



I. Policy

A. Introduction

All significant subject complaints, issues and concerns are to be reported by the Principal Investigator to the IRB within five working days of becoming aware of a subject's complaint, issue or concern.

B. IRB Obligations

The IRB is obligated to receive and respond to all human research related complaints, issues, and concerns regardless of the source. In addition to any complaints or concerns, any suggestions for improvement or compliments should be noted and communicated to the Director of the Office of Research Integrity for incorporation into our quality improvement operation.

II. Definitions

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

A. Significant complaints, issues or concerns

III. Procedures

A. The Principal Investigator should report any complaint/issue/concern about the conduct of human research in writing. This report should include:

1. The name and the HR / PRO number of the protocol;
2. A complete description of the complaint/issue/concern;
3. Actions taken to resolve the complaint/issue/concern; and
4. Actions requested by the individual sharing the complaint, issue/concern.

- B.** Complaints/issues/concerns may be communicated directly to the IRB by telephone, US mail, e-mail, or the MUSC Compliance Hotline. The IRB Program Manager or Administrators will initially process all complaints.
- C.** The IRB chairs in consultation with the IRB Administrators and MUSC Legal Counsel and MUSC Risk Management Office, as appropriate, will determine what actions will be taken to investigate the complaint/concern/issue in preparation for review by the convened Board. If the report of the complaint/issue/concern is made to the IRB by a person other than the Principal Investigator, the Principal Investigator will be notified of the complaint/issue/concern and asked to submit a written report regarding the incident when appropriate. The name of the individual reporting the complaint/issue/concern will not be released unless the individual has given permission and it is pertinent to the investigation and resolution.
- D.** The Board will work with the Principal Investigator to determine the resolution of the complaint/issue/concern and the actions to be implemented to prevent similar incidents. The Board will determine if the complaint/concern/issue represents an unanticipated problem, a protocol violation or investigator noncompliance. The Board's discussion and decisions will be recorded in the meeting's Minutes.
- E.** Upon resolution, as expeditiously as possible, the IRB Chair or senior IRB administrator to the specific IRB will contact (by phone or email) the subject to discuss the resolution of the concern and elicit any additional relevant information the subject may have to offer. This will be followed by a formal communication to the subject and, if appropriate, a follow-up phone call.
- F.** If appropriate, a copy of the formal communication will be filed in the research folder.

III. References