MUSC
Medical University of South Carolina

I. Policy

A. Introduction

In 1996, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) developed "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance" [ICH GCP guidance (E6)]. This document provides a unified standard for the European Union (EU), Japan, and the United States to comply with the regulatory authorities in these countries.

B. Assessment

The MUSC IRBs comply with ICH GCP guidance (E6) only to the extent that it is compatible with FDA and DHHS regulations. GCP standards contained in the ICH GCP guidance (E6) document are not regulatory requirements in the United States.

However, selected industry-sponsored studies may require institutional adherence to ICH GCP guidance (E6) *beyond that required by FDA and DHHS.*

If the contract requirement for ICH GCP guidance (E6) is confirmed, the Associate Provost for Research and the Director of the Office of Research Integrity are notified for further review.

If the PI and sponsor attest to the requirement for ICH standards, the APR will consider approval for IRB review in compliance with the ICH-GCP guidance (E6).

II. Definitions

Definitions for the following terms used in this section may be found in HRPP Program Guide Section 1.3 Definitions of Terms:

A. Good Clinical Practice (GCP)

III. Procedures

A. Investigator Responsibilities

1. Before the contract is finalized, the Principal Investigator will meet with the Associate Provost for Research in order to appreciate fully the additional requirements that adherence to ICH GCP (E6) will entail.

2. All study team members must complete the CITI module for ICH GCP (must be current within 3 years).

3. The PI must confirm that all ICH GCP standards will be followed during the research.

4. The PI must submit to the IRB any additional materials required by ICH GCP (e.g., CV).

5. The PI will assume responsibility for reporting requirements, including termination or suspension of the research study by the PI, sponsor, or IRB (see 4.12 of ICH GCP guidance E6).

6. Additional elements will be included in the informed consent document (see 4.8 of ICH GCP guidance E6).

The ICH GCP guidance E6 lists 20 required elements for consent forms used in studies of investigational pharmaceutical agents.

Note: The ICH GCP guidance E6 required elements for consent are not a regulatory requirement in the United States. FDA regulations on consent do not require all consent elements recommended by GCP guidance.

B. IRB Responsibilities

1. When evaluating study materials, IRB reviewers will take into account the additional requirements of ICH GCP.

2. The IRB will not release approval of documents until investigators have complied with the above procedures.

C. University Compliance Responsibilities

When auditing studies that require adherence to ICH GCP, University Compliance will follow a separate IRB approved checklist for ICH GCP requirements.

IV. References

A. Guidance for Industry E6 Good Clinical Practice (ICH GCP guidance (E6)