

University of South Carolina
ADVERSE EVENT (AE) REPORTING GUIDELINES

DHHS regulations [45 CFR 46.103(b)(5)] require institutions to have “written procedures for insuring the prompt reporting to the Institutional Review Board (IRB), appropriate institutional officials, and federal departments or agencies, any unanticipated problems involving risks to human subjects or others.” These problems are frequently referred to as **ADVERSE EVENTS** (defined below). According to FDA regulations (21 CFR 312.32), IND safety reports shall address “any adverse experience associated with the use of a drug that is both serious and unexpected.” Because the IRB is responsible for the continued assessment of the risks versus benefits of research involving human subjects, investigators are required to notify the IRB of any adverse event fulfilling the following criteria:

1. The adverse event is **SERIOUS** (as defined below),
or
2. The adverse event is not serious, but is **UNEXPECTED** and its association with the study drug, device, or research-related procedure is either **DEFINITELY**, **PROBABLY**, or **POSSIBLY RELATED**, or **UNKNOWN** (as defined below).

The Adverse Event Reporting Form should be used to report these events. This policy is not limited to adverse events resulting from investigational drugs, but also includes AEs involving any investigational device or research-related procedure. Federal policy [45 CFR 46.116(b)(5)] also requires that investigators inform subjects of any important new information that might affect their willingness to continue participating in the research. The IRB should receive copies of any such information conveyed to subjects. When an adverse event necessitates changes to the consent/assent form(s) and/or protocol, or that notification is given to currently or previously enrolled subjects, an amendment request should be submitted in conjunction with the adverse event report. The IRB will make a determination whether any new findings, new knowledge, or adverse effects should be communicated to subjects.

If the adverse event involved the death of a subject enrolled by a USC investigator, it should be reported immediately. Serious unexpected adverse events are to be reported to the IRB within 48 hours, and all others within 10 working days of notification of the event.

In some instances, adverse events or “unanticipated problems” result in social or psychological harm rather than physical harm to subjects or others. These events should also be reported to the IRB within 10 days, unless they are considered “serious”. A letter format may be used for reporting these events instead of the Adverse Event Reporting Form, as applicable.

Please send the completed form and additional materials (if necessary) to:

Office of Research Compliance
Room 515, Byrnes Building
University of South Carolina
Columbia, SC 29208
Email: researchrisksinfo@osu.edu

The IRB will review all serious adverse event reports to reevaluate the risks and benefits of the research, need for changes, etc. All other reportable adverse events (i.e., unexpected and related or unknown) will be reviewed administratively, unless IRB review is recommended. Principal investigators will be notified of any action taken, usually within 30 days.

DEFINITIONS

Adverse event: Any unfavorable and unintended sign (including abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure; also an “unanticipated problem” of any nature (e.g., psychological or social harm) (designated as unrelated, definitely related, probably related, or possibly related; see below)

Serious adverse event: Any adverse event that is fatal or life threatening, is permanently disabling, requires inpatient hospitalization or prolongs hospitalization, or results in a congenital anomaly or birth defect

Life-threatening event: Any adverse event in which the subject is at immediate risk of death from the reaction as it occurs; does not include a reaction that, if it were to occur in a more serious form, might cause death

Unexpected event: Any adverse event that is not identified in nature, severity, or frequency in the investigator brochure, study protocol, consent form, or IND application; or the event was more serious than anticipated

Association:

Definitely Related: An adverse event that has a timely relationship to the administration of the investigational drug/study procedure and follows a known pattern of response for which no alternative cause is present

Probably Related: An adverse event that has a timely relationship to the administration of the investigational drug/study procedure and follows a known pattern of response, but for which a potential alternative cause may be present

Possibly Related: An adverse event that has a timely relationship to the administration of the investigational drug/study procedure, follows no known pattern of response, but a potential alternative cause does not exist

Not related: An adverse event for which there is evidence that it is definitely related to a cause other than the investigational drug/agent; in general, no timely relationship to the administration of the drug/procedure exists, or if so, the event does not follow a pattern of response and an alternative cause is present