



**MU Guidance for Investigators When Studies Require Compliance with the International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice (GCP) (E6)(R2)**

**MU HRPP Roles and Responsibilities SOP**

The SOP states “Regulations set forth by the International Conference on Harmonization (ICH)/Good Clinical Practice are also applied to the extent required by FDA regulations.”

To further clarify this statement, MU HRPP expects MU investigators follow the guideline when required by a study protocol, but compliance will not be enforced or monitored if the guideline is not required by FDA regulations. The guidance below relates to requirements of ICH-GCP (E6)(R2) that are in addition to FDA requirements; therefore, MU investigators are responsible for ensuring study compliance.

**ICH-GCP (E6)(R2) Guidelines**

Adequate Support:

The available nonclinical and clinical information on an investigational product is adequate to support the proposed clinical trial.

Consent Disclosures Include:

1. The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the participant.
2. A statement that if the results of the trial are published, the participant’s identity will remain confidential.

Documentation of the Consent Process Include:

1. Prior to a participant’s participation in the trial, the written consent document should be signed and personally dated by the participant or by the participant's legally acceptable representative.
2. Prior to a participant’s participation in the trial, the written consent document should be signed and personally dated by the person who conducted the informed consent discussion.

3. If a participant 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.
  - a. After the written consent document and any other written information to be provided to participants is read and explained to the participant or the participant's legally acceptable representative, and after the participant or the participant's legally acceptable representative has orally consented to the participant's participation in the trial and, if capable of doing so, has signed and personally dated the consent document, the witness should sign and personally date the consent document.
  - b. By signing the consent document, the witness attests that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative, and that consent was freely given by the participant or the participant's legally acceptable representative.
  - c. Prior to participation in the trial, the participant or the participant's legally acceptable representative should receive a copy of the signed and dated written consent document and any other written information provided to the participants.

#### Employing Sound Study Design

1. During and following a participant's participation in a clinical trial, the researcher ensures that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the clinical trial.
2. The researcher follows the clinical trial's randomization procedures, if any, and ensures that the code is broken only in accordance with the protocol. If the clinical trial is blinded, the researcher promptly documents and explains to the Sponsor any premature unblinding.
3. A qualified physician (or dentist, when appropriate), who is a researcher or a co-researcher for the clinical trial, is responsible for all clinical trial-related medical (or dental) decisions.
4. Researchers inform participants when medical care is needed for other illnesses of which the researchers become aware.

#### Subject Recruitment

1. The researcher informs the participant's primary physician about the participant's participation in the clinical trial if the participant has a primary physician and if the participant agrees to the primary physician being informed.
2. Although a participant is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, the researcher makes a reasonable effort to ascertain the reason, while fully respecting the participant's rights.

## Qualifications – Training and Experience

1. The researcher is familiar with the appropriate use of the investigational product, as described in the protocol, in the current investigator's brochure, in the product information, and in other information sources provided by the sponsor.
2. A qualified physician (or dentist, when appropriate), who is a researcher or a co-researcher for the clinical trial, is responsible for all clinical trial-related medical (or dental) decisions.
3. During and following a participant's participation in a clinical trial, the researcher ensures that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the clinical trial.
4. The researcher ensures the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor.
5. The researcher permits monitoring and auditing by the sponsor and inspection by the appropriate regulatory authority.
6. The researcher maintains the clinical trial documents as specified in Essential Documents for the Conduct of a Clinical Trial and as required by the applicable regulatory requirements.

## Appropriate Oversight

The researcher must maintain a list of appropriately qualified persons to whom they have delegated significant clinical trial-related duties.

## Reporting Requirements

Upon completion of the clinical trial, the researcher informs the organization; the IRB with a summary of the trial's outcome; and the regulatory authority with any reports required.