

## REGISTRATION INFORMATION

### REGISTRATION FEES

Registration Fees = RM 900.00

The course fee includes all supporting documentation, course materials (such as software where applicable), refreshments and lunches.

*For MOH personnel, if you are undertaking trial with a company, the company will usually pay the course fee. Otherwise you may apply to Training Division MOH, to the relevant professional society or to CRC to sponsor the fees. CRC will issue an invitation letter to enable you to claim for other expenses if you are allowed to do so.*

### CANCELLATION

Any 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 this course without liability other than return of the course fee.

### PAYMENT

Payment must be submitted at least 2 weeks before the workshop. Cheque / bank draft / local order / postal order to be made payable and send to:

\* ASSOCIATES OF CLINICAL RESEARCH PROFESSIONAL MALAYSIA SDN BHD  
2nd Floor, MMA House  
124, Jalan Pahang  
53000 Kuala Lumpur

\* Please spell out correctly in full

### FOR FURTHER ENQUIRIES, PLEASE CONTACT:

Ms Amy Yu / Ms Haniza Secretariat  
Tel : 03-4043 3809  
Fax : 03-4043 3808  
Email : [contact@acrpm.com.my](mailto:contact@acrpm.com.my)

## REGISTRATION FORM

Name: Prof/ Dr/ Mr/ Mrs/Ms

.....  
*(Please print name in block letters as you wish it to appear in the certificate)*

IC No: .....

Department: .....

Institution: .....

Designation: .....

Specialty: .....

Contact Address: .....

Tel: .....(O).....(HP)

Fax: .....

Email: .....

Signature: .....

Meal request  
 Vegetarian

Sponsored by:

Public (Government)

Contact person: .....

Tel: .....

Private (Company Name): .....

Contact person: .....

Tel: .....

Self

\* Attendance is compulsory for the whole duration of workshop.

# GOOD CLINICAL PRACTICE WORKSHOP

Date : 22 - 24 September 2010

Venue : The Royale Chulan Hotel,  
Kuala Lumpur

In Collaboration with:  
CRC, National Institutes of Health and ACRPM  
Sdn. Bhd.



Associates of Clinical Research Professional Malaysia  
Sdn Bhd

## OVERVIEW

GCP is a set of rules and regulations that is provided by 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 provides assurance that the

- 1) data and reported results are credible and accurate, and
- 2) rights, integrity and confidentiality of trial subjects are protected.

## 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 research credibility of 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 requirement.

## OBJECTIVES

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 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.

## WHO SHOULD PARTICIPATE?

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

## COURSE CONTENTS

- Overview of ICH/GCP and Malaysian 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
- IT for clinical trial\*
- GXP (good clinical data management practice, good statistical practice, good laboratory practice, good documentation practice)\*

(\* optional)