



## **I. Policy**

### **A. Introduction**

The purpose of this policy is to define the policies and procedures of MUSC for addressing allegations and findings of non-compliance with HRPP requirements.

### **B. Guidance on Additional Requirements of Federal Funding Agencies**

Please note that protocols conducted by MUSC and sponsored by any of the following federal agencies

- the Department of Defense (DOD),
- Department of Education,
- Department of Energy,
- Department of Justice (DOJ) / National Institute of Justice (NIJ) and Bureau of Prisons (BOP) or
- Environmental Protection Agency (EPA)

have additional operational and review requirements. In addition, protocols following the International Committee on Harmonisation – Good Clinical Practices (ICH-GHP) have additional requirements. Further information available on the [MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>](http://research.musc.edu/ori/irb/resources.html) ).

**C.** Investigators, research staff or anyone with allegations of non-compliance or continuing non-compliance regarding human subjects research will report allegations to the IRB or University Compliance Office.

**D.** In a convened meeting, the IRB will discuss the non-compliance, with reference to all study materials including the protocol and informed consent documents, and decide if the non-compliance is 1) non-serious and/or non-continuing or 2) serious and/or continuing.

**E.** In situations of non-compliance determined to be neither serious or continuing, the IRB may:

1. issue a letter of guidance/reprimand to the investigator that is copied to the appropriate chair, division director or dean;

2. request the investigator appear at a convened meeting to answer questions of non-compliance;
  3. request the investigator perform a quarterly or semi-annual self-audit of the research study activities and report the findings to the board;
  4. request the investigator and/or research staff complete additional HRPP training;
  5. request that the university compliance office perform an audit of the study protocol and associated activities and provide a written report to the IRB , and/or
  6. initiate any other measures deemed appropriate by the IRB.
- F.** The IRB will report any instance of serious or continuing noncompliance with federal or state regulations governing the protection of human subjects, VHA 1200.05 (for VA protocols) and IRB requirements to the Director, Office of Research Integrity and the Organizational Officials(s) [21 CFR 56.108(b); 45 CFR 46.103(b)(5)].
- G.** The IRB Chair will notify the ORI Director and Organizational Officials(s) within 24 hours if a research study is suspended due to an issue of serious or continuing noncompliance; followed by a written report within 10 working days after review of the event by the convened Board.
- H.** The Organizational Official(s) 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 regarding serious or continuing noncompliance, including those occurrences resulting in IRB suspension/termination of research.
- I. 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 may be found in the HRPP Program Guide Section 1.3 – Definitions of Terms

### **A. Allegation of Non-Compliance**

**B. Continuing Non-Compliance**

**C. Non-Compliance**

**D. Serious Non-Compliance**

**III. Procedures**

- A.** Investigators, research staff or anyone with allegations of non-compliance or continuing non-compliance regarding human subjects research will report allegations to the IRB or University Compliance Office.
- B.** The allegation report should include 1) Study Title, 2) HR#, 3) Name of the Principal Investigator, 4) Description of the alleged non-compliance, 5) timeframe, 6) other individuals involved, 7) other relevant information.
- C.** An allegation, concern, or issue of noncompliance initially will be reviewed by the IRB Program Manager and IRB Chair.
- D.** The IRB Program Manger and the IRB Chair will conduct a preliminary investigation to determine the nature of the noncompliance including interviewing the individuals involved in the allegation, concern or issue.
- E.** If the preliminary investigation determines no basis of fact (i.e., there are no documents or statements supporting the allegation) of non-compliance, the IRB Program Manager and the IRB Chair will present the case to the convened IRB for review. The convened IRB may dismiss the allegations as unjustified and take no further action.
- F.** If the preliminary investigation finds serious evidence (i.e., there are supporting documents or statements) of non-compliance, the IRB Program Manager and the IRB Chair will decide if the nature of the non-compliance warrants immediate suspension of protocol enrollment/participation or other immediate corrective actions.
- G.** The IRB Chair or their designee will contact the principal investigator responsible for the protocol(s) involved in the issue of noncompliance. If the protocol(s) is suspended to enrollment or continued participation of current subjects, the IRB chair will write a letter to the principal investigator stating the scope of this suspension, the reason for the suspension, and actions that should be taken to protect currently enrolled subjects.
- H.** The IRB Chair and IRB Program Manager will conduct a full investigation of alleged noncompliance including requesting the University Compliance Office to conduct an audit of the protocol(s). As part of this investigation, the IRB Program Manager and the IRB Chair will determine if subjects were harmed and if subjects were notified of the non-compliance.

- I. All findings will be reported to the Board at the next scheduled meeting. The Board will be provided with written documents used in the investigation. These documents may include an audit report, e-mail correspondence, letters between the IRB and the Principal Investigator. The investigator involved in the allegation of non-compliance will be invited to attend the Board meeting when appropriate.
  
- J. If the Board decides the evidence supports the determination of “serious” or “continuing” noncompliance, the Board will determine corrective actions which may include:
  - 1. suspension or termination of a particular protocol,
  - 2. suspension of the investigator’s privilege to conduct human subject research with the requirements necessary for the privilege to be reinstated identified,
  - 3. notification of current participants (required when such information might related to participants’ willingness to continue to take part in research),
  - 4. the requirement that no data collected during the research in question may be used for publication, and/or
  - 5. random audits of other research studies to detect if a pattern is present.

The Board may also decide to implement additional corrective actions such as:

- 1. modification of the research protocol,
  - 2. modification of the information disclosed during the consent process,
  - 3. additional information provided to past participants,
  - 4. requirement that current participants re-consent to participation,
  - 5. modification of the continuing review schedule,
  - 6. monitoring of the research, and/or
  - 7. monitoring of the consent process.
  
- K. The Chair will prepare a letter for the Organizational Official(s) copied to the principal investigator that will include:
  - 1. the name of the institution,

2. title of the research study,
3. the name of the principal investigator,
4. number assigned by the IRB and any numbers assigned by another agency/sponsor,
5. the IND or IDE number if applicable,
6. a detailed description of the noncompliance, and
7. actions the IRB has taken relative to the issue.

**L. VA Research**

1. Within five business days of becoming aware of any apparent or possible serious or continuing non-compliance, members of the VA research community are required to ensure that the apparent non-compliance has been reported in writing to the IRB.
2. Within five business days of identifying apparent serious or continuing non-compliance based on a consent document audit, regulatory audit, or other systematic audit of VA research, the IRB chair, or designee must provide a written report of the apparent non-compliance directly (without intermediaries) to:
  - a) Medical Center Director,
  - b) Associate Chief of Staff for Research and
  - c) The Research and Development Committee.
3. The IRB must review a report of apparent serious or continuing non-compliance at its next convened meeting.
4. Should the IRB determine that the reported incident constitutes serious non-compliance or continuing non-compliance, within five business days after the determination, the IRB chair, or designee must provide a written report of the determination directly to the following individuals or committees at the Ralph H. Johnson VAMC:
  - a) Medical Center Director,
  - b) Associate Chief of Staff for Research,
  - c) The Research and Development Committee
  - d) Other relevant research review committee.

5. An initial report of an IRB determination that serious non-compliance or continuing non-compliance occurred is required, even where the determination is preliminary or disposition of the matter has not been resolved at the time of the report.
6. The IRB must research a determination that serious or continuing non-compliance did (or did not) occur within 30-45 days after receiving a report of apparent non-compliance.
7. Remedial actions involving a specific study or research team must be completed within 90-120 days after the IRB's determination.
8. Remedial actions involving programmatic non-compliance must be completed within 120-180 days after the IRB's determination, unless remediation requires substantial renovation, fiscal expenditure, hiring, or legal negotiations.
9. Members of the VA research community must report possible serious or continuing non-compliance with VA or other federal requirements related to human research or with IRB requirements or determinations to the Associate Chief of Staff for Research and Development and the IRB within five business days after becoming aware of it.