SOP 903: Non-Compliance/ Scholarly Misconduct

1. POLICY

The IRB takes seriously its role in assuring prompt reporting of violations of applicable laws and regulations, requirements or determinations of the IRB, and allegations of scholarly misconduct made about researchers, staff, students, other employees, and/or members or consultants of the IRB from the organization as well as from other sites operating under the auspices of the IRB. All researchers, staff, students, other employees, and/or members or consultants of the IRB from the organization as well as from other sites operating under the auspices of the IRB shall report any allegations of violations of applicable laws and regulations, requirements or determinations of the IRB and/or scholarly misconduct to the IRB and/or the appropriate University officials.

The IRB may address issues of human research non-compliance in SOP 407: Protocol Deviations and Unanticipated Problems, as well as in this policy. The University also addresses issues of research non-compliance as described in the University’s Ethics in Research and Compliance policies.

All credible reports of non-compliance and allegations of scholarly misconduct made to the IRB are referred to the Director of Compliance for the NC, the HSC Vice President for Research for HSC, and reported to the Senior Vice President and Provost or designee for the applicable campus.

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

The IRB has the authority to suspend or terminate approval of human research that is not being conducted in accordance with the IRB policies, is not in compliance with local, state, federal or foreign law and/or regulations, has been associated with unexpected serious harm to participants, or involves allegations of scholarly 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 human research project being conducted at any facility under the jurisdiction of the IRB could adversely affect the rights and welfare of human 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 the Director of Compliance, Vice President for Research, and/or the Senior Vice President and Provost or designee in accordance with the University’s Ethics in Research Policy.

1.2 Non-Compliance

If an allegation of non-compliance is reported to the IRB, the HRPP Director, QI Coordinator, and/or the IRB Chair will conduct an initial evaluation to determine if the allegation of non-compliance can be substantiated 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 that technical 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 Modification/Notification Form regarding minor changes to a human research project that do not involve risks to participants.

1.2.2 Serious non-compliance is defined as disregarding or failing to comply with applicable laws and/or regulations, the ethical principles of the Belmont Report, IRB policies and procedures, or 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 human research protocol (unless the change is to prevent imminent harm to current participants), conducting human research without IRB approval, failure to provide IRB requested information, and failure to obtain informed consent from a participant.

For purposes of VA research projects, serious compliance is defined as a failure to adhere to the laws, regulations, or policies governing research involving human participants that may reasonably be regarded as involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research participants, research staff, or others, or substantively compromising the effectiveness of a VA facility’s HRPP. The determination that non-compliance is “serious” rests with the IRB.

1.2.3 Continuing non-compliance is defined as a pattern or repeated incidents of failure to comply with applicable laws and/or regulations, the ethical principles of the Belmont Report, IRB policies and procedures, or 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 human research protocol (unless the change is to prevent imminent harm to current participants), to conduct human research without obtaining prior IRB approval, to provide IRB requested information, and to obtain informed consent from a participant.

For purposes of VA research projects, continuing non-compliance is defined as Continuing non-compliance is a persistent failure to adhere to the laws, regulations, or policies governing human research. The determination that non-compliance is “continuing” rests with the IRB.

1.3 Evaluation of Non-Compliance

1.3.1 An initial evaluation is conducted by the HRPP Director, QI Coordinator, and/or the IRB Chair. If all issues are resolved through this process and the initial evaluation concludes 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 during the initial evaluation, or if the IRB determines 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 could expand as indicated by the evaluation findings.

Evaluation findings will be presented to the convened IRB and Director of Compliance and HSC Vice President for Research, as necessary.

1.3.3 If the IRB 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 to the Senior Vice President and 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. Documents will be provided to all members and may include evaluation reports and communications between the investigator and the IRB as well as any supplemental information such as relevant applicable laws and/or regulations, the ethical principles of the Belmont Report, IRB policies and procedures, or determinations of the IRB.

1.4.2 Corrective actions are based upon the nature and degree of the non-compliance. In the evaluation of non-compliance, the convened IRB may consider one or more of the following actions as appropriate:

- 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 process.
- Suspending the research.
- Terminating the research.
- Referring non-compliance to other University offices.
- Requiring education for one or more members of the research team.
• Requiring increased reporting to the IRB.
• Restricting use of the research data for publication.
• Restricting or terminating the investigator’s research privileges.

1.4.3 Following the convened IRB review of the serious or continuing noncompliance, more than minor modifications to the approved protocol or research documentation shall be submitted as described in SOP 405: Modification/Notification, for review by the convened IRB.

2. SCOPE

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

3. RESPONSIBILITY

3.1 All researchers, staff, students, other employees, and/or members or consultants of the IRB from the organization as well as from other sites operating under the auspices of the IRB are responsible for reporting any allegations of violations of applicable laws and regulations, requirements or determinations of the IRB and/or scholarly misconduct to the IRB and/or the appropriate University officials.

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

3.3 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.

3.4 The HRPP Director and IRB Chair are responsible for the initial review of allegations of non-compliance and for determining the appropriate course of action after the initial review of allegations.

3.5 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 303C: Meeting Minutes
SOP 308: Reporting to Regulatory Agencies and Institutional Officials.
SOP 405: Modification/Notification
SOP 901: Quality Improvement Program
6. ATTACHMENTS

901-A Quality Improvement Evaluation.

7. PROCESS OVERVIEW

7.1 Reports of Non-Compliance/Scholarly Misconduct

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

Concerns of non-compliance may be identified at a convened IRB meeting or during the expedited review process for IRB submissions related to Continuing Review, Protocol Modifications, Protocol Deviations, Unanticipated Problems, and/or during a QI/Evaluation.

7.2 Review and Determination

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

7.2.2 The HRPP Director and the IRB Chair shall consult the OU Faculty Handbook and any applicable University policies 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 the suspected or apparent allegation of scholarly misconduct in human research in writing to the Senior Vice President and Provost or designee, who may report in writing allegations of scholarly misconduct to the federal 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 IRB 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 University officials in accordance with SOP 308, Reporting to Regulatory Agencies and Institutional Officials.

7.3.2 Either the IRB Chair or IRB designee or the QI Coordinator or HRPP 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: 08/31/2014
NEXT ESTABLISHED REVIEW DATE: AUGUST 2016