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 provides 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 classroom setting.
3. To provide some of theresources required to design and to conduct GCP trial.
4. To achieve an overall understanding on how to conduct GCP compliant clinical studies.

Why GCP?

In clinical studies, the protection of the subject is paramount especially when untested therapy is used. There must also be assurance about the conduct of clinical studies 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 study may be put at risk or the clinical data submitted may be rejected by health authorities and the scientific committee, if found to be unreliable. Also, the researcher and the research institution's credibility may be damaged.

GCP is adopted in 1999 in Malaysia. Since then doctors are required to undergo training on GCP leading to certification prior to participation in clinical trials and other clinical studies. This course is specially designed to meet this requirement.

Workshop Contents

Day 1: 8 am – 5 pm

- Clinical research in Malaysia and role of CRC
- Overview of ICH/ GCP and Malaysian GCP Guideline
- Overview of ethics of clinical research, ethical principles & requirements
- Ethical problems in clinical research
- Informed consent
- Independent ethics committee
- NMRR registration

Day 2: 8 am – 5 pm

- Investigator's responsibility
- Clinical trial protocol &investigator's brochure
- Sponsor's responsibility
- Adverse event reporting and safety surveillance
- Role of study coordinator

Day 3: 8 am – 5 pm

- Good clinical data management
- Regulation of clinical research in Malaysia
- Oversight and funding for clinical research in MOH

Who should participate?

- Clinicians, nurses and allied health professionals involved in any clinical research
- Research associates and study coordinators
- Biomedical and research scientists
- Statisticians and database managers
- Experienced research personnel who are interested in updating their knowledge in GCP

REGISTRATION FORM

Name: Prof / Dr / Mr / Mrs / Ms

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

IC No.: .....

Department:

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Institution: .....

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Designation:

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Contact Address:

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Email: .....

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Tel: (Office) .....

(HP) .....

Fax: .....

Sponsored by:

☐ **Public (Government)**

Contact Person:

.....

Tel: .....

☐ **Private (Company Name):**

Contact Person:

.....

Tel: .....

☐ **Self**

Special Meals Request: (No / Yes)

Please specify: .....

Signature:

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

REGISTRATION INFORMATION

REGISTRATION FEES

MOH Staff = RM 720

Non-MOH Staff = RM 880

The registration fee includes all supporting documentation, workshop materials, meals and certificate.

CANCELLATION

Any cancellation must be made in writing to the organizer.

- Full refund for cancellation or replacement at least 4 weeks before date of workshop;
- 50%refund for cancellation within 1 week;
- No refunds for cancellation less than 1 week or absence

We reserve the right to cancel the workshop without liability other than return of the registration fee.

PAYMENT

Payment must be submitted at least 3 weeks before the workshop.

Account Name: Clinical Research and Post-graduate Society of Sibu Hospital [4577-11-SWK]

Bank Name: United Overseas Bank (Malaysia) Bhd

Account No: 192-301-343-7

For further enquiries, please contact:

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Sibu Hospital
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Email : crps_sh@yahoo.com

Good Clinical Practice Certification Workshop

Date : 23 – 25 March 2015

Venue : RH Hotel, Sibu

Organized by:

CLINICAL RESEARCH & POST-GRADUATE SOCIETY HOSPITAL SIBU

MINISTRY OF HEALTH MALAYSIA
Research that matters to patients