Western Carolina University
Office of Research Administration
Institutional Review Board Standard Operating Procedures

SOP# 302.1	TITLE: Non-Compliance	Date Effective: 01/01/2022 Last Revision Date: 06/30/2021

I. Purpose

This procedure sets forth the definition of non-compliance and the IRB process for assessing non-compliance and issuing corrective actions

II. Scope

All university personnel conducting research involving human subjects are expected to comply with the highest standards of ethical and professional conduct in accordance with federal regulations and institutional policies and procedures. Any member of the research team (i.e., faculty, students, staff, or anyone conducting research reviewed by Western Carolina University's IRB) may be subject to allegations or inquiries into non-compliance. Categorization of type of non-compliance will be determined by the IRB based on the totality of circumstances surrounding the event.

III. Definitions

Continuing Non-Compliance is defined as a repeated failure to adhere to the laws, regulations, policies, and procedures governing human subjects research.

Non-Compliance is defined as a failure to adhere to laws, regulations, policies, and procedures during the course of human subjects research. Noncompliance may range from relatively minor, administrative violations to serious violations that pose risks to subjects or violate the subject's rights and/or welfare.

Non-compliance includes, but is not limited to:

- Conducting research under an expired IRB protocol
- Initiating modifications to the protocol without IRB approval
- Enrollment of participants prior to IRB approval

Serious Non-Compliance is defined as a failure to adhere to laws, regulations, policies, and procedures involving human subjects research in such a manner that involves substantive harm or risk of harm to the rights, safety, and welfare of human subjects.

Serious non-compliance may include, but is not limited to:

- Failure to obtain informed consent
- Failure to report adverse events or safety concerns to the IRB
- Purposeful disclosure of confidential information outside the research team

IV. Procedure

<u>Allegations of Non-Compliance</u>

1. Reports or complaints of non-compliance may be submitted to the IRB or to the Office of Research Administration (ORA) verbally or in writing. Reports may arise internally (e.g., from faculty, staff, investigator self-reports, ORA staff, IRB members, etc) or from external

constituents (e.g., participants, regulators). The ORA/IRB will fully maintain the confidentiality of submitter, as permitted by law.

Assessment of Allegations

1. The Director of ORA and the Research Compliance Officer (RCO) will review the allegation to determine whether there are any supporting documents or statements.
2. If the allegation is determined to be unsubstantiated, the ORA Director and RCO may consult with the IRB Chair or their designee. They may decide that no additional action is needed, further inquiry is necessary, or the issue should be presented to the convened IRB.
3. If the allegation is determined not to involve non-compliance, no further action will be taken.
4. If the allegation is substantiated but only involves minor or administrative issues, the RCO will contact the investigator to resolve the concern. The ORA Director and RCO will notify the IRB Chair of the report. They may decide that no additional action is needed, further inquiry is necessary, or the issue should be presented to the convened IRB.
5. If the allegation is substantiated and involves serious or continuing non-compliance, the IRB Chair will be notified, and an inquiry may proceed. If the allegation involves an increased risk of or actual serious or unexpected harm to a participant, the Chair may immediately suspend the project until the inquiry is complete (see SOP 303 Suspension and Termination).
6. At the completion of the assessment, and when it is appropriate, the RCO will communicate the IRB Chair's decision to the complainant, through the complainant's chosen mode of communication.

Inquiry into Non-Compliance

1. The ORA Director, RCO, and IRB Chair make a determination that an inquiry is necessary based on the nature and seriousness of the complaint.
2. An inquiry may also be initiated by the IRB Chair in response to *Adverse Event or Protocol Deviations/Violation* submissions by investigators in situations where multiple reports involving immediate risks to participants have been submitted to the IRB, or at the Chair's discretion.
3. The IRB Chair notifies the Principal Investigator of the inquiry in writing and conveys the nature of the complaint.
4. The IRB Chair designates a sub-committee of at least three individuals, consisting of the RCO, IRB members, and non-members as appropriate to constitute the appropriate expertise to assess the complaint.
5. The sub-committee may review any of the following:
    a. Protocol(s) specific to the complaint.
    b. Review of any sponsor audits, if available.
    c. Review of relevant study records and documents (i.e. consent forms, case reports, data records, etc.).
    d. Conduct interviews with research personnel.
6. If the PI requests or is requested to be present at a sub-committee meeting to be interviewed about the alleged non-compliance, they may be accompanied by a faculty representative, legal counsel, or another member of their department. The role of the individual is to provide support to the PI, they may not engage in the discussion between the IRB and the PI.
7. The sub-committee creates a written report of its findings and recommendations of corrective and/or disciplinary actions.

8. The results of the inquiry are reviewed at a convened IRB meeting where all IRB members will have access to relevant protocol documents and the inquiry report. The sub-committee may provide a report at the convened meeting.
9. If the inquiry suspects research misconduct, the findings are shared with the Research Integrity Officer and further investigation will follow University Policy 56: Ethics in Research.
10. If the inquiry substantiates a finding of serious and/or continuing non-compliance, the IRB votes to determine corrective action(s). Possible corrective actions include, but are not limited to:
    a. Increased monitoring of research procedures including informed consent, by IRB members or ORA staff.
    b. Increased frequency of the continuing review cycle.
    c. Requiring additional education and training for research personnel.
    d. Requiring modifications to protocol or to the consent form.
    e. Notifying current participants of non-compliance if the information may affect their willingness to continue participation.
    f. Requiring re-consent of participants.
    g. Destruction of data.
    h. Preventing release of data to contribute to generalizable knowledge.
    i. Suspension of the study.
    j. Termination of the study.
11. The IRB notifies the Principal Investigator in writing of the determination and basis for determination. The Principal Investigator must implement the corrective actions within the specified time frame determined by the IRB. Failure to fully implement the corrective actions within the specific time frame results in the IRB suspending or terminating IRB approval for the specific study.
12. The PI has 10 days to appeal the decision in writing, if they so choose. The IRB reviews the appeal and decide whether to reject the appeal or to re-open the inquiry.
13. The RCO and Director of ORA assists the IRB in reporting any non-compliance determinations to external sponsors and/or regulatory agencies, if applicable to the study.
14. The IRB Chair is responsible for informing the investigator's department head, dean, and the institutional official of the corrective actions recommended by the committee.

V. Responsibilities

IRB administrators, IRB members, Investigators

VI. References

45 CFR §§ 46.103(b)(5), 46.113