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

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

Payment Details

*Payment can be remitted via CDT / ATM transfer / Online Banking / Cheque / Local Order latest by **8th September 2017** made payable to:*

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

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

Beneficiary A/C no: **21114600014339**

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

CONTACT PERSONS:

Forward your registration or enquiries to;

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

Clinical Research Centre
Sarawak General Hospital
Kuching

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

REGISTRATION FORM

Title : Prof / Dr / Mr / Ms / Mdm / Miss

_____

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

IC / Passport No: _____

Designation: _____

Department: _____

Institution: _____

Contact Details: (Required *)

*Mobile (hp) : _____

*Email : _____

Mode of payment *(please tick √)*

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

Meal request:

☐ Normal ☐ Vegetarian

Signature: ……

For Secretariat use: Date received:	Remarks / Status:

GOOD CLINICAL PRACTICE (GCP) CERTIFICATION WORKSHOP

DATE : 23rd- 25th September 2017
(Saturday - Monday)

VENUE : Imperial Hotel,
Level 5, Boulevard Mall
Kuching, Sarawak.

Limited to 50 seats 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 trials are protected.

WHY GCP?

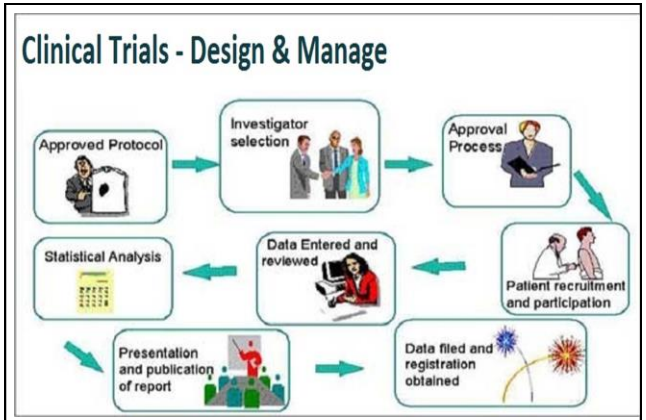
In clinical trials, the protection of the subject is paramount especially when untested therapy is used. There must also be assurance about the conduct of clinical trials in terms of elimination of cheating, fraud or accidental error. Problems of poor study design must be avoided. Adherence to GCP is 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 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 trials
- GXP (good clinical data management practice, good statistical practice, good laboratory practice, good documentation practice)* *(*optional modules)*