

Guidance for Clinical Investigators, Sponsors, and IRBs

Adverse Event Reporting to IRBs — Improving Human Subject Protection

U.S. Department of Health and Human Services

Food and Drug Administration

Guidance for Clinical Investigators,

Contains Nonbinding Recommendations

**Guidance for Clinical Investigators, Sponsors, and IRBs¹
Adverse Event Reporting to IRBs — Improving Human Subject
Protection**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

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The major exceptions to the general rule that an isolated event is not informative are serious AEs that are uncommon and strongly associated with drug exposure, such as angioedema, agranulocytosis, anaphylaxis, hepatic injury, or Stevens Johnson syndrome. In most cases, a single, unexpected occurrence of this type of event would be considered an unanticipated problem involving risk to human subjects and, thus, must be reported to the IRB. Similarly, one or a small number of serious events that are not commonly associated with drug exposure, but are otherwise uncommon in the study population (e.g., tendon rupture, progressive multifocal leukoencephalopathy)

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unanticipated problem involving risk to human subjects. We recommend that a discussion

