REGISTRATION INFORMATION :

MOH : RM 600.00
Non-MOH : RM 650.00
Student : RM 500.00

Fees include workshop manual, materials, lunch and refreshment breaks. Places are only confirmed on receipt of payment – first come first served basis. Payment must be submitted at least 2 weeks before the workshop.
Cheques/Bank draft/Local Order/Postal Order to be **made payable to:**

"PERTUBUHAN PENDIDIKAN PERUBATAN LEPAS IJAZAH"
HOSPITAL KOTA BHARU
15586 KOTA BHARU, KELANTAN
Maybank account no : 553010013567

Closing Date : 22 May 2013

Please return the form to :

Pusat Penyelidikan Klinikal
Hospital Raja Perempuan Zainab II
15586 Kota Bharu, Kelantan

Tel : 097452636 / 2639 Fax : 097452637
Email : (crckelantan@klt.moh.gov.my)

Cancellation

Cancellation must be made in writing to the organizers.

- Full refund for cancellation at least 2 weeks before date of workshop
- 50% refund for cancellation within 1 week
- No refunds for cancellations less than 1 week or no show

We reserve the right to cancel the course without liability other than refund of the course fee.

REGISTRATION FORM :

Name:.....

NRIC : .....

Department/Institution:.....

.....

Designation:.....

Specialty:.....

Contact Address: .....

.....

.....

Tel : .....Fax : .....

Email : .....

Meal Request: ☐ Normal ☐ Vegetarian

Sponsorship:

☐ Ministry of Health
☐ Private(Company Name) : .....

Contact Person : .....\

☐ Self

Method of Payment:

☐ Cash ☐ Cheque
☐ Bank Draft ☐ Local Order

GOOD CLINICAL PRACTICE WORKSHOP

Date
18 – 20 June 2013

VENUE :
Rural Transformation Centre (RTC)
Terminal Agribisnes Negara (TEMAN)
Lebuh Raya Pasir Mas - Salor
Kota Bharu. kelantan

ORGANIZED BY :

IN COLLABORATION WITH :
PGMES
Hospital Raja Perempuan Zainab II
Kota Bharu, Kelantan

OVERVIEW

GCP is a set of rules and regulations that is provided by ICH, an internatinal body thar 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 provides assurance that the:

I. Data and reported results are credible and accurate, and
II. Rights, integrity and confidentiality of trial subjects are protected.

OBJECTIVES

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

WHY GCP?

In clinical trials, the protection of the subject is paramount especially when untested therapy is used. There must also be assurance about the conduct of clinical trials in terms of elimination of cheating, fraud or accidental error. Problems of poor study design must be avoided. Adherence to GCP is vital otherwise subjects participating in the trials may be put at risk or the clinical trial data submitted may be rejected by health authorities and the scientific committee, if found to be unreliable. Also, the researcher and the research institution may be damaged.

Malaysia adopted GCP in 1999, and since then doctors are required to undergo training on GCP leading to certification prior to participation in clinical trials. This course is specifically designed to meet this requirements.

WHO SHOULD PARTICIPATE?

- Clinicians, nurses and allied health professionals involved with research.
- Research Associates and Study Coordinators.
- Biomedical and research scientists.
- Statistician and database managers.
- Experienced research personnel who are interested in updating their knowledge regarding GCP.

COURSE CONTENT

- Overview of ICH/GCP and Malaysia GCP
- Clinical trials design and protocol development
- Ethics and regulation of clinical trials
- Role of IRB/IEC
- Informed consent
- 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)
- Legal aspects of clinical trials including research agreement
- Financial aspects of clinical trials
- Clinical trials publication*
- GXP (good clinical data management practice, good statistical practice, good laboratory practice, good documentation practice)*

*Optional