

IRB Adverse Event Reporting Form
Human Participants in Non-medical Research

Primary investigators are required to report unanticipated problems and adverse events promptly after their occurrence. PIs should submit their report no more than five working days after the incident is reported to the investigator. A separate report must be filed for each incident.

Unanticipated problems are regarded as “unanticipated problems involving risks to subjects or others” (HHS regulations at 45 CFR part 46) and have been further specified by the OHRP as “any incident, experience, or outcome that meets **all** of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.”

Adverse effects are defined as: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research. However, some examples of such incidents that are not limited to biomedical research include (but are not limited to): physical or emotional harm, a breach in confidentiality or privacy, and any problem that increases the risk to participants’ rights and safety.

Project Title:

Principal Investigator:

Date Submitted: _____ :

Date of Event:

1. DESCRIBE THE UNANTICIPATED PROBLEM/ADVERSE EVENT:

- a. Describe the nature and timing of the event.
- b. Describe any corrective action that was required due to the event (e.g., hospitalization, supportive treatment, etc.).
- c. Assess the likelihood that the event was caused by participation in the research:
 Definitely yes
 Probably yes
 Possibly yes
 Probably no
 Definitely no
- d. Will the participant continue in the study?

2. ASSESS FUTURE RISK

- a. Does this event require modifications to the procedures involved in the study? yes no
- b. Does this event require modifications to the consent document for the study? yes no
- c. Describe actions taken to minimize reoccurrence.