

OFFICE OF RESEARCH OVERSIGHT
Summary of Major Changes in Research Compliance Reporting Requirements
Under VHA Handbook 1058.01 Issued June 15, 2015

*The revision of VHA Handbook 1058.01, issued June 15, 2015, generally simplifies and reduces reporting requirements. This summary **only** lists **major** changes resulting from the revision. It is **not** a comprehensive list of **all** changes.*

4. DEFINITIONS

- x. **Systemic Deficiency.** A systemic deficiency is a fundamental, underlying problem that jeopardizes the effectiveness of the facility's research protection system(s).

5. SYSTEMIC REQUIREMENTS AND RESPONSIBILITIES

- b. **Reports to ORO.** The Facility Director must ensure that ORO is notified within 2 business days of: (a) Any research-related citation or determination of regulatory noncompliance issued by any State or Federal agency; or (b) Any situation covered by this Handbook that has generated media attention or Congressional interest.
- h. **Systemic Deficiencies.** VA personnel must ensure written notification of the R&D Committee within 5 business days after becoming aware of any apparent systemic deficiency.
- i. **R&D Committee Responsibilities.** ➤ Convened R&D Committee must determine within 30 business days whether the deficiency could substantially compromise the Facility's research protection programs, and if so determine what remedial actions are warranted and notify the VA facility Director and the ACOS/R&D within 5 business days. ➤ Facility Director must report R&D Committee determinations to ORO within 5 business days.
- j. **Voluntary Alerts to ORO.** ORO welcomes voluntary "preliminary" and "near miss" alerts about incidents that are unusual, likely to result in reportable events, or could have resulted in reportable events.

6. HUMAN RESEARCH

- a. **Local Research Deaths.** ➤ **Immediate oral notification** (written notification within 5 business days) of IRB of any local research **death** that is **both** unanticipated **and** related to the research. ➤ IRB must alert ORO by email or telephone within 2 business days of oral notification. ➤ Within 5 business days of written notification, IRB Chair/member must determine/document whether actions are warranted to eliminate apparent immediate hazards to subjects. ➤ IRB must determine/document at next convened meeting that the death was or was not unanticipated and related to the research or there is insufficient information to make a determination; whether modifications are warranted; and whether/when/how investigators must notify or solicit renewed consent from enrolled subjects. ➤ IRB must notify facility Director within 5 business days of determinations. ➤ Facility Director must report to ORO within 5 business days after notification.
- b. **Local SAEs / c. Serious Problems.** ➤ Written notification of IRB within 5 business days of incidents that are **both** unanticipated **and** related to the research. ➤ Rapid (48-hour) alert to ORO no longer required. ➤ Review within 5 business days by IRB/Chair and review by convened IRB as above. ➤ Notification to Facility Director of IRB determinations if actions were taken to protect subjects, IRB requires modifications, or IRB determines incident was unanticipated and related to the research or there is insufficient information to make a determination. ➤ Facility Director must report to ORO within 5 business days after notification.

7. ANIMAL RESEARCH and 8. RESEARCH SAFETY

- 7.g. and 8.f. **Additional Review of Reported Incidents.** Within 5 business days of receipt, the Facility Director must notify ORO and the IACUC/SRS of any separate determination by other Facility officials or committees that a reportable animal research incident or research safety incident has occurred.

10. RESEARCH INFORMATION SECURITY

- b. **Review of Incidents.** Except for issues requiring an Issue Brief to VHACO, notification of or provision of credit monitoring to an individual, notification under the HITECH Act, or notification to OIG, **only** incidents determined by the relevant review committee to be a "serious problem" must be brought to the attention of the MCD and ACOS/R&D, and then to ORO.