://docs.google.com/forms/d/1hltMMDv5WlmbfB6wo4rtYkk8uDI8P5jsxMIMEfoyxkXQ>

For registered candidates course materials will be sent by E-mail and they should read the course material and participate in the workshop scheduled on 08-09-2021.

The session will be basically an interactive session. The necessary link for the online course on workshop will be shared to the registered candidates in due course of time. You are once again kindly requested to give wide publicity for this program and encourage the faculty to register for the workshop.

Thanking you,

REGISTRAR

To,
Director and Deans/ Principals Of all Affiliated colleges of RGUHS.
Copy to,
PA to VC, Registrar, Registrar Evaluation and office copy.

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES

Short course on SENSETIZATION ON REGULATORY ASPECTS IN CLINICAL TRIALS

Date: 08th September, 2021

*Time: 10.00am to 1.00pm

- Course objectives:
- To gain an understanding of essential regulatory issues in the conduct of international and Indian clinical trials.
- Organized by:
- RGUHS and St. John's Medical College and Research Institute in collaboration with Indian Society for Clinical Research (ISCR)
- Pre reads:
- New drugs and clinical trial guidelines; US FDA & EMEA guidelines (summary articles) and 3-4 short articles.
- Intended audience:
- Faculty of colleges affiliated to RGUHS

AGENDA

Topic	Speaker/Affiliation	Durn.	Time*
Welcome and Opening remarks	Dr. Dayananda M	5 mins	10:00-10:05 am
Course objectives and methods	Dr. Denis Xavier	5 mins	10:05-10:10 am
International regulations for clinical trials	ISCR (name TBC)	20 mins	10:10-10:30 am
New drugs and clinical trial guidelines (Indian)	ISCR (name TBC)	20 mins	10:30-10:50 am
Academic clinical trials in India	Dr. Denis Xavier/ other	20 mins	10:50-11:10 am
Break		10 mins	11:10-11:20
Clinical trials in special situations (EUA, etc.)	ISCR	20 min	11:20-11:40 am
Ethics, insurance, medical management and compensation	Dr. Prem Pais	20 mins	11:40-12:00 pm
Panel discussion	All speakers + few others Moderator: Dr. Denis Xavier	50 mins	12:00-12:50 pm
Concluding remarks	Dr. Dayananda M	10 mins	12:50-01:00 pm