Registration Fee	
Category	**Registration Fee**
MOH staff / Student	RM 800.00
Non-MOH Staff	RM 900.00

This course fee includes workshop materials, refreshments, lunches and registration to sit for the examination

Payment Details

Payment can be remitted via CDT / ATM transfer / Online Banking / Cheque / Local Order latest by ***27th July 2018*** *made payable to:*

LOGOS BIOMED SYSTEMS SDN BHD
Company Reg ID: 863019-H

Receiving Bank: **RHB Bank Berhad**
(Jalan Simpang Tiga Branch)

Beneficiary A/C no: **21114600014339**

We reserve the rights to cancel the workshop without liability other than the return of your registration fee

Contact Person & Enquiry

Forward your registration or enquiries to;

Mr Sim Kian Tong or **Puan Zuriah Sarkawi**
simktg.crc@gmail.com zuriah.crc@gmail.com

Clinical Research Centre
Sarawak General Hospital
93586 Kuching, Sarawak

Tel: 082 - 276820 (Direct line)
082 - 276666 (Hospital ext. 1074)
Fax: 082 - 276823

REGISTRATION FORM

Title : Prof / Dr / Mr / Ms / Mdm / Miss *(please circle)*

_____

Please print ***full name clearly*** *as in your identification card or passport for your examination registration*

IC / Passport No : _____

Designation / Post : _____ Grade: ____

Department / Unit / Ward : _____

Institution / Hospital / Clinic : _____

Contact Details*: (* Required & please write clearly your email)*

*Mobile (hp) no. : _____

* Email Address : _____

Mode of payment *(please tick √)*

☐ Cash (Fund Transfer / ATM / Online Banking)
☐ Cheque / Bank draft
☐ LPO *(Approval given by Supervisor or HOD)*

Meal request:

☐ Normal ☐ Vegetarian

Signature: .....

For Secretariat use: Date received:	Registration No: GCP e-handbook: Receipt/Invoice: Calling Letter:	Status/Remarks:

GOOD CLINICAL PRACTICE (GCP) CERTIFICATION WORKSHOP (2/2018)

Date : 11th - 13th August 2018
(Saturday - Monday)

Venue : Imperial Hotel Kuching
Level 5, Boulevard Mall
93250 Kuching, Sarawak.

Limited to **50** candidates only!

Organiser

CRC
SARAWAK GENERAL HOSPITAL
Research that matters to patients

In collaboration with

LOGOS BIOMED

Attendance is compulsory for the entire duration of the workshop to be eligible to sit for the examination

OVERVIEW

Good Clinical Practice (GCP) is a set of rules and regulation 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, analyse and reporting of clinical trials that provides assurance that the;

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

WHY GCP?

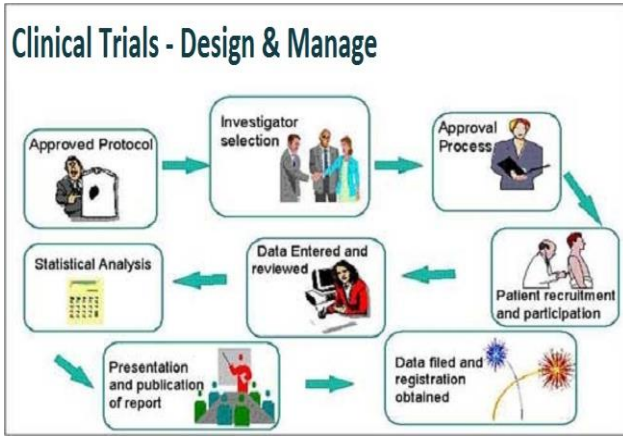
In clinical trials, the protection of the subject is paramount especially when untested therapy is used. There must also be assurance about the conduct of clinical trials in terms of elimination of cheating, fraud or accidental error. Problems of poor study design must be avoided. Adherence to GCP is 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 health professionals 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 settings.
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 Good Clinical Practice



COURSE CONTENTS

- Introduction to Good Clinical Practice
- Clinical Research in Malaysia and Role of Clinical Research Centre
- Overview of ICH/GCP and Malaysian GCP guidelines compared.
- Overview of ethics of clinical research, ethical principles & requirements
- Independent Ethics Committee (IRB/IEC)
- Informed Consent
- Case studies and ethical problems in clinical research & research misconduct
- Clinical Trial Protocol & Investigator's Brochure
- Investigator's responsibility
- Sponsor's responsibility
- Adverse event reporting & Safety surveillance
- Regulatory Aspects of Clinical Trials in Malaysia
- GCP Inspection – Trial site, sponsor/CRO, Phase 1 unit, BE & EC
- *Oversight and Funding for clinical research in MOH: Role of NIH, MOH guidelines for clinical research, MREC and MOH Research Grant
- *GXP (good clinical data management practice, good statistical practice, good laboratory practice, good documentation practice) * *(*optional modules)*