FEES

RM400 (POSTGRADUATE STUDENT UM/UMMC)

RM600 (POSTGRADUATE STUDENT / STAFF UM/UMMC)

> RM800 (OTHERS)

PAYMENT METHOD: ONLINE BANKING

PAYABLE TO: PUSAT PERUBATAN UNIVERSITI MALAYA 14171010007496 (BANK ISLAM)

REGISTRATION FEES INCLUDES COURSE MATERIALS AND REFRESHMENTS

CONTACTS

CLINICAL INVESTIGATION CENTRE, 5TH FLOOR, EAST TOWER, UNIVERSITY MALAYA MEDICAL CENTRE, 59100 LEMBAH PANTAI, KUALA LUMPUR.

> Dr. Moohita Ms. Hafizah Mdm. Anis Athirah Ms. Zulaikha

03 - 7949 2351

moohita@ummc.edu.my hanishafizah@ummc.edu.my athirah.ah@ummc.edu.my zulaikhasyaz@ummc.edu.my

http://www.clinicalinvestigationcentre.com/





Clinical Investigation Centre presents

Good Clinical Dractice Workshop 2023

23 - 25 MAY 2023 | 08 - 10 AUG 2023

<u>DAY 1 & 2</u> Virtually VIA Zoom 8AM - 5PM

<u>DAY 3</u> Paum Clubhouse 8am - 1Pm

	DAY 1- VIRTUAL SESSION		
	8.00AM - 8.15AM	Welcoming and briefing	
	8.15AM - 9.15AM	Overview if GCP and Clinical Research in Malaysia	
	9.15AM -10.15AM	International Council of Harmonization (ICH): GCP Compared to	
		Malaysian Guideline for GCP	
	10.15AM -11.30AM	Ethical Issues in Clinical Trial	
		 Overview of Ethical Issues 	
		Role of IRB/IEC	
	11.45AM - 1.00PM	Clinical Trial Protocol	
		 Study Design 	
		 Protocol Amendment 	
	1.00PM - 2.00PM	Lunch	
	2.00PM - 3.00PM	Investigator's Responsibility	
		Compliance of Protocol	
		Study Reports	
	3.00PM - 4.30PM	Informed Consent Process	
		Exercise on Informed Consent Process	
DAY 2- VIRTUAL SESSION			
	8.15AM - 9.15AM	Role of Study Coordinator (SC)	
	9.15AM - 11.15AM	Sponsor's Responsibility	
		 Role of the Monitor 	
		 Handling of Investigational Products (IP) 	
		 Drug Accountability and Archiving 	
	11.15AM -12.15PM	Safety Monitoring and Reporting	
		Adverse Events	
	12.15PM - 12.30PM	Quizzes and Break	
	12.30PM - 1.30PM	Lunch	
	1.30PM - 2.45PM	Investigator Brochure (IB) and Essential Documents	
	3.00PM - 4.30PM	Audit and Inspection	
	DAY 3 – Physical Session (PAUM Clubhouse)		
	8.00AM - 8.30AM	Registration	
	8.30AM - 9.30AM	Regulatory Aspects of Clinical Trials in Malaysia	
\geq	9.30AM - 10.20AM	GCP Inspection	
	10.20AM - 11.30AM	Self-Preparation for Examination	
	11.30AM - 12.30PM	GCP Certification Exam	
	12.30PM - 1.00PM	Lunch and End	

CANCELLATION

Cancellation must be made in writing to the organizers. Full refund for cancellation done more than 3 weeks and 50% refunds for cancellation done not less than 10 days. No refund for cancellation done less than 7 days and no show. We reserved the right to change the date(s) or speaker(s) of this course, if deem fit, without prior notice. We further reserved the right to cancel the course without liability other than return of the course fee.

Endorsed by Ministry of Health

