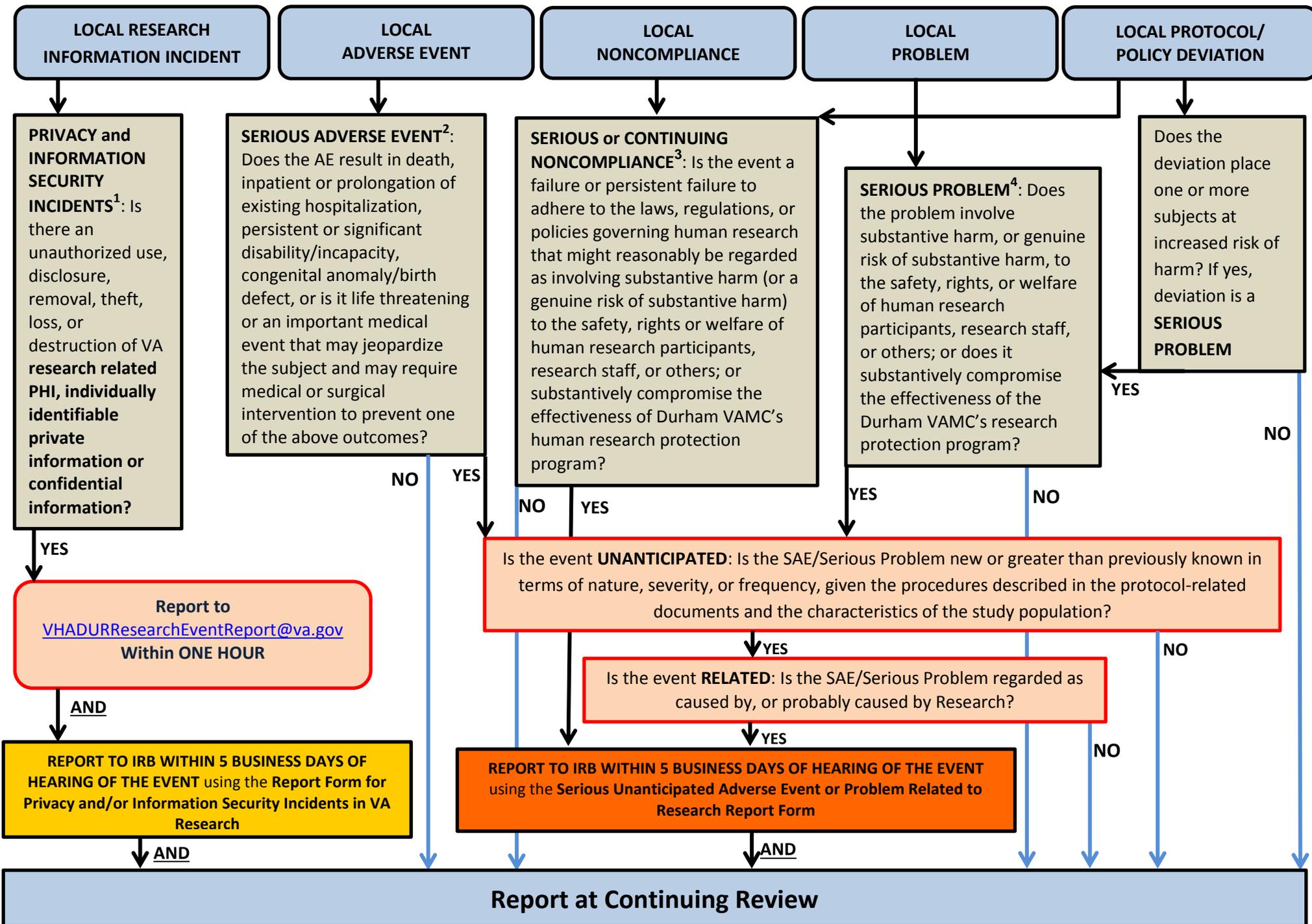


# Durham VAMC Local Research Reporting: Noncompliance, Research Information Incidents, Adverse Events, Protocol Deviations and Problems



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### <sup>1</sup>**PRIVACY and INFORMATION SECURITY INCIDENTS**

- Privacy and Information Security incidents related to VA research, include any inappropriate access, loss or theft of PHI; noncompliant storage, transmission, removal, or destruction of PHI; or theft, loss or noncompliant destruction of equipment containing PHI

### <sup>2,4</sup>**SAE and SERIOUS PROBLEM REPORTING:**

- VA personnel, including WOC and IPA appointees, must ensure written notification of the IRB within 5 business days after becoming aware of any local SAE or serious problem that is **both unanticipated and related to the research**. SAEs and Serious Problems that are anticipated and/or unrelated to research will be reported at continuing review.

### <sup>3</sup>**EXAMPLES of SERIOUS NONCOMPLIANCE:**

- Initiation of VA human subject research, regardless of level of risk or number of subjects, without written notification from the ACOS for Research that the project may begin.
- Initiation of VA human subject research, regardless of level of risk or number of subjects, without approval by the IRB.
- Initiation of research interactions or interventions with one or more subjects prior to obtaining required informed consent.
- Lack of a required, signed informed consent document or lack of a required, signed Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule authorization for one or more subjects.
- Use of an informed consent document, for one or more subjects, whose content was not approved by the IRB.
- Failure to report one or more unanticipated and related SAEs or unanticipated and related serious problems involving risks to subjects or others to the IRB.
- Participation by one or more members of the research team in the conduct of an active protocol without the required credentialing, privileging, or scope of practice, or engaging in activities outside the approved scope of practice.
- Continuation of interactions or interventions with human subjects beyond the specified IRB approval period.
- Implementation of protocol changes without IRB approval, except where necessary to prevent immediate hazard to a subject.
- Involvement of prisoners in VA research, or conduct of international VA research, without the required approval by the VHA Chief Research and Development Officer (CRADO).

### <sup>4</sup>**EXAMPLES OF SERIOUS PROBLEMS:**

- Interruptions of subject enrollment or other research activities due to concerns about the safety, rights, or welfare of human research subjects, research staff, or others.
- Any work-related injury to personnel involved in human research or any research-related injury to any other person that requires more than minor medical intervention (i.e., basic first aid), requires extended surveillance of the affected individual(s), or leads to serious complications or death.
- Any VA National Pharmacy Benefits Management (PBM) Bulletins relevant to a research project.
- Any DMC, DSMB, or DSMC report describing a safety problem.
- Any sponsor analysis describing a safety problem for which action at the facility level may be warranted. **NOTE: Sponsor AE reports lacking meaningful analysis do not constitute “problems.”**
- Any protocol deviation that places one or more subjects at increased risk of harm.