A Serious Adverse Event (SAE) or a Problem Involving Risks to Subjects or Others occurs in VA research.

The SAE or problem is **UNANTICIPATED** (i.e., it reflects a **risk** that is **NEW** or **GREATER** than previously known).

The event or problem **MAY REASONABLY BE REGARDED AS**:
- Involving **SUBSTANTIVE HARM** (OR **A GENUINE RISK OF SUBSTANTIVE HARM**) to the safety, rights, or welfare of human research subjects, research staff or others; **OR**
- **SUBSTANTIALLY COMPROMISING THE EFFECTIVENESS** of the facility’s human research protection or human research oversight programs.

**SPECIAL REPORTING IS REQUIRED**: The individual identifying the event or problem must ensure that it is reported to the IRB within **5 BUSINESS DAYS**.

The convened IRB or a qualified IRB member-reviewer must **CATEGORIZE** the event or problem within **5 BUSINESS DAYS** after the report.

The convened IRB or qualified IRB member-reviewer categorizes the event or problem as **UNANTICIPATED and SERIOUS and RELATED** to the research.

**SPECIAL REPORTING IS REQUIRED**:
- The **IRB Chair** must report the Unanticipated SAE or Serious Unanticipated Problem to ORO (phone or email) within **48 HRS** and to the **Facility Director** within **5 BUSINESS DAYS**.
- A simultaneous copy of the report to the Facility Director must be sent to the ACOS/R and the R&D Committee.
- The **Facility Director** must report the Unanticipated SAE or Unanticipated Serious Problem to the **ORO Regional Office** within **5 BUSINESS DAYS**.

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1. An SAE is an untoward physical or psychological occurrence in human subject participating in research that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect, or that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome [VHA Handbook 1058.01 §§4b & 4w].

2. "Related" means the event or problem may reasonably be regarded as caused by, or as probably caused by, the research [VHA Handbook 1058.01 §4p].

3. The convened IRB or qualified IRB member-reviewer must also document whether or not action is needed to prevent an immediate hazard to subjects. If consent or protocol modifications are required, the convened IRB must determine whether previously enrolled subjects must be notified, and if so, when and how notification must occur and be documented [VHA Handbook 1058.01 §6d].

[ORO: 12.01.2011]