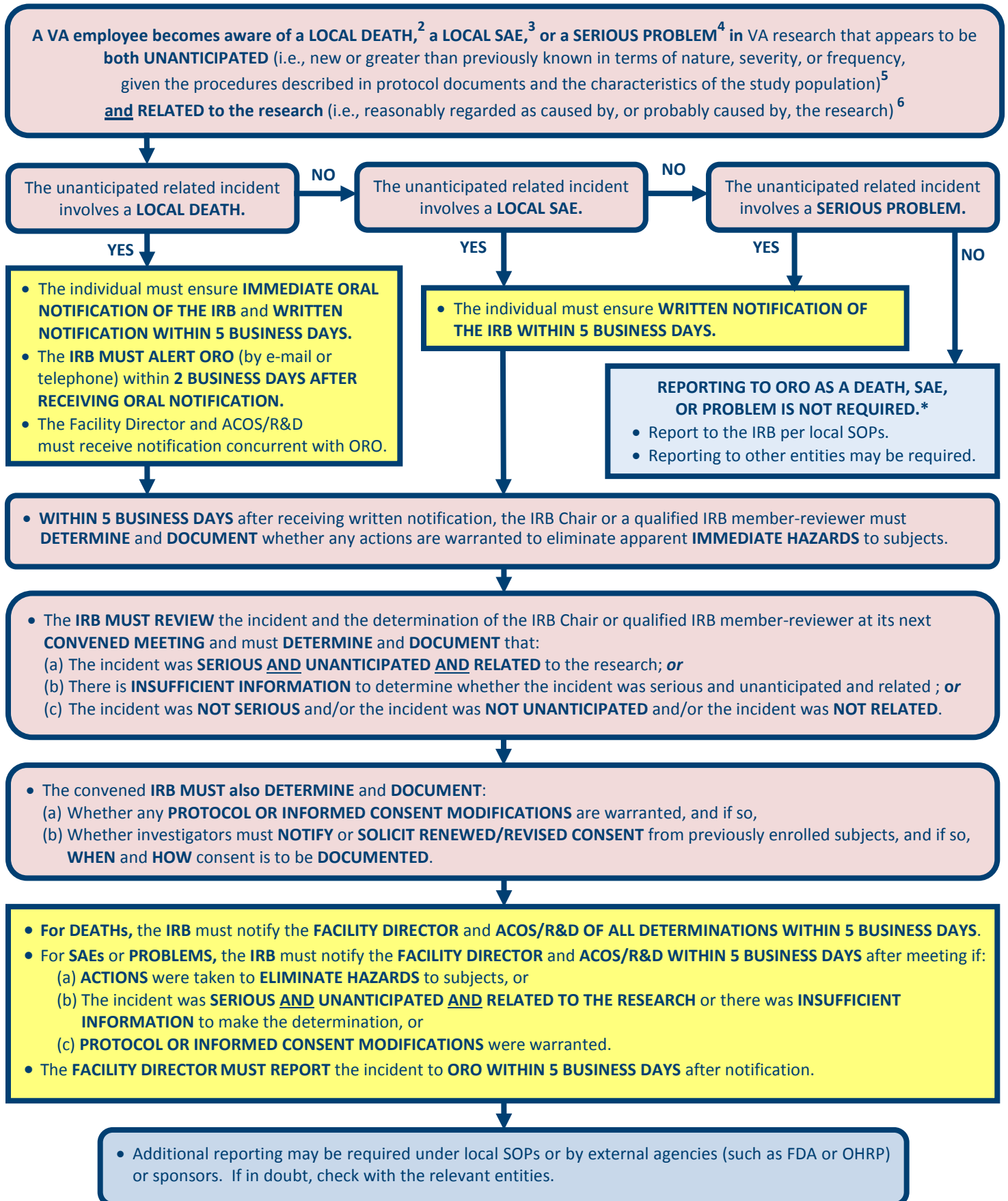


Reporting Local Deaths, Local Serious Adverse Events (SAEs), and Serious Problems in VA Research¹

September 14, 2015



OFFICE OF RESEARCH OVERSIGHT

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NOTES

¹ For complete details, see 38 CFR 16.103(b)(5)(i); 21 CFR 56.108(b)(1), 312.32(a), & 812.3(s); and VHA Handbook 1058.01 §4g, §4j, §4r, §4t, §4y, & §§6a-6.d. This chart does not cover other reportable situations (e.g., program changes, suspensions/terminations). Also see the following ORO guidance;

- *Examples and a Brief Guide for Reporting Apparently Serious Research Information Security Problems That May Be Reportable to ORO under VHA Handbook 1058.01 (Revised September 14, 2015).*
- *Examples and a Brief Guide for Reporting Apparently Serious or Apparently Continuing Noncompliance in Human Research That May Be Reportable to ORO under VHA Handbook 1058.01 (Revised September 14, 2015).*

² **Local** means occurring at the reporting facility's own research site(s). (VHA Handbook 1058.01§4g)

³ An **SAE** is an untoward occurrence in human 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§4r)

⁴ A **serious problem** is a problem in human research or research information security that may reasonably be regarded as: (1) Presenting a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or (2) Substantively compromising a facility's HRPP or research information security program. (VHA Handbook 1058.01§4t)

Examples of apparently serious problems in human research that may be reportable to ORO include the following:

- (1) Any situation that requires action to prevent an immediate hazard to subjects or others.
- (2) Any serious research-related injury to human research subjects, research personnel, or others.
- (3) Any problem described in a VA Pharmacy Benefits Management alert relevant to local human subjects.
- (4) Any problem described in a Data Monitoring Committee report.
- (5) Any combination of problems that collectively present a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others, or substantively compromise a facility's HRPP.

⁵ **Unanticipated/unexpected** refer to an event/problem in human research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol documents and the characteristics of the study population. (VHA Handbook §4y)

⁶ A **related** adverse event (AE, VHA Handbook §4a), death, or problem is one that may reasonably be regarded as **caused by**, or **probably caused by**, the research. [(HA Handbook §4j)]