



## **I. Policy**

### **A. Introduction**

This section details the policy and procedures established at MUSC for evaluating IRB-Approved research for possible suspension or termination to comply with the regulatory requirements in 45 CFR 46.103(b)(5)(ii) and 21 CFR 56.108(b)(3) requiring IRBs to have written procedures ensuring prompt reporting to the IRB, appropriate institutional officials, Office for Human Research Protections, and, when applicable, the Food and Drug Administration (FDA), any suspension or termination of IRB approval.

**B.** MUSC grants the IRB authority to suspend, or terminate approval of human research that is not being conducted in accordance with regulatory requirements of the IRB, institution, state and federal agencies. Such actions may be based on IRB determination of unanticipated problems involving risk to participants, study staff or others. Study termination may also occur for serious or continuing non-compliance or other findings arising from continuing reviews, information from medical literature and/or subject complaints or if the research has been associated with unexpected serious harm to participants.

**C.** Suspension or termination of IRB approval will generally be determined by a convened IRB. Under emergency circumstances, a board Chair, Vice-Chair or ORI director may immediately suspend a human research protocol. At the next convened IRB meeting, the matter will be reviewed by full board. Actions which the board may take include:

1. lifting the suspension,
2. continuing the suspension or
3. terminating the study.

**D. Suspensions and terminations do not include:**

**Interruptions in research resulting solely from the expiration of a protocol approval period.**

## **E. Memorandum of Understanding**

In aspects where the MUSC IRB is being utilized by the Ralph H. Johnson VA Medical Center, both parties will abide by the agreements set forth in the current "Memorandum of Understanding Between The Ralph H. Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina's Institutional Review Boards".

## **II. Definitions**

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

- A. Sponsored-Imposed Hold**
- B. Suspension of IRB Approval**
- C. Termination of IRB Approval**

## **III. Procedures**

- A.** In circumstances of major concern and with sufficient evidence, the IRB will notify the investigator of the suspension or termination of the human research protocol, possible remediation and of the time and date of the next convened IRB meeting where the protocol will be discussed.
- B.** On occasion, a sponsor may notify the PI of intent to suspend a study. Such sponsor-imposed holds may be made for interim data analysis; inadequate drug availability; response to DSMB report/recommendation; or a pre-planned stopping point, as well as for changes in the potential risk-benefit ratio for participants.
- C.** Following determination of sponsor-imposed hold, suspension or termination, the IRB will take the following actions:
  - 1. ensure that current subjects are notified of the hold, suspension or termination of the study through communication which receive IRB approval;
  - 2. ensure that procedures for withdrawal of enrolled subjects consider the rights and welfare of the subjects, making arrangements for clinical medical care, and/or transfer to another investigator for continued research treatment;
  - 3. ensure the method of informing current participants of the hold, suspension or termination is appropriate to the circumstances (in person contact, telephone call, email, or letter);

4. ensure that subjects are informed of any follow-up procedures permitted or required by the IRB;
5. ensure that any reportable adverse events/unanticipated problems involving risks to subjects or others are reported to the IRB and the sponsor when follow-up of subjects is permitted or required by the IRB and
6. for suspensions or terminations of VA research, the IRB will report the suspension or termination to the local VA facility.

#### **D. Reporting Requirements**

1. **Whenever the IRB suspends or terminates a research protocol,** the IRB Chair will submit a written report to the Organizational Official(s) copied to the Principal Investigator within 10 working days after review of the event by the convened Board. This report will include:
  - a) title of the study;
  - b) the name of the Principal Investigator;
  - c) number assigned by the IRB and any numbers assigned by another agency/sponsor;
  - d) the IND or IDE number if applicable;
  - e) the nature of the event; and
  - f) the findings of the IRB; actions taken by the PI, and/or the IRB to address the issue.
2. The Organizational Official(s) will review the action and discuss the report with the IRB chair and the Director of the Office of Research Integrity. The Organizational Official will notify OHRP, the FDA if appropriate, the sponsor, and other agency officials as appropriate within 30 working days of receiving the Chair's report.
3. If the research study is a VA protocol, any termination or suspension of research (e.g., by the IRB or other research review committee, or by the Associate Chief of Staff for Research or other VA facility official) related to concerns about the safety, rights, or welfare of human research subjects, research staff, or others, must be reported in writing within five business days after the termination or suspension occurs to
  - a) the Associate Chief of Staff/Research & Development,

- b) the Medical Center Director (responsible for reporting to the Office of Research and Development, The Regional Office of Research Oversight and, if the report involves violations of information security requirements, the Information Security Officer),
- c) the Research and Development Committee,
- d) other relevant research review committees, and
- e) the VA Privacy Office (when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information). VA policy for reporting to the VA Office of Research Oversight will be followed.

### III. References

- A. [45 CFR 46](#)
- B. [21 CFR 56](#)