

**RESEARCH COMPLIANCE PROGRAM STANDARDING OPERATING PROCEDURE
(SOP) INCREASED MONITORING**

1. **PURPOSE:** Provide a formal plan for human subject research protocols that require increased monitoring.
2. **POLICY:** The requirement to increase the frequency of audits or to audit specific aspects of the study can be based on such considerations as: Involvement of vulnerable populations, level of risk, involvement of FDA approved drugs for which there has been a safety warning, or change in the labeling that indicates increased risks, previous issues of noncompliance, or data breaches.
3. **ACTION:** Request to impose additional monitoring on a research protocol can come from one or more of the following: UTHSCSA IRB, STVHCS R&DC, ACOS/R, Medical Center Director, and Research Compliance Officer.

a. Formal correspondence will be sent to the Principal Investigator regarding the decision to apply more frequent monitoring to a specific research protocol. This memorandum will include, but is not limited to the following:

- (1) Rationale for increasing the auditing activities of a research protocol.
- (2) A schedule of how often monitoring will occur.
- (3) Relevant contact information.
- (4) Documents, logs, and/or files that will need to be available.
- (5) Milestones to be met to facilitate a decrease in the monitoring activity.

b. **RCO Responsibilities:**

(1) Once formal correspondence has been sent to the PI, the RCO will follow up to create a notification plan, schedule appointment(s), and request relevant study materials to begin the additional auditing.

(2) The RCO will be responsible to carry out all auditing as outlined in the formal correspondence to the PI.

(3) The RCO is responsible for providing progress reports to all relevant committees, subcommittees, ACOS/R and Medical Center Director.

(4) The initiating oversight committee will be responsible to review the reports provided by the RCO and determine when it is appropriate to decrease or discontinue the additional auditing activities.

4. **REFERENCES:** VHA Handbook 1200.05
5. **RESPONSIBILITY:** Research Compliance Officer (003C)
6. **RESCISSIONS:** Research Compliance Program Standard Operating Procedures (SOP), dated January 14, 2011
7. **RECERTIFICATION:** July 2018

A handwritten signature in black ink, appearing to read "Celeste Burton". The signature is fluid and cursive, with the first name "Celeste" written in a larger, more prominent script than the last name "Burton".

Celeste Burton, MSA
Research Compliance Officer