THE MALAYSIAN GUIDELINE FOR GCP

CHANGES FROM 2ND EDITION TO 3RD EDITION

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6	**1.6 Approved Training in Good Clinical Practice** Training which is approved by the National Committee for Clinical Research (NCCR). The content of the training must incorporate the co-curriculum as stipulated by the committee.	**1.6 Approved Training in Good Clinical Practice** Training which is approved by the National Committee for Clinical Research (NCCR). The content of the training must incorporate the curriculum as stipulated by the committee.	9
7	**1.46 National Committee for Clinical Research (NCCR)** A committee established for the purpose of coordinating and promoting clinical research in Malaysia, chaired by the Deputy Director of Health (Research & Technical Support), MOH.	**1.46 National Committee for Clinical Research (NCCR)** A committee established for the purpose of coordinating and promoting clinical research in Malaysia, chaired by the Director General of Health, Ministry of Health Malaysia.	14
8	**1.48 Opinion** (*in relation to Independent Ethics Committee*) The judgement and/or the advice provided by an Independent Ethics Committee (IEC).	**1.48 Opinion** (*in relation to Independent Ethics Committee/ Institutional Review Board*) The judgement and/or the advice provided by an Independent Ethics Committee (IEC) or an Institutional Review Board (IRB)	15

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10	**4.1.1** The investigator(s) should be qualified by education, approved training in Good Clinical Practice certification, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority (ies).	**4.1.1** The investigator(s) should be qualified by education, approved training in Good Clinical Practice, and experience to assume responsibility for the proper conduct of the trial; should meet all the qualifications specified by the applicable regulatory requirement(s); and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority(ies).	25
11	**4.8.9** If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects, is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has orally consented to the subject's participation in the trial and, if capable of doing so, has signed and/or thumbprinted and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and appropriately understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.	**4.8.9** If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects, is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has orally consented to the subject's participation in the trial and, if capable of doing so, has signed and/or thumbprinted and dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and appropriately understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.	29

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13	**4.8.14 e)** The approval/favourable opinion of the IRB/IE is expressly sought on the inclusion of such subjects, and the written approval/favourable opinion covers this aspect.	**4.8.14 e)** The approval/favourable opinion of the IRB/IEC is expressly sought on the inclusion of such subjects, and the written approval/favourable opinion covers this aspect.	31
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15	**5.6.1** The sponsor is responsible for selecting the investigator(s)/institution(s). Each investigator should be qualified by training (including approved GCP training) and experience and should have adequate resources (see 4.1, 4.2) to properly conduct the trial for which the investigator is selected. If organization of a coordinating committee and/or selection of coordinating investigator(s) are to be utilized in multicentre trials, their organization and/or selection are the sponsor's responsibility.	**5.6.1** The sponsor is responsible for selecting the investigator(s)/institution(s). Each investigator should be qualified by training (including approved GCP training) and experience and should have adequate resources (see 4.1, 4.2) to properly conduct the trial for which the investigator is selected. If organization of a coordinating committee and/or selection of coordinating investigator(s) are to be utilized in multicentre trials, their organization and/or selection are the sponsor's responsibilities.	38
16	**5.8.1** If required by the applicable regulatory requirement(s), the sponsor must provide insurance or must indemnify (legal and financial coverage) the investigator/the institution against claims arising from the trial except for claims that arise from malpractice and/or negligence.	**5.8.1** If required by the applicable regulatory requirement(s), the sponsor should provide insurance or should indemnify (legal and financial coverage) the investigator/the institution against claims arising from the trial except for claims that arise from malpractice and/or negligence.	38

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17	**7.1** Generally, the sponsor is responsible for ensuring that an up-to-date IB is made available to the investigator(s) and the investigators are responsible for providing the up-to-date IB to the responsible IRBs/IECs. In the case of an investigator sponsored trial, the sponsor -investigator should determine whether a brochure is available from the commercial manufacturer. If the investigational product is provided by the sponsor- investigator, then he or she should provide the necessary information to the trial personnel. In cases where preparation of a formal IB is impractical, the sponsor-investigator should provide, as a substitute, an expanded background information section in the trial protocol that contains the minimum current information described in this guideline.	**7.1** Generally, the sponsor is responsible for ensuring that an up-to-date IB is made available to the investigator(s) and the investigator(s) are responsible for providing the up-to-date IB to the responsible IRBs/IECs. In the case of an investigator sponsored trial, the sponsor -investigator should determine whether a brochure is available from the commercial manufacturer. If the investigational product is provided by the sponsor- investigator, then he or she should provide the necessary information to the trial personnel. In cases where preparation of a formal IB is impractical, the sponsor-investigator should provide, as a substitute, an expanded background information section in the trial protocol that contains the minimum current information described in this guideline.	54
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FOREWORD TO THE THIRD EDITION

It has been more than a decade since the publication of the first edition of the Malaysian Good Clinical Practice Guideline. The second edition followed five years later and this latest (third) edition marks another important milestone for clinical research in Malaysia.

Over the last decade more than one thousand Malaysian doctors, pharmacists, nurses and medical scientist have been GCP-certified, using this Guideline as a basis for the training. In parallel to this development, there has also been an exponential increase in clinical trials (both industry sponsored and investigator initiated) performed in Malaysia. Malaysian investigators had over the past decade been involved in major clinical outcome trials which had subsequently been published in high impact medical journals. More importantly, the output from these clinical trials had been translated into improved patient care and contributed to evidence based practice.

Progress in medicine and medical research goes hand in hand. Although there have been phenomenal advances in medicine over the last fifty years, there are still uncharted territories to explore in the continuous effort to enhance health and improve the quality of life, hence the need for more research, development and innovation activities in medicine.

This latest edition of the Malaysian GCP Guideline has taken stock of the latest development in clinical research over the last decade including the latest revision to the Declaration of Helsinki (2008) by the World Medical Association. I would like to thank members of the subcommittee for their efforts and the painstaking task that have been undertaken to come out with this edition. Although most of the members are new to the subcommittee, their collective experience in conducting and regulating clinical trials in Malaysia have been invaluable in coming out with this edition. It is my fervent hope that all those involved with clinical trials in Malaysia would strictly adhere to this guideline and never at any time compromise on the highest scientific and ethical standards expected of them.

Dato' Dr Hasan Abdul Rahman
Director General of Health, Malaysia
Chairman National Committee for Clinical Research

Ministry of Health
Kuala Lumpur
July 2011

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Introduction to Malaysian Guidelines for GCP

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects. It is of utmost importance that this standard is upheld at all times when research involving human are conducted. In so doing, all those who are involved in clinical trials will provide the assurance that the rights, safety and well being of the study subjects are safeguarded; in keeping with the principles that have their origin in the Declaration of Helsinki.

The objective of the Malaysian GCP Guideline is to ensure that all drug-related clinical trials conducted in Malaysia are in accordance with the highest international ethical and scientific standards while at the same time taking into consideration the national issues and local realities without compromising the standards.

This guideline should be strictly adhere to when generating clinical trial data as this will also facilitate the mutual acceptance of clinical data that are intended to be submitted to regulatory authorities.

Though primarily aimed at drug related trials for regulatory purposes, the principles established in this guideline may also be applied to other clinical investigations that have impact on the safety and well-being of human subjects.

The Malaysian Guideline for GCP should be read in tandem with the Declaration of Helsinki and the requirements of the national regulatory authority.

Since definitions in similar documents such as the ICH Guidelines on GCP from which the Malaysian Guideline for GCP is derived from may slightly differ, it is important that the reader read and understand the terminologies listed in the Glossary before proceeding to the subsequent chapters.