University of Wisconsin-Oshkosh
Institutional Review Board (IRB)

STANDARD OPERATING PROCEDURES (SOP)	
SOP Number: 9 Effective Date: May 18, 2017 Updated: September 18, 2023, October 24, 2023 Last Reviewed: September 18, 2023 Attachment: Page 1 of 7 Prepared By: Anca Miron, Kelly Schill	Title: **Noncompliance Reporting Procedure for Human Subjects Research**

1) Overview

The Institutional Review Board (IRB) oversees compliance with federal regulations, applicable state and local laws, and institutional policy relating to human subjects research. The IRB will review reports of noncompliance and take action, when necessary, to ensure the ethical conduct of human subjects research.

Investigators or study team members are required to self-report IRB related noncompliance within 3 business days of discovery by submitting an IRB Noncompliance Report. Any individual may submit a noncompliance report anonymously to report instances of potential noncompliance related to human subject research to the IRB.

2) Definitions

Noncompliance: Failure (intentional or unintentional) to comply with applicable federal regulations, state or local laws, the requirements or determinations of the IRB, or university policy regarding research involving human subjects. Noncompliance can result from action or omission.

Categories of Noncompliance:
Noncompliance is categorized as a) non-serious (minor), b) serious, and c) continuing.

a) Non-serious/minor noncompliance: Noncompliance that does not increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or the human research protection program.

Some examples of minor noncompliance may include, but are not limited, to the following:

- Lapses in continuing IRB approval
- Failure to obtain exempt determination before exempt research involving human subjects is conducted

- Minor deviations from an approved protocol without IRB approval that do not impact risk to participants

b) Serious noncompliance: Noncompliance that increases potential risks to participants or others, compromises safety, rights, or welfare of the participants or others, results in change of risk/benefit ratio of the study or affects the integrity of the research project and data.

Examples of serious noncompliance may include, but are not limited, to the following:

- Conducting or continuing non-exempt human subjects research without IRB approval
- Lack of informed consent from research participants or repeated informed consent discrepancies, such as missing participant signatures in consent documents.
- Failure to report or review or late reporting of serious adverse events or unanticipated problems
- Willful or knowing misconduct on the part of the study team
- Significant protocol deviations from approved research plan impacting risk level
    i. e.g., the study team enrolled ineligible participants, did not perform safety procedures, enrolled subjects into the study without proper consent, or implemented a substantive change to the research without IRB approval (unless implemented to avoid imminent harm to subjects) (Emory IRB noncompliance guidance).
- Inappropriate oversight of research to ensure the safety of human subjects.
- Misplacing or sharing identifiable data outside of what was approved in the IRB protocol.

c) Continuing noncompliance: Noncompliance (serious or non-serious) that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of human subjects protection requirements that may affect research participants or the validity of the research and suggest the potential for future noncompliance without intervention.

Examples of continuing noncompliance may include, but are not limited to, the following:

- Repeated failure to provide or review progress reports resulting in lapses of IRB approval during which human subjects research occurs.
- Inadequate oversight of ongoing research; or
- Failure to respond to or resolve previous allegations or findings of noncompliance.

3) <u>Reporting Requirements for IRB Noncompliance</u>

a) What needs to be reported to the IRB?

- All cases of non-compliance (or potential noncompliance) should be reported to the IRB promptly using the online IRB Noncompliance Report within 3 business days of discovery.

4) Procedure for Submission of IRB Noncompliance Report

The following procedure describes how instances of noncompliance are reported to the IRB. Potential noncompliance incidents may be reported by any individual or employee (anonymously or non-anonymously).

Investigators are required to self-report instances of minor/non-serious, serious, or continuing noncompliance within 3 business days of discovery using the online IRB Noncompliance Report. If an individual, whether Investigator, study staff, or other, is uncertain whether there is cause to report noncompliance, the IRB Chair (or designee) may be contacted to discuss the situation informally. Additionally, if a person reporting an incident is unsure of the category of noncompliance, a noncompliance report may be submitted, and the IRB will determine the course of action.

The reporting party is responsible for making noncompliance reports in good faith, maintaining confidentiality, and cooperating with any IRB and/or Institutional review of these reports. Wisconsin's Whistleblower Law protects employees from retaliation for reporting in good faith. Under Sections 230.80-85 of the Wisconsin Statutes, an employee of the State of Wisconsin, except for certain exceptions listed in s. 230.80(3), may not be retaliated against for disclosing information regarding a violation of any state or federal law, rule or regulation, mismanagement or abuse of authority in state or local government, substantial waste of public funds or a danger to public health or safety. If a party wishes to report a concern anonymously, the UW System Ethics and Integrity hotline (855) 827-4950 or EthicsPoint electronic submission system may be used.

5) Procedure for Initial Review of IRB Noncompliance Reports

All noncompliance reports will be vetted by the IRB Chair (or their designee) and reported to the Research Integrity Officer (Sponsored Programs). If the IRB chair has a conflict of interest, another member of the IRB will be designated to review the noncompliance report. The IRB may request the following study information:

1. The last approval letter from the IRB
2. The last approved IRB Application
3. The last approved Consent Form document
4. The grant, if applicable; and
5. Any other pertinent information/supporting documents (e.g., questionnaires, debriefing documents, training documents, etc.).

The IRB Chair (or designee) will review the noncompliance report within **10 business days**. All noncompliance reports are tracked by IRB administrative staff. The IRB Chair or Institutional Official for Research has the authority to temporarily suspend research activity at their discretion; however only the convened IRB can terminate research. If the chair suspends research, this action must be documented and submitted to the convened IRB. If the issue can be resolved by the IRB Chair (or designee), the outcome report (resolution/corrective plan) will be documented and communicated to the IRB at the next IRB meeting.

The IRB Chair (or designee) may determine that additional expertise or assistance is required to make a determination and may appoint an ad hoc committee if needed to assist with the review and fact gathering process. Noncompliance reports outside of the scope of the IRB will be referred to the appropriate office. When an ad hoc committee assists in the review process, the Chair (or designee) is responsible for assuring that minutes of the meeting are generated to support any recommendations made by the committee.

If in the judgment of the IRB Chair (or designee) or ad hoc committee, any allegation or findings of noncompliance are considered true, the noncompliance incident will be processed according to section 6 below.

6) Review of Findings of IRB Noncompliance

A. Noncompliance is not Serious (Minor) and not Continuing Noncompliance

Instances of minor noncompliance (which are not repeated instances) will be reviewed by the IRB Chair (or their designee). The IRB Chair (or their designee) will review the PI's corrective actions and reserves the right to request further action if necessary.

B. Serious Noncompliance or Continuing Noncompliance

Incidents of serious noncompliance or continuing noncompliance are referred for review by the full IRB at the next convened available meeting or at an emergency meeting called by the IRB Chair (or designee). If the complaint or concern is of the nature that the safety, rights and welfare of participants are at immediate risk or hazard, the IRB Chair (or designee) will contact the PI to establish an interim measure to be taken to protect participants pending formal inquiry and review by the full committee. This measure may include a temporary suspension of some or all of the study. All findings of serious or continuing noncompliance referred to the IRB will be reviewed at a convened meeting. All IRB members will receive:

- Documents relevant to the allegation
- The last approval letter from the IRB
- The last approved IRB Protocol; and
- The last approved consent document and other supporting materials.

The convened IRB may make the following determinations at a convened meeting:

1) Find that there is no issue of noncompliance
2) Find that there is noncompliance that is neither serious noncompliance nor continuing noncompliance (considered minor) and that an adequate corrective action plan is in place
3) Find that there is serious noncompliance or continuing noncompliance and approve any changes proposed by the IRB Chair/or designee
4) Request additional information.
5) Find that there may be serious noncompliance or continuing noncompliance and direct that a formal inquiry (described below) be held.

Formal Inquiry Procedure for Serious or Continuing Noncompliance

A determination may be made by the IRB that a formal inquiry is necessary based on several issues that may include but are not limited to:

1. Subjects' complaint(s) that rights were violated;
2. Report(s) that Investigator is not following the protocol as approved by the IRB;
3. Unusual and/or unexplained adverse events in a study;
4. Repeated failure of Investigator to report required information to the IRB.

A subcommittee is appointed by the Institutional Official for Research (IO) consisting of IRB members, and non-members if appropriate, to ensure fairness and expertise. The subcommittee is given a charge by the IRB, which can include any or all of the following:

1. Review of protocol(s) in question;
2. Review of Sponsor audit report of the Investigator, if appropriate;
3. Review of any relevant documentation, including consent documents, case report forms, subject's investigational files, as they relate to the Investigator's execution of her/his study involving human subjects;
4. Interview of appropriate personnel if necessary;
5. Preparation of either a written or oral report of the findings, which is presented to the convened IRB at its next meeting;
6. Recommend actions if appropriate.

Final IRB Review for Serious or Continuing Noncompliance following Formal Inquiry

The results of the inquiry will be reviewed at a convened IRB meeting where the IRB will receive a report from the subcommittee. If the results of the inquiry substantiate the finding of serious or Continuing Noncompliance, the IRB's possible actions could include, but are not limited to:

1. Request a correction action plan from the Investigator
2. Verification that participant selection is appropriate and observation of the actual Informed Consent
3. An increase in data and safety monitoring of the research activity
4. Request a directed audit of targeted areas of concern
5. Request a status report after each participant receives intervention
6. Modify the continuing review cycle/frequency
7. Request additional Investigator and staff education
8. Notify current subjects, if the information about the non-compliance might affect their willingness to continue participation
9. Require modification of the protocol
10. Require modification of the information disclosed during the consent process
11. Require current participants to re-consent to participation
12. Suspend the study

13. Terminate the study

In cases where the IRB determines that the incident of noncompliance also meets the definition of Unanticipated Problem, the policy and procedure for review of such events will also be followed. The Investigator is informed of the IRB determination and the basis for the determination in writing and is given a chance to respond. If the IRB determines that the Noncompliance was serious or continuing, the results of the final review will be reported to the IO and applicable agencies (OHRP, FDA).

If a non-compliant event is considered research misconduct, the procedure in the Faculty Handbook under Gen 1.5.(2) of the Scientific Misconduct in Research will be followed. The Research Integrity Officer (Sponsored Programs) will be the point of contact for any research misconduct cases.

Upon completion of IRB review of noncompliance cases, the IRB Chair and/or Administrator will document actions taken on the IRB Noncompliance Report Form (Appendix A).

References:

- UCLA OHRPP (2020); Policy and Guidance: Complaints, Concerns and Suggestions, and reports of undue influence regarding the conduct of human participants research. http://ora.research.ucla.edu/OHRPP/Documents/Policy/11/Complaints.pdf

- Tulane IRB Complaints and Non-compliance policy (2010). https://tulane.app.box.com/s/aohexaqo8ejvuot5xgcj7pjk4naw58d0

- The Ohio State University: Noncompliance HRPP Policy (2022). https://orrp.osu.edu/files/2022/04/38-IRB-Reporting.pdf

- University of Wisconsin-Madison. IRB Policy on Reportable Events (2023).

https://irb.wisc.edu/manual/investigator-manual/post-approval-responsibilities/reportable-events/?tab=reporting-requirements

- Emory University IRB Full Board Review of Noncompliance and Unanticipated Problems (2021). https://irb.emory.edu/_includes/documents/sections/nc_up_guidance.pdf

Appendix A: IRB Noncompliance Report Form

This form is completed by the IRB Chair and/or IRB Administrator to document noncompliance reports and corrective actions.

Date of Event/ Problem:		**Date Reported:**	
Location of Event:			
Name of Individual Reporting Event:			
Protocol Number, Title, PI (if applicable):			
Funding Source:			

1.	**Provide a description of the noncompliance reported:**
2.	**Provide a description of actions taken by the IRB when reviewing the noncompliance:**
3.	**Provide a description of any corrective actions taken:**

4.	**Follow up Details and Closure of Case**