1.0 Purpose

The purpose of this policy is to establish procedures for handling allegations and findings of noncompliance.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the Health Sciences Institutional Review Board.

Collected Rules - 420.010 Research Dishonesty

http://www.umsystem.edu/ums/departments/gc/rules/research/420/010.shtml

3.0 Policy/Procedure

In order to demonstrate appropriate oversight of research activities and to comply with federal and state statutes, regulations, policies and guidelines; and applicable University policies and procedures, all findings and allegations of research non compliance will be investigated and
resolved. Findings and allegations of noncompliance will be directed to the appropriate IRB staff and to the IRB for investigation and corrective action. When allegations of noncompliance cannot be resolved informally, the chair and the Board have the authority to investigate and take appropriate action to ensure compliance or to terminate the research.

IRB Procedures

Receiving Reports of Allegations and Findings Noncompliance

Reports of noncompliance may be provided to the IRB Chair, IRB members, IRB Staff, or Research Compliance Office from anyone inside or outside of the University Community who has reason to believe that the noncompliance with the IRB Policies and procedures has occurred. These complaints will be accepted verbally or in writing.

The research staff is required to report allegations and findings of noncompliance to the IRB.

Allegations of Noncompliance

Investigation

The Compliance Officer and if necessary, the Chair will investigate the allegation upon notification of the alleged noncompliance. The matter will be reported to the full IRB at its next scheduled meeting.

Investigator

The investigator will be contacted via telephone or e-mail by the Compliance Officer to discuss the allegation of noncompliance. The Compliance Officer will begin the investigation at this time.

Administrative Review

The Administrative review is designed to determine whether the allegations of research noncompliance can be substantiated. An Administrative review is initiated when an allegation is received from an individual; it is deemed by the Office of Research or the chair of the IRB that a review is necessary, or when informal or formal monitoring activities reveal potential research noncompliance.

Administrative Reviews are conducted by the IRB Compliance Officer and if necessary the Chair. An Administrative Review may include: review of files, literature, and documents from the Investigator and others, which could serve to validate or dismiss the allegation.

If the allegation of noncompliance involves VA research the HS IRB Compliance Officer and the VA R&D Human Research Compliance Officer will interact to determine whether the allegations of research noncompliance can be substantiated and which entity should take the lead in the investigation of the issue. The resolution of the issue will be discussed between all applicable parties.

Determinations
Possible outcomes of an Administrative Review are:

- Determine that the allegation of noncompliance has no basis in fact.
- Determine that the allegation of noncompliance is substantiated.

Noncompliance
If the allegation of noncompliance is determined to have no basis in fact, no other actions are taken.

The IRB staff will communicate the results of an Administrative Review in writing to the Investigator (with a copy to the IRB chair) at the conclusion of the review. This communication will either; notify the Investigator that the allegation of noncompliance was determined to have no basis in fact or was substantiated. The investigator will be asked to respond in writing to the determination. The investigator will have 14 days to respond. If the investigator needs more time, an extension may be requested from the IRB Chair in writing. The written response will be presented to the full board at a convened meeting for review.

At a convened IRB meeting the Compliance Officer and Chair will present the issue to the IRB. All IRB members will receive, the investigation report, synopses of any communication between the investigators and the investigator, the last approved IRB application or continuing review, the approved consent, protocol and any other pertinent information. All members attending the IRB meeting will review all the documents and:

- Determine that the allegation of noncompliance has no basis in fact.
- Confirm that the allegation of noncompliance is substantiated.
- Request more information defer to future meeting pending receipt of additional information

If the IRB determines that the allegation of noncompliance to have no basis in fact, no other actions are taken.

If the IRB determines that all allegation of noncompliance is substantiated, it is referred back the Compliance Officer to be handled as a finding of noncompliance.

Findings of Noncompliance

Investigation

The Compliance Officer and if necessary, the Chair will investigate the noncompliance upon notification.

Investigator

If not already aware of the finding of noncompliance, the Research Compliance Officer will notify investigator will be contacted via telephone or e-mail to discuss the finding of noncompliance. The Compliance Officer will begin the investigation at this time.

Administrative Review
The Administrative review is implemented if there is a need to gather more information about the extent or nature of the noncompliance to determine whether the noncompliance is serious or continuing.

Administrative Reviews are conducted by the IRB Compliance Officer and if necessary the Chair. An Administrative Review may include: review of files, literature, and documents from the Investigator and others, which could serve to determine whether the noncompliance is serious or continuing.

If the finding of noncompliance involves VA research the HS IRB Compliance Officer and the VA R&D Human Research Compliance Officer will interact to determine the extent of the noncompliance and which entity should take the lead in the investigation of the issue. The resolution of the issue will be discussed between all applicable parties.

Not serious and not continuing: If it is determined by the Compliance Officer and Chair that the finding of noncompliance is not serious and not continuing, the investigator will be notified by the Compliance Officer or Chair. In addition, the Compliance Officer or Chair will discuss the issue with the investigator and an action plan will be drafted. The final action plan will be forwarded to the investigator via letter or e-mail and the information will be included in the IRB agenda as an information item.

Noncompliance that may be Serious or continuing: The investigator will be notified by the Compliance Officer or the Chair, of the findings or requests for information by phone call, letter or e-mail. The investigator will be asked to respond in writing to the finding of noncompliance and depending on the response, the investigator may be asked by the Compliance Officer or Chair to attend the IRB meeting or a meeting with the IRB Chair.

Board Review

Review of Findings of Noncompliance by the IRB Committee: All incidences of noncompliance that cannot be determined to be neither Serious nor Continuing will be presented to the IRB and the IRB votes to determine whether the noncompliance was serious or continuing (or defers the decision to a future meeting pending receipt of additional information), and that the results of the vote are documented in the minutes.

At a convened IRB meeting the Compliance Officer and Chair will present the issue to the IRB. All IRB members will receive, the investigation report, synopses of any communication between the investigators and the investigator, the last approved IRB application or continuing review, the approved consent, protocol and any other pertinent information. All members attending the IRB meeting will review all the documents and determine:

- There is no issue of serious and continuing non-compliance
- There is serious and continuing non-compliance
- More information is needed and determination is deferred to future meeting pending receipt of additional information

The IRB reserves the right to request any appropriate additional consultation and expertise to resolve non-compliance.

If the investigator offers a timely and satisfactory explanation for the concern and a plan to
eliminate future incidents of such noncompliance, and the IRB accepts the explanation and plan, the IRB may elect to terminate the noncompliance investigation process and report that the noncompliance issue was satisfactorily resolved with no further action.

If the corrective action plan calls for any changes to the previously approved research an amendment form must be submitted and if the change involves more than minor modifications the modification must be reviewed by the convened IRB. If the change is only a minor modification the change can be reviewed by expedited review.

If the Investigator does not provide a timely response, or offers an unsatisfactory explanation or corrective action plan, the IRB may ask the investigator to meet with the chair or attend an IRB meeting to discuss the issue.

*NOTE: During the investigation, the IRB may impose restrictions to the research study until satisfactory answers are received by the IRB.

**The IRB considers the following actions:**

1. No action  
2. Administrative Hold (in accordance with SOP on Suspension and Termination of IRB approval)  
3. Suspension: Suspend enrollment or all research procedures for the specific research study in question; (in accordance with SOP on Suspension and Termination of IRB approval)  
4. Termination of the research; (in accordance with SOP on Suspension and Termination of IRB approval)  
4. Require a response from the investigator with a plan for corrective action;  
5. Initiate audits of all or some part of the Investigator's active protocols;  
6. Modification of the research protocol;  
7. Modification of the information disclosed during the consent process;  
8. Additional information provided to past participants;  
9. Modification of the continuing review schedule;  
10. Obtain more information pending final decision;  
11. Conference with other IRB’s involved with the research  
12. Requirement that current participants re-consent to participation;  
13. Provide information to current participants whenever such information might relate to the participant's willingness to continue to part in the research.  
14. Monitoring of the research  
15. Monitoring of the consent process

The results of an IRB Review will be communicated by the IRB chair in writing to the Investigator (with a copy to the appropriate protocol file). This communication will either: notify the Investigator whether the IRB determined the noncompliance to be serious or continuing and the actions of the IRB.

**Reporting**

All cases of non-compliance which the IRB determines to be serious or continuing noncompliance will be reported according to the SOP on Reporting.