

OFFICE OF RESEARCH OVERSIGHT
Implementation of Changes in Research Compliance Reporting Requirements
Under VHA Handbook 1058.01 (Revised August 19, 2015)

The revision of VHA Handbook 1058.01, issued June 15, 2015, became effective immediately upon publication and should be implemented as quickly as possible. However, ORO recognizes that research facilities need a reasonable period of time to update their Standard Operating Procedures (SOPs) to comply with the revised requirements. **ORO strongly recommends that all such revisions be completed and fully implemented no later than October 1, 2015.**

The revised Handbook generally simplifies and reduces research compliance reporting requirements. Major changes are listed in the attached summary. However, this summary **only** lists **major** changes resulting from the revision. It is **not** a comprehensive list of **all** changes. Research facilities should review the Handbook carefully to identify any modifications in local SOPs that are needed to ensure compliance. Of course, **facilities are free to retain local requirements that exceed those required by the revised Handbook** where such requirements are working well and serve the needs of the local research oversight program.

Additional Clarifications:

1. Until instructed otherwise, reports and questions should continue to be directed to the responsible ORO Regional Office or Specialty Group as follows:
 - a. Research and Development (R&D) Committee and Human Research Protection Program (HRPP) issues (including privacy issues per Paragraphs 6 and 10 of the revised Handbook) should be directed to the ORO Regional Office to which the facility has been assigned.
 - b. Research Compliance Officer (RCO) issues should be directed to ORO's Research Compliance Education Program (RCEP).
 - c. Institutional Review Board (IRB) Memorandum of Understanding (MOU) and Federalwide Assurance (FWA) issues should be directed to the ORO/RCEP FWA Administrator (currently Ms. Priscilla Craig).
 - d. Laboratory animal welfare, research safety, and research laboratory security issues should be directed to ORO's Research Safety and Animal Welfare (RSAW) program.
 - e. Research information security issues should be directed to ORO's Research Information Security Program (RISP).
 - f. Research Misconduct issues should be directed to the ORO Research Misconduct Officer.
2. New VHA publication guidelines resulted in the deletion of Handbook links to the ORO SharePoint library that houses the RCO audit tools and related requirements. This information continues to be available at:

<https://vaww.vha.vaco.portal.va.gov/sites/ORO/RCO/Audit%20Tools/Forms/AllItems.aspx?RootFolder=%2Fsites%2FORO%2FRCO%2FAudit%20Tools%2FCURRENT%20Audit%20Tools%20%28Reporting%20Period%20June%201%2C%202015%20%2D%20May%2031%2C%202016%29&FolderCTID=0x012000D755A7FBD1AA0E47ACCCDA8594B4591C&View={9A70B2B7-857B-4131-9C0E-35BE15F7B590}>

and

[https://vaww.vha.vaco.portal.va.gov/sites/ORO/RCO/Audit%20Tools/CURRENT%20Audit%20Tools%20\(Reporting%20Period%20June%201,%202015%20-%20May%2031,%202016\)/2015-16%20ORO%20Guidance%20for%20RCO%20Research%20Audit%20and%20Training%20Requirements.docx](https://vaww.vha.vaco.portal.va.gov/sites/ORO/RCO/Audit%20Tools/CURRENT%20Audit%20Tools%20(Reporting%20Period%20June%201,%202015%20-%20May%2031,%202016)/2015-16%20ORO%20Guidance%20for%20RCO%20Research%20Audit%20and%20Training%20Requirements.docx)

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3. In an effort to provide improved guidance that more clearly emphasizes the **Handbook definitions at §§4.t and 4.s**, ORO has issued updated, more instructive examples of possibly reportable, apparently serious problems and noncompliance. Examples previously provided by ORO may still be illustrative, although ORO does not recommend strict reliance on “numbers” of events in distinguishing between reportable versus non-reportable situations. Likewise, ORO did not wish to imply in previous guidance that continued use of identifiable private information beyond the specified approval period was a “permissible” or “less serious” form of noncompliance as compared with continued interactions or interventions with human subjects beyond the specified approval period; hence the revision in the current examples.
4. The **revised Handbook at §5.g** indicates that “required” RCO notifications to the facility Director must be made in writing without intermediaries. Although the Handbook lists no specific “required” notifications from the RCO to the facility Director (a change from the prior version of the Handbook), the intent here is to make clear that any RCO notifications to the facility Director, where deemed warranted by the RCO, must be transmitted directly to the facility Director and cannot be routed through intermediaries for review or clearance. ORO recommends that local SOPs provide examples of any such notifications that the facility chooses to encourage or require locally.
5. The **revised Handbook at §5.h** requires that the Research and Development (R&D) Committee be notified “of any apparent systemic deficiency that has a reasonable likelihood of substantially compromising the facility’s research protection programs.” The “reasonable likelihood” language is intended to screen out frivolous complaints of systemic deficiencies that have no demonstrable relationship to program effectiveness. ORO recommends that local SOPs describe supplemental procedures for providing additional, timely notification of the facility Director and the Associate Chief of Staff for Research and Development (ACOS/R&D) regarding any apparent systemic deficiencies involving the R&D Committee.
6. The **revised Handbook at §6.a** requires oral and written notifications to the IRB and rapid email/telephone alerts to ORO of apparent unanticipated deaths related to VA research. The IRB has two business days after receiving the oral notification to confer with the investigator to clarify and confirm the accuracy of the notification before a call or email to ORO is required. If during that time the investigator and the IRB agree that the notification was made in error (for example, because the death did *not* reasonably appear to be both unanticipated and related to the research), no call/email to ORO is required, and the error should simply be documented in the IRB protocol file. Most deaths reported to ORO under the special 2-day and 5-day timelines are characterized as “apparent” unanticipated, related deaths, pending the IRB’s final determination (which often takes weeks or months to resolve). These requirements stem from a direct mandate from the Secretary of Veterans Affairs that ORO rapidly report all such suspected deaths to the Secretary’s Incident Response Committee. *NOTE: An unanticipated death of a research subject that does not reasonably appear to be related to the VA research is not required to be reported under the procedures at §6.a.*
7. The **revised Handbook at §§6.a, 6.b, and 6.c**, requires that VA personnel provide notifications of local research deaths, local SAEs, and serious problems that reasonably appear to them to be both unanticipated and related to the research. These notifications do not represent formal determinations that the incident was, in fact, unanticipated and related to the research. Such formal determinations are reserved for the IRB.
8. The **revised Handbook at §6.d** requires that the IRB Chair “or a qualified IRB member-reviewer” determine and document, within 5 business days after the IRB receives written notification of an SAE or

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serious problem in VA research, whether any actions are warranted to eliminate apparent immediate hazards to subjects. This “determination” requirement is to be distinguished from the authority granted at **§6.f(1)** under which the IRB Chair may take interim action to eliminate apparent immediate hazards to subjects resulting from serious or continuing noncompliance. The latter authority is limited to the IRB Chair (or the Acting IRB Chair as designated under local SOPs). *NOTE: Investigators may themselves take such action under either scenario in accordance with VHA Handbook 1200.05 §7.a(3).*

9. The **revised Handbook at §6.f(3)(e)** requires that the IRB track its determinations and notifications regarding apparent serious or continuing noncompliance. Reporting of this information will begin with the Facility Director Certification (FDC) submitted in CY2016 (i.e., for the reporting period that began June 1, 2015). Facilities will be asked to provide (a) the number of notifications received by the IRB (from the Research Compliance Officer (RCO) or any source outside the IRB or IRB office) of apparent serious or continuing noncompliance, and (b) the number of such notifications determined by the IRB to represent actual serious or continuing noncompliance.
10. The **revised Handbook at §6.g** states that “[t]he IRB must be notified of, and review, other apparent noncompliance (not covered by paragraph 6.f) in accordance with local SOPs.” For example, single instances of “non-serious” noncompliance with IRB or other human research protection requirements are generally not reportable to the IRB under VHA Handbook 1058.01. Nonetheless, local facilities *may* require that such noncompliance be reported to the IRB pursuant to its own local SOPs.
11. The **revised Handbook at §7 and §8** does not include the examples of reportable incidents involving **laboratory animal welfare and research safety** that were provided in the previous version of the Handbook. However, the examples in the previous version remain illustrative since they are considered deviations from applicable VHA Handbooks (1200.06, 1200.07, and 1200.08) and/or Federal requirements. Determining non-compliance often involves a careful examination of all contributing factors related to the incident. ORO defers to local oversight committees to make such determinations, as other complex factors often enter into this type of decision. Once a determination has been made, the oversight committee must consider all other relevant reporting requirements to determine if, in addition to ORO, any external agencies should be notified. External agencies have specific reporting requirements and provide guidance to assist programs in determining what to report, as well as when and how reporting should occur. As an example, the NIH Office of Laboratory Animal Welfare (OLAW), which primarily focuses on noncompliance involving research supported by the Public Health Service (PHS), provides examples of reportable situations at Notice Number: [NOT-OD-05-034](#).
12. Although the **revised Handbook** does not specifically reference suspensions or terminations of research related to laboratory animal welfare and research safety, **§7.e and §8.c** require that VA personnel notify the pertinent oversight committee of any incident that appears to be reportable under relevant VHA Handbooks or applicable Federal requirements, and **§7.f(3) and §8.d(3)** require that ORO be notified whenever the oversight committee determines that such an incident is, indeed, reportable. For example, PHS-supported protocols suspended by the IACUC must be reported to OLAW in accordance with Notice Number: [NOT-OD-05-034](#), and any suspension/termination involving USDA-regulated species must be reported to the USDA Animal and Plant Health Inspection Service (APHIS) per USDA regulations at 9 CFR 2.31(d)(7). Consequently, such suspensions/terminations must also be reported to ORO.
13. The number for ORO’s toll free **telephone complaint line** (hot line) is 1-877-343-6562.