Guidance for Identifying and Reporting Noncompliance

Noncompliance can result from a number of factors during the research process. This guidance provides directions for identifying and reporting potential non-compliance occurring during the conduct of research involving human subjects.

All researchers conducting research involving human subjects at Lindenwood University are expected to conduct research consistent with IRB approval and all applicable federal, state, and institutional policies. Noncompliance with respect to research involving human subjects violates Lindenwood University's Federalwide Assurance (FWA). Even in the absence of knowledge or intent, noncompliance may place researchers, research participants, or others at risk. Researchers (Principle Investigators) are primarily responsible for compliance with all applicable policies and regulations.

In order to demonstrate thorough oversight of research involving human subjects at Lindenwood University and to comply with federal and state regulations, the Lindenwood IRB will investigate and respond to all cases and allegations of noncompliance. A funding agency or other federal entities may have reporting requirements in addition to those described in this guidance.

1. What is Noncompliance?

- *Noncompliance* is a failure to follow regulations, policies, and ethics guiding research involving human subjects or determinations of the Lindenwood University IRB. Examples of Noncompliance include:
    - Conduct of a research activity without IRB approval or acknowledgement.
    - Use of outdated Consent Forms.
    - Failure to obtain consent from a research participant.
    - Accidental disclosure of research data.
    - Enrollment of participants outside approved inclusion and exclusion criteria.
    - Enrollment of vulnerable populations without prior approval.
    - Use of an individual not on the approved research team to perform research activities.
- *Serious Noncompliance* is Noncompliance that adversely affects the rights and welfare of participants or others. Serious Noncompliance is a failure to follow regulation or policy in such a way that, in the judgment of the convened IRB, increases risks to participants or others, decreases potential benefits to participants, or compromises the integrity of the research.
- *Continuing Noncompliance* is a pattern of Noncompliance which indicates an unwillingness to comply with regulations and policies that may that may place participants or others at increased risk. Continuing Noncompliance is that which will continue unless the IRB or other institutional entities intervene. Examples of continuing noncompliance include:
    - Repeated violations of institutional policies related to research involving human subjects.

- Repeated instances of failure to submit research for approval or acknowledgment prior to the conduct of research.
- Repeated instances of failure to submit required IRB applications, such as Continuing Reviews, Modifications, and Reportable Events.
- Repeated failure to respond to the IRB's inquiries, contingencies, or request for documentation.

2. What is a Major or Minor Deviation?

Noncompliance can take the form of a Major Deviation or Minor Deviation. A deviation is any change made to an IRB approved research protocol without prior approval by the IRB. In determining if an event is a deviation, the researcher should consider the effect the event may have on the safety, rights, and welfare of participants or others and the ongoing scientific validity of a study. A deviation is an event which may adversely affect either of these critical elements of study conduct.

Changes may be made to a study without IRB approval if a research participant or others may experience immediate hazard, in the judgment of the researcher (45CFR46.103(b)(4)(iii), 21CFR56.108(a)(4), and ICH 4.5.2). These events must be subsequently reported according to the timelines outlined in this section.

Any change to IRB approved materials and documents must be approved prior to implementation. This includes items such as the study protocol, recruitment materials and plans, consent documents and plans, or data collection forms. A deviation can differ in severity, each of which requires a different reporting process:

- *Minor Deviation*: A minor change to a study which does not have the potential to adversely affect the rights, safety, or welfare of participants or others.
    - Examples of Minor Deviations include: Participant signs a consent form but does not provide printed name, study visits occurring out of window, participants not compliant with minor elements of the protocol, minor alterations to a sequence of protocol events, enrollment of a few participants over approved target.
    - A summary of Minor Deviations must be reported to the IRB at the time of Continuing Review or Study Closure, if no Continuing Review is submitted.
    - An example of a summary report: "There were several minor deviations from the approved protocol. Two participants did not bring their nutritional diaries to the study visit. One participant performed an intervention out of sequence. These deviations did not increase risk to these participants."
- *Major Deviation*: Any change to a study which has the potential to adversely affect the rights, safety, or welfare of participants or others.
    - Examples of Major Deviations include: Failure to complete a consent process or obtain necessary signatures, use of unapproved recruitment method or material, enrollment of participants who do not meet inclusion/exclusion criteria, administering wrong dosage of study drug or agent, performing activities not described in the approved IRB application, alteration of data security measures, failure to adhere to IRB application and reporting guidelines.

- A Major Deviation must be reported to the IRB within 10 calendar days of discovery of the deviation by any member of the Research Team.

3. How can Noncompliance, Major Deviations, or Minor Deviations be identified?

Deviations from a protocol are primarily identified by the researcher or research team members. Researchers are expected to provide training and oversight research team members, which will increase the chance that deviations will be identified and properly reported. A Researcher (Principle Investigator) is primarily responsible for compliance with all applicable policies and regulations.

Noncompliance is commonly identified in the following ways:

- A report or complaint received from a participant, research team member, or others.
- A report initiated by the Investigator through a Reportable Event Form.
- Information provided in a Continuing Review Form.
- Discovery during audits conducted by the IRB Office or designees.
- A report by the study sponsor or funding agency.

4. When should I report Noncompliance, Major Deviations, or Minor Deviations?

The following reporting timelines apply to these events. Funding agencies or federal entities may have additional requirements, as applicable:

- Minor Deviation: A summary of Minor Deviations must be submitted with the next Continuing Review application or Study Closure Form.
- Major Deviation: 10 calendar days from discovery of the deviation by any research team member. If the deviation is related to a Serious Adverse Event (SAE) or Unanticipated Problem (UP), then SAE and UP reporting timelines take precedence.
- Noncompliance: 10 calendar days from discovery of the noncompliance by any research team member.

5. How will the IRB respond to complaints, allegations, or reports?

The IRB will initially review all allegations or reports of Noncompliance and make one of the following determinations:

- The allegation or report is not substantiated and no further review is required.
- Further information is needed to make a determination.
- The allegation or report is substantiated and will be referred to the IRB for further review.