REGISTRATION INFORMATION

REGISTRATION FEES:

MOH staff / Student = RM 550.00

Non-MOH staff = RM 650.00

The fee includes all supporting documentations, workshop materials, meals and certificate

- The number of participants is **limited to 50**
- Closing date for registration **29th March 2018**
- Only completed form will be processed after payment notification is received
- Attendance is compulsory for the duration of workshop and participants will sit for an examination at the end of the course to get certified

PAYMENT

Payment must be submitted before **29th March 2018** and kindly notify the CRC HSNZ committee by email

Method of payment (please √):

	Cash
	Bank Transfer
	Local Order

Bank Transfer to / Local Order to be made payable to:

PGMES HSNZ

Maybank Islamic Berhad

Account number : 5630 1902 3310

Kindly bring a copy of your payment receipt/ Local Order on the registration day. Failure to do so will disable you from participating in this workshop.

CANCELLATION

Any cancellation must be made in writing to CRC HSNZ. No refund for cancellation 1 week before the date of workshop.

NAME : Prof / Dr / Mr / Mrs / Ms

_____

_____

*(Please print your name in **BLOCK LETTER** as you wish it appear in the certificate)*

NRIC NO. : _____

DESIGNATION : _____

GRADE : _____

INSTITUTION/ DEPARTMENT: _____

EMAIL ADDRESS : _____

TEL NO. : _____

MEAL REQUEST : ☐ **Normal** ☐ **Vegetarian**

SIGNATURE : _____

For further information, please contact:

Clinical Research Center,
Hospital Sultanah Nur Zahirah.

Tel: 09-6212121 Ext: 2167

Fax: 09-6233824

Email :crcterengganu@gmail.com

GOOD CLINICAL PRACTICE (GCP) WORKSHOP 2018

DATE : 10 – 12 APRIL 2018

TIME : 8.00 AM – 5.00 PM

VENUE : SUMAI HOTEL & APARTMENT KUALA TERENGGANU.

Organized by: CRC Sultanah Nur Zahirah Hospital — *Research that matters to patients*

In Collaboration with: PGMES HSNZ

OVERVIEW

Good Clinical Practice (GCP) is a set of rules and regulations that is provided by International Conference on Harmonisation (ICH), an international body that regulates clinical trials involving human subjects. It is a standard for the design, conduct, performance monitoring, auditing, recording, analyses and reporting of clinical trials that provide assurance that the data and reported results are credible and accurate; and the rights, integrity and confidentiality of trial subjects are protected.

OBJECTIVES OF THE WORKSHOP

1. To understand the principles underlying GCP and its specific rules of conduct.
2. To provide experience in the key skills required through simulation in a classroom setting.
3. To provide some of the resources required to design and conduct GCP trial.
4. To achieve an overall understanding on how to conduct GCP compliant clinical studies.

Malaysia adopted GCP in 1999. Since then doctors are required to undergo training on GCP leading to certification prior to participation in clinical trials. This workshop is specifically designed to meet this requirement.

WORKSHOP CONTENTS

- Overview of ICH/GCP and Malaysian GCP
- Overview of ethics of clinical research
- Ethics and regulations of clinical trials
- Role of IRB/IEC
- Informed consent
- Clinical Trial Protocol & Investigator's Brochure
- Safety monitoring and reporting
- Investigator's responsibility (Study initiation, patient recruitment, CRF completion and source documents, drug accountability, role of site coordinator, essential documents, archiving at site)
- Working with Sponsor (selection of investigator/site, agreement including finance, compensation for trial related injury, archiving central lab, audit and inspection
- Oversight and funding for clinical research in MOH
- Regulation of clinical research in Malaysia

MALAYSIAN GUIDELINE FOR GOOD CLINICAL PRACTICE

You may download the copy of the GCP handbook (3rd edition) from www.crc.gov.my/guidelines/ and read beforehand.

WHO SHOULD PARTICIPATE

- Clinical physicians in Ministry of Health
- Any clinicians that involved with clinical trial
- Clinical Research Associate
- Clinical trial pharmacist
- Postgraduate students
- Clinical trial statistician

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