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IV. Adverse Event

- a. Date/Time of Incident:
- b. Subject(s) ID or Initials:
- c. In your opinion, is this a serious adverse event?
 Yes No Comments:
- d. In your opinion, is this an unexpected adverse event?
 Yes No Comments:
- e. In your opinion, was this incident related to participation in this study?
 Yes No Comments:
- f. Was medical treatment provided for this event?
 Yes No Comments:
- g. Does the subject require further medical treatment?
 Yes No Comments:
- h. Will the subject remain in the study?
 Yes No Comments:
- i. Are consent form changes required to better inform subjects of newly identified risks?
 Yes No Comments:
- j. Include a detailed description of the event:

V. Study Completion

- a. Indicate why you consider the study to be co

Complete research protocols should be submitted electronically to:

The Office of Sponsored Projects
Attention: Compliance Specialist
irb@wiu.edu

Assurance and Submission

Your submission certifies that as a part of the research personnel you understand and accept the following obligations to protect the rights and welfare of research subjects in this research:

COMPLIANCE WITH FEDERAL AND UNIVERSITY REGULATIONS AND STANDARDS

I recognize that as a member of the research team, it is my responsibility to ensure that this research and the actions of all research personnel involved in conducting the study will conform with the IRB approved protocol, IRB policies, and all applicable federal regulations including but not limited to HHS, FERPA, PPRA, and/or HIPAA regulations.

I understand that failure to comply with all applicable HHS, FERPA, PPRA, and/or HIPAA regulations, IRB policies and procedures, and the provisions of the protocol as approved by the IRB may result in suspension or termination of my research project, notification of appropriate governmental agencies by the IRB, and/or suspension of my freedom to present or publish results.

IRB APPROVAL OF ALL PROTOCOLS

I will not initiate any change in protocol without IRB approval except when it is necessary to reduce or eliminate a risk to the subject in which case the IRB will be notified as soon as possible.

I understand that IRB approval is valid for no more than one year with continuing review by the IRB required at least annually in order to maintain approval status. I will not enter subjects in the study before IRB approval or if IRB approval expires. In the latter case, I will immediately contact the IRB to obtain permission to continue subjects in the research study.

I recognize that it is my responsibility to ensure that the study has been reviewed for scientific merit and ethical content.

I recognize that it is my responsibility to ensure that there is constant open dialogue between myself and the other research personnel to ensure that the research is conducted correctly, and the safety and protection of the subjects are ensured.

I recognize that it is my responsibility to ensure that valid informed consent/assent/parental permission has been obtained from all research subjects or their legally authorized representatives. I will ensure that all project personnel involved in the process of consent are trained properly and are fully aware of their responsibilities relative to the obtainment of informed consent according to the IRB guidelines and applicable federal regulations. I will use only the currently approved, informed consent form or script for recruiting subjects.

I understand that I am part of the collaborative effort to maintain the integrity of the human subjects' research approval process and procedures to ensure continuous quality improvement and academic excellence at WIU.

COMMUNICATION WITH THE IRB

I will promptly inform the IRB of any event that requires reporting in accordance with IRB policies and procedures on unanticipated events involving risks to subjects or others and adverse events (serious and/or unexpected).

I will inform the IRB immediately of *any* significant negative change in the risk/benefit relationship of the research as originally presented in the protocol and approved by the IRB.

I will inform the IRB immediately if I become aware of any violations of HHS regulations (45 CFR 46), FERPA regulations (34 CFR 99), PPRA regulations (34 CFR 98), HIP Tc 476a8 Tc 13.08 0 T(4)-6.021j0 Tc [Tj024()21.084(C)-769),

IRB MONITORING OF STUDIES

I will maintain all required research records and recognize that the IRB and federal government is authorized to inspect these records.

I understand that, per OHRP/FDA guidelines, the IRB will be monitoring adherence to approved research protocols. The oversight process does not end with approval of a research protocol.

PRINCIPAL INVESTIGATOR/FACULTY ADVISOR ASSURANCE

I certify, as a faculty sponsor, that the student investigator is knowledgeable about the IRB policies and applicable federal regulations governing research with human subjects and has sufficient training and experience to conduct this study in accord with the approved protocol. In addition, I will meet with the student investigator on a regular basis to monitor study progress. Should problems arise I agree to be available personally to supervise the student investigator in solving them. If I will be away, I will arrange for an alternate faculty sponsor to assume my responsibilities.

By submitting this request to irb@wiu.edu