PROCEDURES FOR INVESTIGATING ALLEGATIONS OF NON-COMPLIANCE

All investigations conducted under this policy shall be handled confidentially and all proceedings and records of any investigation shall be confidential to the extent allowed by law.

Allegations of non-compliance may be reported to the:
- Human Research Protection Program (HRPP)
- Institutional Review Board (IRB)
- IRB Chair
- Director of UC Office of Research Integrity (UCORI)
- Institutional Official
- Office of General Counsel
- Compliance Hotline

INITIAL REVIEW OF NON-COMPLIANCE ALLEGATION

The Director of UCORI, the HRPP Director, a representative from the Office of the General Counsel, and the IRB Chair will initially review all allegations of non-compliance to determine the validity of the allegation. If the allegations involve studies at the Veterans Affairs Medical Center (VAMC), that VAMC’s Research Compliance Officer (RCO) will also participate in review of the allegations.

If the alleged non-compliance occurred at an affiliated non UC site, the UCORI Director will notify the appropriate administrative authority at the external site in writing, detailing the alleged non-compliance. The UC HRPP will conduct an investigation as described below in cooperation with any investigation conducted by the external site.

If it is determined that an allegation has no basis in fact, the Director of UCORI will notify all involved parties as appropriate.

If it is determined that an allegation cannot be investigated adequately, the Director of UCORI will attempt to obtain additional information on the allegations. If it is determined an allegation is actually an unanticipated problem involving risks to participants or others, the matter will be handled either as an instance of noncompliance under this policy or under HRPP Policy II.02 Reporting to the IRB Unanticipated Problems. If it is determined an allegation has a basis in fact a preliminary investigation will be conducted as described below.
The Director of UCORI will notify the following of the determination of the initial review of the allegations:

- IRB
- Institutional Official
- If the alleged non-compliance is associated with a specific protocol, the Principal Investigator (PI) of the study and the PI’s Department Head
- If the non-compliance is not associated with a specific protocol, the Department Head of the department in which the alleged non-compliance occurred.

If the allegation of non-compliance involves studies at a VAMC a PI from one of these facilities, the information must be reported to the respective facility Director within 5 business days, with copies to the VAMC Associate Chief of Staff for Research, VAMC Research and Development Committee, the respective facility’s Research Compliance Officer, and any other relevant research review committees.

The VAMC facility Director will report information regarding the allegation to the appropriate Veterans Affairs (VA) Office of Research Oversight regional office, with a simultaneous copy to the Veterans Integrated Service Network (VISN) Director and the Veterans Health Administration (VHA) Office of Research and Development (ORD) within 5 business days after receiving such notification, unless the noncompliance was already reported based on Research Compliance Officer audit findings.

For studies at any of three VAMC facilities listed above, within 1 hour of becoming aware of any situation that involves the unauthorized use, disclosure, transmission, removal, theft, loss or destruction of VAMC research-related protected health information (PHI), individually identifiable private information, or confidential information, members of the research community must be report the situation to the Associate Chief of Staff (ACOS) for Research, the facility’s Information Security Officer, the facility’s Privacy Officer, and the facility’s Research Compliance Officer.

The VAMC Principal Investigator, study Sponsor, or appropriate VAMC facility official may initiate voluntary interruption of research enrollments and ongoing research activities only if the hold does NOT apply to interruptions related to concerns regarding the safety, rights, or welfare of human research subjects, research investigators, research staff or others, or used in an effort to avoid reporting deficiencies or circumstances addressed in VA Handbook 1058.01 (e.g. non-compliance).

In any case in which the initial review of an allegation reveals a likelihood of immediate injury to the health or well-being of a participant in human research, an employee or student of the
university, or a member of the public, the IRB Chair, in consultation with the HRPP Director and the Institutional Official, shall promptly take such steps as shall be reasonably necessary to eliminate such danger, up to and including: suspension or termination of the research in accordance with Human Research Protection Program Procedure 322–Suspensions and Terminations of IRB Approved Research.

PRELIMINARY INVESTIGATION

The IRB Chair will lead the preliminary investigation. The IRB Chair will form a Preliminary Investigation Committee to conduct the preliminary investigation. In any instance when the IRB Chair is not available or is implicated in the alleged non-compliance or has any other conflict of interest, the Director of UCORI shall direct the investigation.

The Preliminary Investigation Committee will be comprised of the following:

- the IRB Chair (or designee)
- the Director of UCORI (or designee)
- an IRB Vice Chair
- a representative of the Office of General Counsel
- HRPP Director (or designee)
- VAMC Research Compliance Officer (if non-compliance involves VAMC)

No person implicated in the alleged non-compliance or having any other conflict of interest relating to the investigation may serve on the committee.

The PI of the study or the Department Head in which the alleged non-compliance occurred will make available all relevant records and provide reasonable access to members of the research staff who may have information about the events surrounding the allegations of non-compliance.

The results of the preliminary investigation shall include a determination as to whether substantial credible evidence exists to support a finding of non-compliance, and if so, whether the non-compliance may be serious or continuing.

The IRB Chair will provide the results of the preliminary investigation to the following within seven (7) business days of the determination:

- IRB
- UCORI Director
- Institutional Official
- If alleged non-compliance is associated with a specific protocol, the study’s Principal Investigator and the PI’s Department Head
If the alleged non-compliance is not associated with a specific protocol, the Head of the department in which the alleged non-compliance occurred.

If the alleged non-compliance, involves studies at the VAMC or a VAMC PI, the results of the preliminary investigation regarding the credibility of the evidence must be reported to the respective facility Director within 5 business days, with copies to the VAMC Associate Chief of Staff for Research, VAMC Research and Development Committee, the respective facility’s Research Compliance Officer, and any other relevant research review committees. This preliminary report shall include a determination as to whether substantial credible evidence exists to support a finding of non-compliance, and if so, whether the non-compliance may be serious or continuing. The VAMC facility Director must report the preliminary investigation evidence to the appropriate VA ORO regional office, with a simultaneous copy to the VISN Director and the VHA ORD within 5 business days after receiving such notification if monthly reports with updates regarding the case were not already being sent to these offices and individuals. Once a case is opened with the ORO regional office, new information is provided to these offices in monthly reports.

In any case in which a preliminary investigation concludes that credible evidence supports a finding of serious or continuing non-compliance, a full investigation will be conducted as provided below.

In any case in which a preliminary investigation concludes there is no credible evidence to support a finding non-compliance, the Director of UCORI will notify all involved parties.

In any case in which a preliminary investigation concludes there is credible evidence to support a finding of non-compliance that is not serious or continuing, the IRB Chair (or designee) will take appropriate actions to limit reoccurrence of the non-compliance.

If the preliminary investigation concludes there is credible evidence of a violation of the university policy on misconduct in scientific research, the report shall so state, and the Institutional Official shall refer the matter to the Research Integrity Officer who shall take any action set forth in University Rule 10-17-05 Conduct and ethics: Policy for investigation of research misconduct.

In any case in which a preliminary investigation reveals a likelihood of immediate injury to the health or well-being of a participant in human research, an employee or student of the university, or a member of the public, the IRB, in consultation with the Director of UCORI and the Institutional Official, shall promptly take such steps as shall be reasonably necessary to eliminate such danger, up to and including: suspension or termination of the research in accordance with IRB Procedure 322 Suspensions and Terminations of IRB Approved Research.
FULL INVESTIGATION

The Director of UCORI shall convene a Full Investigation Committee, which shall consist of at least:

- Director of UCORI (or designee)
- The IRB Chair (or designee)
- An IRB Vice Chair
- A non-affiliated IRB member
- An affiliated IRB member
- One representative from the Office of General Counsel
- The HRPP Director (or designee)
- VAMC RCO – If non-compliance involves the VAMC.

No person implicated in the alleged non-compliance nor having any other conflict of interest relating to the investigation may serve on the committee.

The Full Investigation Committee shall review all relevant records and provide an opportunity for the PI of the study in which the alleged non-compliance occurred or the Department Head of the department in which the alleged non-compliance occurred to provide information concerning the allegations. The PI or Department Head will make available all relevant records and will provide reasonable access to members of the research staff who may have information about the events surrounding the allegations of non-compliance.

The PI or Department Head will be provided the opportunity to appear before the Full Investigation Committee to provide information and/or answer questions.

The Full Investigation Committee shall complete its investigation with all due speed given the complexity of the investigation.

If the determination of non-compliance involves studies VAMC facilities, or a PI from one of these facilities, the IRB must reach a determination that serious or continuing noncompliance did or did not occur within 45 days of receiving a report of apparent noncompliance, and consultation with the applicable VA ORO should be sought if it is anticipated that additional time may be needed due to the complexity or unusual circumstances of the case.

The Full Investigation Committee may extend its investigation to other research related to the study under investigation if it determines that there is a reason to believe that such an extension may find related instances of non-compliance.
Upon completion of its investigation, the Director of UCORI shall prepare a written report and recommendations which shall be provided to the IRB, with a copy provided to the Institutional Official in accordance with Policy VII.02, “Reporting of Unanticipated Problems, Non-Compliance, Suspensions and Terminations to the Appropriate Institutional Officials, Departments and Agencies.”

The report shall include:

- A description of the event being investigated and all facts upon which the recommended action was based
- A listing or description of the documents reviewed, personnel interviewed, and other sources of information upon which the Full Investigation Committee relied in preparing its report
- A finding as to whether serious or continuing non-compliance has occurred, including a specific, detailed summary of the circumstances of such non-compliance;
- Any further investigation, monitoring, or other action deemed appropriate.

In addition to the report, the IRB will be provided with copies of all documents relevant to the investigation upon which the preliminary Investigation Committee relied on in preparing its report.

The IRB Chair will present the Full Investigation Committee report and recommendations to the IRB at a convened meeting. People relevant to the investigation (aka Involved Parties) may request or be requested to appear before the IRB to provide information or answer questions. The Involved Parties do not have the right to be represented by legal counsel, but may be accompanied by counsel if the IRB agrees. The Involved Parties may not be in attendance for the IRB’s deliberations and decision on the matter. No person involved in the research that is the subject of the action before the IRB may vote on the matter or be present in the room during the vote.

The IRB may ratify the report or request additional information. If the Board requests additional information, it will be sent back to the Full Investigation Committee with specific requests for additional information. The amended report will be returned to the IRB and reviewed as described above.

After the IRB ratifies a report, the IRB will approve a corrective action plan (CAP) to limit reoccurrence of the non-compliance.

For studies at the VAMC, remedial actions involving a specific study or research team must be completed within 120 days of the IRB’s determination. Remedial actions involving programmatic noncompliance must be completed within 180 days after the IRB’s determination,
unless remediation requires substantial renovation, fiscal expenditure, hiring, or legal negotiations.

Types of corrective actions the IRB might take:
- Suspension of the research in accordance with IRB Procedure 322 Suspensions and Terminations of IRB Approved Research;
- Termination of the research in accordance with IRB Procedure 322 Suspensions and Terminations of IRB Approved Research;
- Notification of current or past participants (required when such information might relate to participants’ willingness to continue to take part in the research);
- Modification of the research protocol;
- Modification of the information disclosed during the consent process;
- Reconsent of current participants;
- Modification of the continuing review schedule;
- Monitoring the research;
- Monitoring the consent process;
- Suspension or termination of research privileges;
- Additional training of the PI and research staff;
- Other actions the IRB deems appropriate under the circumstances that will protect research participants;
- No action.

The IRB meeting minutes will include a description of the event, the findings, actions taken, and corrective actions mandated.

The IRB may either accept the Final Report and/or Corrective Action Plan (CAP) as written or direct the Chair to revise the Final Report and/or CAP in accordance with its instructions. Upon acceptance by the IRB, the Report and CAP shall be final.

The IRB Chair will communicate the final report and CAP to:
- If non-compliance is associated with a specific protocol, the study PI and the PI’s Department Head;
- If the non-compliance is not associated with a specific protocol, the Head of the department in which the non-compliance occurred;
- Administrative leadership of external sites;
- For studies at the VAMC, the final report with the determination regarding serious and/or continuing non-compliance and corrective action plan must be reported to the respective facility Director within 5 business days, with copies to the VAMC Associate Chief of Staff for Research, VAMC Research and Development Committee, the respective...
facility’s Research Compliance Officer, and any other relevant research review committees. The VAMC facility Director must report the final determination regarding serious and/or continuing non-compliance and corrective action plan to the appropriate VA ORO regional office, with a simultaneous copy to the VISN Director and the VHA ORD within 5 business days after receiving such notification if monthly reports with updates regarding the case were not already being sent to these offices and individuals. Once a case is opened with the ORO regional office, new information is provided to these offices in monthly reports.

REPORTING

The Director of UCORI will communicate the final report and CAP in accordance with HRPP Policy VII.02 “Reporting of Unanticipated Problems, Non-Compliance, Suspensions and Terminations to the Appropriate Institutional Officials, Departments and Agencies.”

MODIFICATIONS TO POLICIES

If the IRB determines that the non-compliance represents a pattern or practice in the university’s human subjects’ research program, it shall make recommendations for new or revised policies or for any other action which will increase compliance with policy

Applicable Regulations and Documents:

45 CFR 46.103(b)(4)(5)
21 CFR 56.108(b)
VHA Handbook 1200.05 October 15, 2010
VA Handbook 1058.01 – Research Compliance Reporting Requirements (version 11/15/11)
HRPP Policy II.02 Reporting to the IRB Unanticipated Problems
HRPP Policy VII.03 Non-Compliance in Human Subjects Research
HRPP Policy VII.02 Reporting of Unanticipated Problems, Non-Compliance, Suspensions and Terminations to the Appropriate Institutional Officials, Departments and Agencies
HRPP Procedure 322 Administrative Hold, Suspensions, and Terminations of IRB-Approved Research
University Rule 10-17-05 Conduct and ethics: Policy for investigation of research misconduct
**Procedure Number:** 330  
**Procedure for Investigating Allegations of Non-Compliance**  
**Adopted:** 11/2005  
**Revised:** 03/2015  
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**Date Adopted** _March 2015_  
**Signature** _signed copy on file_