

## VA Requirement to Report Serious Adverse Events (SAE) to the IRB

Investigators must report all **local or internal unanticipated** serious adverse events to the IRB **within 5 business days of becoming aware** of the event; **even if** you believe that the event is unrelated to the study.

- The VA defines “**serious adverse event**” (SAE) as follows:  
An SAE in human research is an AE that results in death, a life threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect. An AE is also considered serious when medical, surgical, behavioral, social, or other intervention is needed to prevent such an outcome).

- VHA requires that:  
Within 5 business days of becoming aware of **any local** (i.e., occurring in the reporting individual’s own facility) **unanticipated** SAE in VA research, members of the VA research community are required to ensure that the SAE has been reported in writing to the IRB. *NOTE: This requirement is in addition to other applicable reporting requirements (e.g., reporting to the sponsor under FDA requirements). The unfounded classification of an SAE as “anticipated” constitutes serious noncompliance.* [VHA Handbook 1058.01 Par 7.c]

Note that relatedness is not included in this requirement.

- The IRB requires that:  
“**Reportable new information**” (RNI) that falls into one of thirteen categories must be reported to the IRB within 5 business days of becoming aware of the information.
  - **Item 13** of the list of RNI items to be reported to the IRB within 5 days is as follows:  
For Veterans Administration (VA) research all local or internal unanticipated serious adverse events.

- Therefore:
  - For your VA research projects, report all local or internal unanticipated serious adverse events to the IRB within 5 business days of becoming aware of the event, even if you believe that the event is unrelated to the study.
  - Submit the information to the IRB through the RNI pathway in CICERO.
  - Per VHA requirements, within 5 business days after a report of a serious unanticipated problem involving risks to subjects or others, or of a local unanticipated SAE, **the convened IRB or a qualified IRB**

**member-reviewer** must determine and document whether or not the reported incident was serious, unanticipated, and related to the research. **NOTE:** *Per subparagraph 4p, related means the event or problem may reasonably be regarded as caused by, or probably caused by, the research.* [VHA Handbook 1058.01 Par 7.d]

- If the convened IRB or the qualified IRB member-reviewer determines that the problem or event is serious and unanticipated and related to the research, the IRB Chair or designee must notify ORO via telephone or e-mail within 48 hours and report the problem or event directly (without intermediaries) to the facility Director within 5 business days after the determination. [VHA Handbook 1058.01 Par 7.d(1)]

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