Good Clinical Practice Workshop

PROGRAMME

TUESDAY, 24 MARCH 2020

0800 – 0830  Registration
0830 – 0930  Overview of GCP and Clinical Research in Malaysia
0930 – 1000  Tea
1000 – 1100  Overview of ICH GCP Malaysian GCP Guidelines
1100 – 1200  Ethical issues in Clinical Trials
   - Overview of Ethics
   - Role of IRB/IEC
   - Investigator’s Responsibility
   - Investigator’s Brochures
   - Essentials Documents
1200 – 1300  Lunch
1400 – 1500  Informed Consent Process
1500 – 1600  Exercise on Informed Consent Process
1600 – 1630  Tea

THURSDAY, 26 MARCH 2020

0800 – 0830  Registration
0830 – 0930  Clinical Trial Protocol
   - Study Design
   - Protocol Amendment
0930 – 1000  Tea
1000 – 1100  Role of Study Coordinator (SC)
1100 – 1200  Sponsor’s Responsibility
   - Role of the Monitor
   - Investigational Products (IP)
   - Drug Accountability and Archiving
   - Safety Monitoring and Reporting
   - Adverse Events
1200 – 1300  Lunch
1300 – 1400  Audit and Inspection
1400 – 1600  Tea
1600 – 1630  Tea

CONTACTS

CLINICAL INVESTIGATION CENTRE,
5TH FLOOR, EAST TOWER,
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PAUM Clubhouse
24 - 26 March 2020
8AM - 5PM
REGISTRATION FORM

NAME : PROF. / ASSOC. PROF. / DR / MR / MRS / MS

(PLEASE PRINT NAME IN BLOCK LETTERS AS YOU WISH IT TO APPEAR IN THE CERTIFICATE)

IC NUMBER :

INSTITUTION / DEPARTMENT / UNIT / PTJ :

CONTACT ADDRESS :

TEL :

E-MAIL :

STUDENT OF UM/UMMC

STAFF OF UM/UMMC

OTHERS

STUDENT NUMBER :

MODE OF PAYMENT :

CASH

ONLINE BANKING

CHEQUE

PAYABLE TO:

PUSAT PERUBATAN
UNIVERSITI MALAYA
14171010007496
(BANK ISLAM)

FEES

RM400
(POSTGRADUATE STUDENT UM/UMMC)

RM600
(POSTGRADUATE STUDENT / STAFF UM/UMMC)

RM800
(OTHERS)

PAYMENT METHOD :

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