

“Unanticipated Problems” What They Are and How to Report Them



Continue to report events/problems considered to be “serious adverse events, major protocol violations, or serious adverse drug effects, etc. using the “Serious Events/Problems Report (SEPs)

Federal Regulations for reporting “Unanticipated Problems”

Federal regulations now require prompt reporting to the IRB **not only** of untoward events **but ALSO** unanticipated events/problems that “**suggest**” that there may be **increased risk** of untoward events to subjects or others. “Others” refers to investigators, research staff, or other individuals who were affected or who may be affected by the event/problem.

What does this mean for investigators?

This means that investigators are now responsible for reporting the following:

- **Continued reporting** of events/ problems considered to be “serious adverse events,” “major protocol violations,” and “serious adverse drug events, etc.,
AND
- **Additionally to report** “unanticipated” events/problems that “**SUGGEST**” that there may be increased risk to subjects or others – **regardless of whether an untoward event has occurred**. Risks may be physical, psychological, economic, or social.

The “Serious Events/Problems (SEPs) - Initial Report Form”

To help investigators meet new reporting requirements, the “Serious Events/Problems Report (SEPs) Form - Initial Report” has been developed to **combine** the reporting of SAEs and other serious events and problems (with which investigators are already familiar) together with the new reporting requirements for “unanticipated problems involving increased risk to subjects or others” (note: unanticipated increased risk is considered to be “serious”). The form provides a step-by-step process for investigators to assess whether an event/problem is serious and, if it is, how and when to report it to the IRB.

Examples of “unanticipated problems” that suggest increased risk:

- *As a result of a processing error by a pharmacy technician, a subject enrolled in a clinical trial receives a dose of an experimental agent that is 10-times higher than the IRB-approved protocol dose. While the dosing error increased the risk of toxic manifestations of the experimental agent, the subject experienced no detectable harm or adverse effect after an appropriate period of careful observation. Nevertheless, this constitutes a reportable event that was unanticipated and it increased risk to the subject.*
- *A subject on a study medication reports feelings of aggression which is not a side effect listed in the IRB-approved protocol or consent document. While there was no indication that the subject took any action on the aggressive feelings, this is a reportable event because it was unexpected and the subject and “others” may be at increased risk.*
- *Data from a survey that asks questions about illegal drug use is stored (without encryption) on a flash drive. The flash drive is lost or stolen. This is a reportable event because it was unanticipated and the risk of breach of confidentiality of the study data has increased – placing subjects at greater risk of psychological, social, and/or legal harm.*



Also report “unanticipated” events/ problems that “**SUGGEST**” there may be **increased risk** to subjects or others — **regardless of whether an untoward event has occurred** using the “Serious Events/Problems Report (SEPs) - Initial Report Form”