University of Wisconsin-Oshkosh
Institutional Review Board (IRB)

STANDARD OPERATING PROCEDURES (SOP)	
SOP Number: 9 Effective Date: May 18, 2017 Last Reviewed: May 18, 2017 Attachment: Page 1 of 5 Prepared By: Anca Miron, Kelly Schill	Title: **Noncompliance Procedure**

1) Policy Goals

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 allegations of noncompliance and take necessary action, when necessary, to ensure the ethical conduct of human subjects research.

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.

Noncompliance may be a) non-serious (minor), b) serious, and c) may also be considered continuing noncompliance.

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, or minor changes in or deviations from an approved protocol without IRB approval.

b) Serious noncompliance: Noncompliance that increases risk to research participants, compromises participants' rights or welfare, or affects the integrity of the research/data or the human research protection program. 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 legally effective informed consent from research participants; failure to report or review serious adverse events, unanticipated problems, or substantive changes in research; or inappropriate oversight of the research to ensure the safety of human subjects and the integrity of the research/data.

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 failures to provide or review progress reports resulting in lapses of IRB approval, inadequate oversight of ongoing research, or failure to respond to or resolve previous allegations or findings of noncompliance.

3) Procedure for Reporting Allegations of Noncompliance or Self-reporting Incidents

The following procedures describe how allegations of noncompliance are reported to the IRB. An allegation of noncompliance is defined as an unconfirmed report of noncompliance. Potential noncompliance incidents may be reported by any individual or employee. Researchers must self-report incidents of possible noncompliance upon discovery.

The reporting party is responsible for making these 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.

Investigators and their study staff are required to report instances of possible noncompliance related to their study. The PI is responsible for reporting any possible human subjects research noncompliance by study personnel to the IRB. If an individual, whether Investigator, study staff or other, is uncertain whether there is cause to report noncompliance, he or she may contact the IRB Chair (or designee) directly to discuss the situation informally.

Reports of noncompliance must be submitted to the IRB promptly within 3 business days of discovery of this non-compliance. The details of the incident may be reported on the IRB Noncompliance Form.

4) Procedure for IRB Review of Allegations of Noncompliance

All allegations of noncompliance will be vetted by the IRB Administrator and forwarded on to the IRB chair or reported directly to the IRB chair. If the IRB chair has a conflict of interest, another member of the IRB will be designated to review the allegation of noncompliance. The IRB may request the following study information in order to review the allegation:

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, etc.).

The IRB Chair (or designee) will review the allegation within **10 business days**. If the issue can be resolved by the IRB Chair (or designee), the outcome report (resolution/corrective plan) will be documented in the IRB Use Section of the Form.

The IRB Chair (or designee) may determine that additional expertise or assistance is required to make a determination and **may form an ad hoc committee** if needed to assist with the review and fact gathering process. 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 and kept to help support any determinations or findings made by the ad hoc 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 5 below.

5) Review of Findings of Noncompliance

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

When the IRB determines that Noncompliance occurred, but the Noncompliance does not meet definition of Serious Noncompliance or Continuing Noncompliance, the determination is reported in writing to the PI and if applicable the reporting party. The IRB chair (or designee) will work with the PI to develop a corrective action plan to prevent future Noncompliance. The IRB Noncompliance Report which includes the corrective action plan is stored in the protocol file and can be reviewed by IRB members upon request. If however, the PI refuses to cooperate with the corrective action plan, the matter is referred to a convened meeting of the IRB.

B. Serious Noncompliance or Continuing Noncompliance

When the IRB Chair (or designee) determines that Noncompliance has occurred and that the Noncompliance meets the definition of Serious Noncompliance or Continuing Noncompliance, the IRB Noncompliance Report is referred for review by the full IRB at the next convened available meeting. However, the IRB Chair (or designee) may use discretion and call an emergency IRB meeting should the circumstances warrant such an urgent meeting. 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:

- All 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 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 and/or ad hoc committee
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 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
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 the non-compliance is considered research misconduct, the procedure in the Faculty Handbook under Gen 1.5.(2) of the Scientific Misconduct in Research will be followed.

References:

6. UCLA OHRPP; 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
7. Tulane IRB Complaints and Non-compliance policy. http://www2.tulane.edu/asvpr/irb/upload/Section-10-Complaints-and-NonCompliance.pdf
8. The Ohio State University: Noncompliance HRPP Policy

UW Oshkosh

Office of Sponsored Programs and Faculty Development

IRB Noncompliance Report

Please email this form promptly (within 3 business days) following an incident of potential noncompliance to: IRB@uwosh.edu and copy the IRB Chairperson: Dr. Anca Miron, mirona@uwosh.edu. Please provide as much detail as possible.

Noncompliance Allegation or Incident Description			
Date of Incident:		**Date Identified:**	
Location of Event (if applicable):			
Name of Individual Reporting Event:			
Protocol Number:			
Study Title:			
Principal Investigator:			

1.	**Provide a description (include dates and details) of the incident:**
2.	**Provide a description of any actions taken to manage the incident (if applicable):**

----------(This section IRB USE ONLY- completed by IRB Chair or Designee)----------

Follow up Details/Resolution: