Investigations of General, Serious, or Continuing Noncompliance

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Policy Statement

All investigators engaged in UIW IRB-approved research are required to comply with all ethical standards, institutional policies, governmental regulations, and conditions placed on the conduct of research involving human participants. Failure to adhere to these requirements may constitute noncompliance. All instances of suspected noncompliance must be reported to the Office of Research and Sponsored Projects Operations (ORSPO). General noncompliance may be managed by the ORSPO in consultation with the IRB Chair. Suspected serious or continuing noncompliance will be referred to the convened IRB for review. Serious noncompliance and continuing noncompliance are findings that are determined by the convened IRB. The ORSPO reports serious and continuing noncompliance determinations in accordance with the requirements of federal oversight agencies.

Definitions

General Noncompliance: Failure on the part of any member of the research team to follow

- the terms of UIW IRB approval;
- applicable laws, regulations; and/or
- UIW policies related to the conduct of research involving human participants.

Examples of general noncompliance may include, but are not limited to

- failure to obtain an institutional exempt determination prior to beginning exempt research;
- continuing research activities beyond study expiration date or during protocol suspension;
- failure to conduct the research as described in and required by the Protocol;
- enrolling more participants in the study than were approved by the IRB;
- implementing changes to a protocol without prior IRB approval, unless the change is necessary to eliminate apparent immediate hazard to participants; and/or
- not following IRB approved informed consent procedures.

Note that these examples could constitute serious or continuing noncompliance, depending on circumstances and potential for harm.

Serious Noncompliance: Noncompliance that

- presents actual or potential increased risk to participants or to research personnel;
- adversely affects the rights, welfare, or safety of the participants; and/or
- adversely affects the scientific integrity of the study.

Continuing Noncompliance: Noncompliance that

- is repeated either on a single protocol, or across multiple protocols under an individual investigator, and/or
- represents a pattern of ongoing activities that indicate a lack of understanding of human research requirements that may affect research participants or the validity of the research.

Examples of serious or continuing noncompliance may include, but are not limited to:

- failure to obtain expedited or full board IRB approval prior to initiating human research activities,
- failure to obtain informed consent/assent/parental permission as required by the IRB approved protocol,
- failure to report unanticipated events involving risk to participants or others,
- enrolling participants who do not meet eligibility criteria, and/or
- protocol deviations that adversely affect the welfare of participants and/or the integrity of the research.

Description and Procedures

A. Evaluations and Investigations of Potential Noncompliance

1. Identification of Potential Noncompliance: Noncompliance may be found or alleged in a number of ways, including but not limited to

    - evidence based on materials submitted to the IRB;
    - reported as an unanticipated problem involving risks to participants or others;
    - during post-approval monitoring visits; and/or
    - reported by an individual to the ORSPO, the IRB Chair, or an IRB member.

    Reasonable efforts will be made to protect the confidentiality of any persons who report alleged non-compliance, as well as the confidentiality of the investigator and those involved in the investigative process. Whistleblowers reporting research noncompliance or research misconduct are protected under federal and state whistleblower laws and cannot be retaliated against in any manner for reports made in good faith.

2. Initial Evaluation by the ORSPO and/or IRB Chair/Designee: Identification of problems that clearly constitute non-serious or non-continuing noncompliance may be evaluated and managed by ORSPO staff and IRB Chair or Designee. Events that may or may not constitute noncompliance may require input from IRB leadership and information gathering before a determination can be made. Problems that indicate significant risk or severity will be evaluated to determine if they constitute an unanticipated problem and whether immediate actions are necessary to ensure the ongoing protection of research participants.

3. Fact Finding: If additional information is needed to make a noncompliance determination, the ORSPO may initiate fact-finding activities, which may include reviewing study documentation

or corresponding with the Principal Investigator and research personnel to determine whether the allegation is substantiated. The IRB Chair may participate with the ORSPO. All reports of noncompliance should also be evaluated to determine if the criteria for an unanticipated problem involving risk to participants or others are met.

4. Outcomes of Fact Finding and Initial Evaluation: Possible outcomes of the fact finding may include

   - dismissal of an unsubstantiated allegation;
   - referral to the convened IRB if the problem may involve 1) serious and/or continuing noncompliance or 2) meets the definition of being an unanticipated problem;
   - referral to other appropriate university processes (e.g., misconduct investigation); and/or
   - determination of noncompliance with or without corrective actions required.

   Examples of possible actions that may be imposed in response to a determination of noncompliance that is neither serious nor continuing could include, but are not limited to

   - study specific corrective action(s);
   - education of the investigator(s) and research team;
   - modification to the protocol and/or other study documents;
   - requirement that participants be re-contacted and provided with updated information or re-consented;
   - notification of current participants when such information may relate to participants' willingness to continue participating in the research; and/or
   - requiring post-approval monitoring of the research.

B. Convened IRB Review of Potential Noncompliance

All events that potentially involve serious or continuing noncompliance will be referred to the convened IRB. All members of the IRB at the convened meeting will be provided with submission documentation pertaining to the problem (e.g. a written summary of the noncompliance, the outcome, and any steps taken to prevent recurrence). The IRB (or Principal Investigator) may request the Principal Investigator's presence at the convened IRB meeting in order to provide clarifications. During their review, the IRB should determine whether the problem constitutes serious and/or continuing noncompliance, based on the definitions provided in this policy.

C. Corrective Actions

The IRB will determine whether the investigator satisfactorily resolved the noncompliance, if applicable, and whether corrective actions are needed. If the noncompliance is determined to be neither 'serious' nor 'continuing,' the IRB may determine that general noncompliance has occurred and may require a corrective action plan.

Possible actions imposed by the convened IRB in response to a determination of serious or continuing noncompliance may include, but are not limited to

- study specific corrective action(s),
- education of the investigator(s) and research team,
- modification to the protocol and/or other study documents,

- requirement that participants be re-contacted and provided with updated information or re-consented,
- notification of current participants when such information may relate to participants' willingness to continue participating in the research,
- providing additional information to past participants,
- suspension or termination of the research,
- disqualifying the investigator(s) from conducting research involving human participants at UIW,
- requiring periodic monitoring or auditing of the research,
- requiring monitoring of the consent process, and/or
- enforcing more frequent continuing review.

D. Documentation and Reporting of Findings

The Principal Investigator is notified of a noncompliance determination via a written letter. Findings of serious and/or continuing noncompliance are promptly reported to relevant regulatory agencies and distributed to other individuals and organizational officials according to the procedures described in the "Reporting to Regulatory Agencies" policy.

Effective Date

August 24, 2020

Revision History

References

Suspension or Termination of Previously Approved Research
Reporting to Regulatory Agencies