VA NORTHEAST OHIO HEALTHCARE SYSTEM (VANEOHS)
Medical Research Service
Standard Operating Policy and Procedure (SOP)

Effective Date: June 2, 2022

SOP Title: Sponsor Protocol Deviation Reporting - Device

SOP Number: Human Researchers – HSP-024

SOP Version: .02

1. Purpose.

To provide a procedure for the accurate and timely reporting of protocol deviations from the Sponsor Louis Stokes Cleveland VA Medical Center and/or its designee(s) to oversight bodies for the evaluation of those deviations.

2. Policy.

Applies to all regulatory, nursing, quality assurance (QA), and research coordination staff involved in reporting of deviations on studies sponsored by Louis Stokes Cleveland VA Medical Center and/or its designee(s).

3. Definition/Background.

Department of Health and Human Services (DHHS) and other Federal regulations require that institutions develop written policies and procedures for handling reports of noncompliance with the regulations, requirements of the protocol, IRB or Sponsor Louis Stokes Cleveland VA Medical Center and/or its designees. Investigational sites, if applicable, will report protocol deviations to the Sponsor and/or its designee(s).

4. Responsibility.

In accordance with:
Good Clinical Practices
21 CFR 312 & 812 Sponsor Responsibilities
Personnel responsible: Sponsor named regulatory, QA and designated monitors.

5. Procedure.

1. The principal investigator is responsible for reporting all protocol deviations related to a clinical study to the Sponsor and/or its designee. All enrollment

deviations should be reported as soon as possible but no later than five working days from the day the investigator becomes aware of the event (whichever occurs first). Other deviations may be reported on the appropriate CRF and collected at monitoring visits.

2. Information reported should include the facts of the case, including the date of deviation, impact on the subject's safety, and plan for preventing the deviation in the future (if applicable).
3. Upon receipt of a protocol deviation report, the Sponsor and/or its designee will log the report into the database or files for the study and send a copy of the report to the Office of the ACOS (Associate Chief of Staff) for Research for review. Sponsor and/or its designee may choose to initiate a corrective action plan as a result of the deviation.
4. All protocol deviations involving emergency use or those that affect the safety of the subject will be reported to the reviewing IRB and/or FDA (if appropriate), and to appropriate regulatory affairs staff (by the Sponsor designee(s) and/or investigators).
5. The Sponsor Louis Stokes Cleveland VA Medical Center and/or its designees will determine if additional actions and/or follow-up need(s) to be taken upon review of any deviation report. Additional actions might include:
    a. Seeking additional information from the investigator.
    b. Discussion of protocol compliance with the principal investigator.
    c. Audit of investigator's site by the Sponsor or its designee.
    d. Increase in the frequency of monitoring period for the study.
    e. Retraining of participating study staff.
    f. Suspension or termination of the study.
6. A copy of all correspondence and any reports will be kept in the designated research files for the study.

6. Reference.

IDE Reports | FDA

7. Rescission.

Sponsor Protocol Deviation Reporting – Device dated January 1, 2011 was rescinded. Review date for this policy is June 1, 2025

8. Follow up Responsibility.

Investigator(s)/co-investigator(s) and, when delegated by the investigator(s) with permission of the Sponsor, also sub-investigator(s) and clinical research staff. Designated individuals who monitor sites and those named as responsible for performing quality assurance (QA), monitoring, research coordination, and regulatory affairs by the sponsor, Louis Stokes Cleveland VA Medical Center.