Office of Clinical Research

Chapter 1	Clinical Trial Management	Effective:	June 20, 2008
Section 1.1	Principal Investigator	Revised:	October 8, 2018
Policy 1.1.3	**Sponsor Investigator**	Version:	3

SPONSOR INVESTIGATOR POLICY AND PROCEDURE

1. PURPOSE: To ensure Sponsor-Investigators meet the additional responsibilities they have as both the Sponsor and as the Principal Investigator as detailed in FDA Regulations 21 CFR 312 and 812. This component of the Human Research Protection Program is designed to ensure that Sponsor-Investigators meet all of their obligations under FDA regulations.

   A. Specifically these additional responsibilities include monitoring the progress of the clinical investigation. Proper monitoring is necessary to assure:

      (1) Adequate protection of the rights, safety, and welfare of research participants
      (2) The quality and integrity of the resulting data submitted to the FDA

2. POLICY:

   A. All Sponsor-Investigators are required to complete or have current the Collaborative IRB Training Initiative (CITI module(s) as listed on the Office of Clinical Research (OCR) website.

      (1) Prior to the OCR institutional activation of a new study submission in which they are the Sponsor-Investigator.
      (2) Prior to assuming the role of Sponsor-Investigator on an existing study.
      (3) If OCR determines that minimum training is not current during a routine monitoring review.

   B. Training must be renewed every three years by completing the applicable refresher course(s).

   C. All Sponsor-Investigators are required to submit a Local Sponsor-Investigator Monitoring Plan (Form Inst-H) with new study submissions. Sponsor-Investigators may be required to meet with OCR staff to discuss the specific monitoring plan for their study prior to OCR institutional activation.

3. RESPONSIBILITY:

   A. The Sponsor-Investigator will:

      (1) Complete any required training
      (2) Indicate on IRB protocol submission that they have assumed the role of Sponsor-Investigator
      (3) Review monitoring plan for the study with the OCR when required
      (4) Monitor conduct and progress of the clinical trial
      (5) Report all changes to the IND or IDE to the FDA
      (6) Provide all reports, updates, adverse events, etc., to the FDA as required
      (7) Conduct required evaluations put forth by the FDA
      (8) Adhere to reporting required by the Institutional Review Board
      (9) Maintain records of investigational product control and accountability
      (10) Ensure registration and reporting of applicable clinical trials in clinicaltrials.gov

B. The OCR will review the local Sponsor-Investigator Monitoring Plan and provide institutional activation only after ensuring an adequate monitoring plan is in place.

C. Any additional monitoring will be conducted as indicated in the Quality Assurance & Improvement Program Policy.