SOP: 903
NON-COMPLIANCE/ SCHOLARLY MISCONDUCT

1. POLICY

The IRB takes seriously its role in assuring prompt reporting of violations of applicable state and federal regulations, requirements or determinations of the IRB, and allegations of scholarly misconduct.

The University addresses issues of non-compliance in the Faculty Handbook under its Ethics in Research and Compliance policies. The Office of Compliance and the Office of HRPP also address non-compliance on behalf of the University.

All credible reports of such non-compliance and allegations of scholarly misconduct made to the IRB are referred to the Director of Compliance and reported to the Senior Vice President and Provost or designee.

Reports of non-compliance or scholarly misconduct may come from any source including IRB members, investigators, participants, institutional personnel, the media, anonymous sources, or the public.

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies, is not in compliance with state and federal law and/or regulations, has been associated with unexpected serious harm to participants, or involves allegations of misconduct.

It is the responsibility of the IRB staff and IRB members to act on information or reports received from any source that indicates a study being conducted at any facility under the jurisdiction of the IRB could adversely affect the rights and welfare of research participants.

Specific Policies

1.1 Scholarly Misconduct

If an incident of scholarly misconduct is reported to the HRPP Director, the HRPP Director shall notify an administrator or the Senior Vice President and Provost or designee in accordance with the University's Ethics in Research Policy.

1.2 Non-compliance

Non-compliance is defined as a proven failure to follow the regulations, VHA Handbook 1200.5, or the requirements and determinations of the IRB. Allegation of non-compliance is defined as an unproven assertion of non-compliance. If an allegation of non-compliance is reported to the IRB, the HRPP Director and IRB Chair to conduct an initial evaluation to determine if the allegation of non-compliance can be proved and whether the non-compliance is technical, serious non-compliance, and/or continuing non-compliance.

1.2.1 Technical non-compliance is defined as non-compliance that is neither serious nor continuing non-compliance. To the extent such non-compliance is addressed by other University policies, the corrective actions in this policy shall be in

addition to and not in lieu of any actions or sanctions provided under such other policies.

Examples of technical non-compliance are late submission of a continuing review, although within the required timeframe for review and approval prior to the expiration date; failure to complete IRB education requirements in a timely fashion; or failure to submit a Protocol Modification Form regarding minor changes to a research project that do not involve risks to participants.

1.2.2 Serious non-compliance is defined as a disregard or failure to comply with federal law and/or regulations, the ethical principles of the Belmont Report, Oklahoma law, IRB policies and procedures, or the determinations of the IRB.

Examples of serious noncompliance are failure to provide Continuing Review, failure to report serious adverse events, failure to obtain IRB approval prior to implementation of a change in the research, conducting research without IRB approval, failure to provide Board requested information, and failure to obtain informed consent from a participant.

1.2.3 Continuing non-compliance is defined as a pattern or repeated incidents of failure to comply with federal law and/or regulations, the ethical principles of the Belmont Report, Oklahoma law, IRB policies and procedures, or the determinations of the IRB.

Examples of continuing noncompliance are patterns of or repeated failure to provide Continuing Review, to report serious adverse events, to obtain IRB approval prior to implementation of a change in the research, to conduct research without obtaining prior IRB approval, to provide Board requested information, and to obtain informed consent from a participant.

1.3 Evaluation of Non-compliance

1.3.1 An initial evaluation is conducted by the HRPP Director, QI Coordinator, or IRB Chair by telephone. If all issues are resolved through this process and the person conducting the initial evaluation determines that the non-compliance is neither serious nor continuing, no further action is required except to report the allegation to the convened IRB.

1.3.2 If the issues raised in the allegation cannot be completely resolved through a phone investigation, or if it is determined the non-compliance might be serious or continuing, a For-Cause Evaluation will be conducted in accordance with SOP 901, Quality Improvement Program. The scope of the evaluation will initially be limited to the alleged complaint, but should expand as indicated based upon the evaluation findings.

Evaluation findings will be presented to the convened IRB and Director of Compliance.

1.3.3 If the IRB Chair makes the determination that the allegation meets any of the definitions of serious or continuing non-compliance, the HRPP Director shall report in writing the serious or continuing non-compliance in research to the

Senior Vice President or Provost, or designee and the matter is placed on the agenda of the next IRB meeting for review by the convened IRB.

1.3.4 The IRB shall consider how serious each event is in relation to the protection of participants or others, and whether the allegations of non-compliance are serious and/or continuing incidents.

1.4 Convened IRB's Review of Serious or Continuing Non-Compliance

1.4.1 Documentation of the serious or continuing non-compliance shall be reviewed at the next convened IRB meeting utilizing the primary reviewer system. Documents will be distributed to all members and may include evaluation reports and communications between the investigator and the IRB.

1.4.2 The IRB's review of the serious or continuing non-compliance may be supplemented by statements from the research team, review of the IRB SOPs, Belmont Report, Oklahoma law, and/or the IRB file.

1.4.3 Corrective actions are based upon the nature and degree of the non-compliance. In the evaluation of non-compliance, the IRB may consider one or more of the following actions as appropriate, including, but not limited to::

- Modifying the protocol.
- Modifying the information disclosed during the consent process.
- Providing additional information disclosed during the consent process.
- Providing additional information to past participants.
- Notifying current participants when such information may relate to participants' willingness to continue to take part in the research.
- Requiring current participants to re-consent to participation.
- Modifying the continuing review schedule.
- Monitoring the research.
- Monitoring the consent.
- Suspending the research.
- Terminating the research.
- Referring non-compliance to other organizational entities.
- Requiring education for one or more members of the research team.
- Requiring increased reporting.
- Restricting use of the research data for publication.
- Restricting or terminating the investigator's research privileges.

1.4.4 The corrective actions requested of the investigator by the IRB will be confirmed by the Evaluation Team and reported to the IRB.

2. SCOPE

This policy applies to actions associated with allegations of non-compliance or misconduct in research.

3. RESPONSIBILITY

The Director of Compliance provides guidance and recommendations to the HRPP Director and the IRBs regarding UPs, non-compliance, or scholarly misconduct issues.

The HRPP Director is responsible for reporting in writing to the Director of Compliance and the Senior Vice President and Provost or designee suspected or apparent allegations of scholarly misconduct as well as any suspected or apparent allegations of serious or continuing non-compliance.

The HRPP Director and IRB Chair are responsible for reviewing incidents of non-compliance to determine the appropriate course of action.

The HRPP Director is responsible for reporting in writing serious and continuing non-compliance and suspension or termination of research to OHRP, FDA, sponsor, and/or VA Central Office per SOP 308, Reporting to Regulatory Agencies and Institutional Officials.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.113

21 CFR 56.113

OU Faculty Handbook, Ethics in Research Policy

VHA Handbook 1200.5

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 901, Quality Improvement Program

SOP 303C, Meeting Minutes

SOP 308, Reporting to Regulatory Agencies and Institutional Officials.

6. ATTACHMENTS

901-A Quality Improvement Evaluation.

7. PROCESS OVERVIEW

7.1 Reports from Employees, Staff and Faculty

The IRB may receive reports of non-compliance or scholarly misconduct from a number of sources. Each report must be immediately reported to the HRPP Director for further evaluation and reporting.

Concerns of non-compliance may be identified at a convened IRB meeting or during Expedited review of the Continuing Review, Protocol Modifications, Protocol Deviations, and/or Unanticipated Problems.

7.2 Review and Determination

7.2.1 Initial reports of incidents of non-compliance or scholarly misconduct can be made in person or by telephone, email, or letter. The HRPP Director will schedule a meeting with the IRB Chair to discuss and review the incident report and determine the appropriate course of action.

7.2.2 The HRPP Director and the IRB Chair shall consult the OU Faculty Handbook to determine if the incident meets any of the definitions of scholarly misconduct. If it does meet one of the definitions, the HRPP Director reports in writing the suspected or apparent allegation of misconduct in research to the Senior Vice President and Provost or designee, who may report in writing allegations of scholarly misconduct to the Office of Research Integrity (ORI) if applicable.

7.2.3 Incidents of serious or continuing non-compliance or allegations of scholarly misconduct are also referred to the Director of Compliance.

7.2.4 If the IRB substantiates non-compliance or scholarly misconduct, the HRPP Director or IRB Chair or designee may direct the IRB Administrator to add the issue as a discussion item to the next available IRB meeting, the minutes of which are documented in accordance with SOP 303C, Meeting Minutes.

7.3 Evaluations of Non-compliance

7.3.1 If the IRB determines that non-compliance is serious or continuing the non-compliance is reported to federal and institutional officials in accordance with the SOP 308, Reporting to Regulatory Agencies and Institutional Officials.

7.3.2 Either the IRB Chair or designee or the QI/Education Coordinator continues to monitor and/or follow up on corrective measures instituted by the IRB and/or the investigator.

7.3.3 The HRPP Director provides follow-up reports to federal and/or institutional officials in accordance with SOP 308, Reporting to Regulatory Agencies and Institutional Officials.

APPROVED BY:_____ **DATE:** **09/01/2009**

NEXT ESTABLISHED REVIEW DATE: **MAY 2012**