

UWEC IRB Noncompliance Policy

DEFINITIONS & POTENTIAL CORRECTIVE ACTIONS:

Noncompliance:

Any action or activity associated with the conduct or oversight of research involving human subjects, as defined in ([CFR 45 §46.102](#)), that fails to comply with either the research plan as approved by the designated Institutional Review Board (IRB) or with federal regulations or institutional policies governing human subject research. Noncompliance includes failure to have protocols reviewed by the IRB prior to beginning research with human subjects or deviations from the protocols approved by the IRB. Noncompliance can result from action or omission and may be *minor, serious, and/or continuing*.

Minor Noncompliance:

Any behavior, action or omission in the conduct or oversight of research involving human subjects that deviates from the approved research plan, federal regulations, or institutional policies but, because of its nature, the research project, or subject population, does not or did not:

- harm or pose an increased risk of substantive or considerable harm to a research participant;
- result in a detrimental change to a participant's clinical or emotional condition or status;
- have a substantive or considerable effect on the value of the data collected; and
- result from willful or knowing misconduct on the part of the investigator(s) or study staff.

In general, examples of minor noncompliance include but are not limited to:

- Implementation of minor changes to or deviations from an approval protocol without IRB approval of the protocol modification.
- Implementing minor wording changes in study questionnaires without first obtaining IRB approval.

Corrective actions for minor noncompliance may include, but are not limited to:

- Acknowledgement of the report with no further action needed.
- A warning or reminder to the PI with instructions on how to avoid future incidents, clarifications regarding requirements and rules, etc.
- Requiring additional human subjects protection training.
- Requiring submission of an amendment or report of an adverse event/unanticipated problem
- Requiring the PI to submit a corrective action plan.
- Directing post-approval monitoring visits.
- Directing compliance audits.

Serious Noncompliance:

Any behavior, action or omission in the conduct or oversight of human subjects research that has been determined to:

- adversely affect the rights and welfare of a research participant;
- harm or pose an increased risk of substantive or considerable harm to a research participant;
- result in a detrimental change to a participant's clinical or emotional condition or status

- compromise the integrity or validity of the research; or
- result from willful or knowing misconduct on the part of the investigator(s) or study staff.

Acts that are determined to be flagrant or intentional violations of IRB requirements may also constitute serious noncompliance. The IRB will consider the circumstances surrounding the case when making a decision related to serious noncompliance.

In general, examples of serious noncompliance include but are not limited to:

- Failure to obtain IRB approval or determination of exemption prior to initiating research activities with human subjects, especially if the research potentially poses more than minimal risk.
- Allowing unqualified or untrained individuals to perform research procedures or monitor subject safety.
- Failure to obtain informed consent or failure to provide participants with all information necessary to constitute meaningful informed consent unless a waiver has been previously granted by the IRB.
- Enrolling a child in a research study without the informed consent of a parent or legal guardian unless parental consent was previously waived by the IRB.
- Enrolling subjects from a vulnerable population (i.e., children, prisoners, cognitively impaired individuals, subordinates, etc.) when their inclusion is not described in the IRB-approved protocol or appropriate protections are not in place.
- Enrolling subjects who do not meet the approved eligibility criteria when doing so compromises the safety or well-being of the subjects.
- Failure to follow approved measures for protecting privacy and confidentiality when the failure presents any risk of harm to the research subject (such as harm to their reputation, social or psychological harm, risks of legal or civil liability, embarrassment, harm to workplace or family relationships, etc.).
- Implementing unapproved changes to research activities that increase risks to participants or adversely affect their rights, safety, or welfare (e.g., adding survey questions that collect sensitive information, substantially increasing the duration or intensity of exercise activities, adding plans to collect data from private records without subject consent, changes to confidentiality protections, etc.).
- Failure to report serious adverse events or unanticipated problems involving risks to subjects or others as required by IRB policy.
- Instructing or knowingly allowing subordinates (e.g., research assistants, employees, students, etc.) to engage in activities that are contrary to IRB or institutional policies or regulatory requirements.
- Providing false or intentionally misleading information to the IRB.
- Multiple issues suggesting a lack of oversight, inaction, or negligence such that research subjects' rights, safety, or welfare could be adversely affected.

Corrective actions for serious noncompliance may include but are not limited to:

- Remediation or educational measures required of the research team.
- Monitoring of research activities by a designated person(s).
- Monitoring of the informed consent process by a designated person(s).
- Notification of past or current research participants.
- Re-consenting of participants.

- Modification of the research protocol.
- Increased reporting by the PI of his/her human participants' research activities to the IRB.
- More frequent continuing review (renewal of approval) schedule.
- Periodic audits by the IRB administrator or appointed member of the IRB.
- Restrictions to the PI's research practice, such as limiting the privilege to minimal risk or supervised projects.
- Requiring the PI to submit a corrective action plan.
- Suspension of approval for one or more of the PI's studies.
- Termination of approval for one or more of the PI's studies.
- Referral to other University authorities or committees for possible further review and resolution by those bodies including possible disciplinary action up to and including termination in accordance with the appropriate disciplinary procedures for faculty, staff, and students.

Continuing Noncompliance:

A pattern of noncompliance that:

- indicates a lack of understanding or a disregard for the regulations or institutional requirements that protect the rights and welfare of participants;
- suggests a likelihood that noncompliance will continue without intervention; or
- involves frequent instances of minor noncompliance, such as repeated protocol deviations.

Continuing noncompliance is characterized by the frequency rather than the magnitude of the noncompliance. Examples of continuing noncompliance include but are not limited to:

- Repeated failure to obtain IRB approval prior to initiating human subjects research activities.
- Continuing to engage in noncompliant activities after being notified or advised of concerns.
- Recurring late submissions of continuing review applications resulting in repeated lapses in approval.
- Multiple instances of serious or minor noncompliance; this includes multiple incidents within a single project or multiple incidents by a single investigator across more than one project.
- Failure to respond to incidents of noncompliance or failure to enact required corrective actions.

Corrective actions for continuing noncompliance may include but are not limited to those listed above under minor noncompliance and serious noncompliance.

PROCEDURES:

Initial Report of Potential Noncompliance

Upon receipt of a report or query regarding potential noncompliance, IRB staff forward the information to the IRB Chair/designee. The IRB Chair/designee will promptly review the report/query and inform the Director of the Office of Research and Sponsored Programs (ORSP) and the Institutional Official. If the report/query does not seem to involve serious harm to subjects, the IRB Chair/designee will proceed with an initial inquiry (described in the next section).

If the report/query involves allegations of serious harm to subjects or requires immediate action to prevent such harm, the IRB Chair/designee will immediately inform the Director of the Office of

Research and Sponsored Programs (ORSP) and the Institutional Official, halt study activity, and proceed with an initial inquiry.

Initial Inquiry of Report of Potential Noncompliance

The IRB Chair/designee will promptly undertake an inquiry of the allegation(s). The primary purpose of the inquiry is fact-finding, that is, to determine whether there is evidence to substantiate a claim of noncompliance with institutional, UW System, state, or federal policies/regulations regarding human subjects research. The inquiry may involve examination of study records and discussion with the research team, other personnel, research participants, witnesses, the complainant (if not anonymous), and others as appropriate.

If the report/query is made by someone other than the Principal Investigator (PI), the IRB Chair/designee will notify the PI in writing of the allegation. The PI will have an opportunity to respond to the allegation(s) during this initial inquiry. The results of the inquiry will be shared in writing with the ORSP Director, the Provost/Institutional Official, and others as deemed necessary.

If the allegation/concern is unsubstantiated, no additional action is needed.

If the allegation appears to be substantiated, i.e., the initial inquiry suggests that the actions are in violation of institutional, UW System, state, or federal policies/regulations regarding human subjects research, one of two actions follow. If the allegation is determined to be a clear case of minor noncompliance and is not considered continuing noncompliance by the IRB Chair/designee, and the ORSP Director and Provost/Institutional Official agree with the determination, the ORSP Director in collaboration with the IRB Chair/designee and the Provost/Institutional Official determines corrective action and communicates the outcome in writing to the PI, with a copy to the PI's chair/supervisor, the PI's Dean, the IRB Chair, and the Provost/Institutional Official. If the allegation is not a clear case of minor noncompliance, an IRB Subcommittee investigation ensues. Temporary suspension of study activities may be enacted for the protection of research subjects.

IRB Subcommittee Investigation

If the inquiry reveals noncompliance with institutional, UW System, state, or federal policies/regulations regarding human subjects research that is other than a clear case of minor noncompliance, the IRB Chair/designee will form an IRB Subcommittee of at least two members of the IRB to conduct an investigation. The IRB Subcommittee reviews the report/query, the inquiry report, any related materials, and decides what further information is needed; this information may include meeting with the research team, other personnel, research participants, witnesses, the complainant (if not anonymous), and others as appropriate. The purpose of the investigation is to determine whether the reported incident constitutes noncompliance and if so, whether it is minor noncompliance, serious noncompliance, and/or continuing noncompliance.

The IRB Subcommittee prepares a written report for the IRB Chair/designee, indicating whether the reported incident constitutes noncompliance, and if so, identifying and justifying the action(s) as minor noncompliance, serious noncompliance, and/or continuing noncompliance and recommending specific corrective actions. The IRB Chair/designee reviews the report and shares it with the ORSP Director and the Provost/Institutional Official.

If no noncompliance is found, the IRB Chair/designee communicates the outcome in writing to the PI, the ORSP Director, and the Provost/Institutional Official, and shares the outcome with the IRB Committee.

If the determination is minor noncompliance, the IRB Chair/designee refers the matter to the ORSP Director. The ORSP Director in collaboration with the IRB Chair/designee and the Provost/Institutional Official determines the corrective action and communicates the outcome in writing to the PI with a copy to the PI's chair/supervisor, the IRB Chair, and the Provost/Institutional Official. The IRB Chair shares the outcome with the IRB Committee.

If the determination is serious noncompliance and/or continuing noncompliance, the IRB Chair/designee refers the matter to the ORSP Director and the Provost/Institutional Official. The Provost/Institutional Official in collaboration with the ORSP Director (and potentially the IRB Chair/designee) determines corrective action and communicates the outcome in writing to the PI, with a copy to the PI's chair/supervisor, the PI's Dean, the IRB Chair, and the ORSP Director.

If there is uncertainty or disagreement in the IRB Subcommittee about the determination or type of noncompliance, the IRB Chair/designee refers the matter to the ORSP Director. The ORSP Director in collaboration with the IRB Chair/designee and the Institutional Official undertakes further investigation, if needed, and makes a determination regarding the noncompliance. Procedures described above then followed.

When a determination of noncompliance requires corrective action, the PI must provide written documentation of completion of any corrective action to the IRB within 30 days of being notified, unless otherwise specified. The IRB will provide written confirmation that the corrective action is sufficient and will document all information regarding the incident in the IRB records.

Follow-Up

Principal investigators are responsible for ensuring the corrective actions outlined in the final noncompliance report are implemented by the timeframes established in the report. The ORSP Director will monitor as needed. Failure to meet the conditions established in the report may result in additional sanctions.

Referrals for Additional Review

If information obtained during the initial inquiry or investigation suggest that the activity/activities may potentially violate other University policies, such as research misconduct or financial mismanagement, the IRB will share or refer the complaint to the appropriate University officials. The IRB will cooperate and coordinate its reviews with other University officials, as appropriate.

External Reporting

Incidents of serious noncompliance and/or continuing noncompliance—as well as suspension or termination of IRB approval and/or unanticipated problems involving risks to subjects or others—must be reported to the Office of Human Research Protections per requirements set forth in [45 CFR 46](#) and

the funding agency or sponsor in accordance with their requirements. Similarly, reports of serious or continuing noncompliance must be provided to the Food and Drug Administration for FDA-regulated research in accordance with [21 CFR 56.108\(b\)](#), [21 CFR 56.113](#), [21 CFR 812.150](#). When appropriate, preliminary reports may be filed pending final resolution of the case.

In addition, in cases of serious noncompliance and/or continuing noncompliance, if the study involves other institutions, the IRB administrators and/or collaborating individuals of those institutions will be notified.

Research Conducted Without Prior IRB Approval

No mechanism exists under [45 CFR 46](#) or UWEC [policy](#) for retroactive IRB approval (or disapproval) of a project. Therefore, if the IRB becomes aware of research that has already been conducted without IRB review and approval, the inquiry and investigation processes described above apply. Project activity will be paused, and data collected may not be used for any purposes pending the outcome of the inquiry and/or investigation and subsequent IRB review and approval.

Appeal of Noncompliance Decisions

Appeals of determinations of noncompliance must be made in writing within 10 business days of the date of the report communicating the outcome of the investigation to the ORSP Director or the Provost/Institutional Official, whoever has communicated the decision in writing to the PI. The appeal will be communicated to the IRB Chair/designee, and the IRB Chair/designee will have the IRB Committee review the appeal at the next regularly convened IRB meeting. The PI may attend the IRB meeting at which the appeal is discussed. The IRB Chair/designee will communicate the outcome of the appeal in writing to the PI, with a copy to the PI's chair/supervisor, the PI's Dean, the ORSP Director, and the Institutional Official.

If the PI is not satisfied with the appeal decision of the full IRB Committee, the PI may appeal the decision to the Provost/Institutional Official in writing within 10 days of the date of the communication of the IRB's review of the appeal. The decision of the Provost/Institutional Official is final.

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