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 University 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 Norman Campus (NC) allegations) or the Health Sciences Center (HSC) Vice President for Research (for HSC allegations), as appropriate, 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 or HSC Vice President for Research, as appropriate, and 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 or the requirements and determinations of the IRB.

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:
• 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
• 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 non-compliance:
• failure to provide a Continuing Review Report
• 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
• failure to obtain informed consent from a participant

For purposes of VA research projects, serious non-compliance is defined as a failure to follow requirements for conducting human research that may:
• Present a genuine risk of substantive harm to the safety, rights, or welfare of human research participants, research staff, or others.
• Substantively compromise the effectiveness of the VA facility’s HRPP.

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 governing human participant research.

Examples of continuing noncompliance are patterns of or repeated failure to:
• provide Continuing Review
• report serious adverse events
• 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)
• conduct human research without obtaining prior IRB approval
• provide IRB requested information
• obtain informed consent from a participant

For purposes of VA research projects, continuing non-compliance is defined as 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 When the IRB receives an allegation of non-compliance involving human participant research, 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.

1.3.2 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 allegation but could expand as indicated by the evaluation findings.

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

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 appropriate 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, and 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 University 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 issues.

3.3 The HRPP Director is responsible for reporting in writing to the Director of Compliance and the appropriate Senior Vice President and Provost or designee any suspected or apparent or reported allegations of scholarly misconduct as well as any suspected or apparent or reported 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 Directive 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
6. ATTACHMENTS

901-A HSC Quality Improvement Evaluation Checklist
901-A-1 NC Quality Improvement Evaluation Checklist

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 reports all allegations 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 are referred to the Director of Compliance.

7.2.4 If the IRB substantiates non-compliance, 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: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020