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Procedure Category:	General Study Procedures and Activities
Procedure CLN-06-03:	GCP/ICH Compliance

Procedure Overview

This procedure defines Good Clinical Practice (GCP) and provides a brief overview of GCP compliance from the standpoint of the U.S. Food and Drug Administration (FDA) as well as the International Conference on Harmonization (ICH).

Responsible Individuals

Investigators; Qualified MICHIR personnel (including, but not limited to, Study Coordinator, Research Assistant and Supervisory Personnel); Director, MICHIR

Procedure

Good Clinical Practice is a term which encompasses the federal regulations and industry-accepted standards that govern clinical trials conducted to support applications and subsequent amendments for approval by regulatory agencies. The regulations and standards address issues related to the conduct of the studies, record keeping, informed consent of subjects, collection of scientific data and submissions of information necessary for regulatory agencies to approve or deny a product for market.

United States regulations regarding GCP are found in Title 21 of the *Code of Federal Regulations* (CFR). The following regulations pertain to clinical investigations:

- Part 11, Electronic records and electronic signatures
- Part 50, Informed consent
- Part 54, Financial disclosure by clinical investigators
- Part 56, Institutional Review Boards (IRBs)
- Part 312, Investigational new drug (IND) applications, including the responsibilities of sponsors, monitors and investigators
- Part 314, Accelerated approval

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Approval Signature, Date:	

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- Part 601, Licensing
- Part 812, Investigational device exemption (IDE) applications, including the responsibilities of sponsors, monitors and investigators
- Part 814, Premarket approvals (PMAs) of medical devices

In addition, the FDA has issued several guidance documents pertaining to specific clinical trial issues. These include the *Guideline for the Monitoring of Clinical Investigations*, Information Sheets for IRBs and Clinical Investigators, as well as other guidance documents which outline the FDA's perspective on the activities of sponsors, CROs and investigative sites. These documents are available from the FDA at the following website: www.fda.gov/.


The International Conference on Harmonization was organized to develop tripartite harmonization initiatives with input from both regulatory and industry representatives from three regions: The European Union, Japan, and the United States. A consolidated guideline addressing Good Clinical Practice, guidelines for the Investigator's Brochure (IB), and guidelines for essential documents for the conduct of a clinical study was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies at the ICH meeting held on April 30, 1996.

The consolidated ICH guideline defines Good Clinical Practice and provides unified standards for the design, conduct, recording and reporting of trials that involve participation of human studies. In addition, the consolidated guideline describes the minimum information which should be included in an IB, as well as the purpose of essential documents in clinical studies, and whether these documents should be filed in the investigator's or the sponsor's files. An electronic version of this guideline is available at the Internet address www.fda.gov/cder under the "Regulatory Guidance" section.

Documentation

GCP compliance is documented in a sponsor's or CRO's monitoring reports as well as in audit and inspection reports from the FDA.

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Deviation Approval

The Director, MICHIR or designee, must approve deviation from this procedure. The Director, MICHIR or designee, must store documentation of the deviation approval.

Relevant Definitions

- GCP - Good Clinical Practice
- FDA - U.S. Food and Drug Administration
- ICH - International Conference on Harmonization
- IND - Investigational new drug applications
- IB - Investigator's Brochure

Procedure Author

Manager, Research Support Core

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