Office of Research Oversight

Reporting Systemic Deficiencies and Noncompliance in VA Research[1]

March 12, 2021

VA personnel become aware of **an apparent systemic deficiency[2], or apparent serious[3] or continuing noncompliance[4]** or **animal research event apparently reportable to NIH-OLAW[5]** in VA research.

- The individual ensures that an apparent **systemic deficiency is reported in writing to the Research and Development Committee (R&DC)** within **5 business days.** The R&DC may delegate review to another Research Review Committee (RRC)[6] under certain circumstances.[7]
- The individual ensures that an apparent **serious or continuing noncompliance or animal research event apparently reportable to NIH-OLAW is reported in writing** to the **RRC** having oversight of the research **within 5 business days.**

- The **RRC must review** the report at **its next convened meeting** not to exceed 30 calendar days after the written notification. The RRC must **determine and document within 60 calendar days of the convened initial review:**

  (a) Whether or not **serious or continuing noncompliance** actually occurred, **or** whether an actual **systemic deficiency** exists that could substantially compromise the VA medical facility's research protection programs or information security processes, **or** whether or not an **animal research event reportable to NIH-OLAW** involving VA research has occurred, as applicable; and, if so,

  (b) What, if any, **actions** are needed to **remediate** present noncompliance or **prevent** future noncompliance; or for systemic deficiencies what, if any, remedial actions are needed to **ensure the effectiveness** of research protection programs or information security processes; or, for animal research events reportable to NIH-OLAW, what, if any, **protocol or programmatic changes** are warranted.

NOTE: *For **information security and privacy incidents involving VA research** that are reported and reviewed according to the processes above, the **Information System Security Officer, Privacy Officer or Records Management official**, as applicable, should be consulted when determining whether and what remedial actions are warranted.*

- The RRC must notify the **facility Director, Associate Chief of Staff for Research & Development and Research Compliance Officer** in writing **within 5 business days** after determining that **serious or continuing noncompliance,** a **systemic deficiency,** or an animal research **event reportable to NIH-OLAW** actually exists/occurred**.**

- The **facility Director, or designee, must report** the RRC's determinations to **ORO within 5 business days** after receiving the RRC's written notification of the determination.[8]

Additional reporting may be required under local SOPs or by external agencies (such as the Food and Drug Administration or the Department of Health and Human Services- Office for Human Research Protections) or sponsors. If in doubt, check with the relevant entities.

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Notes

[1]For complete details, see VHA Directive 1058.01, Research Compliance Reporting Requirements, dated October 22, 2020.
NOTE: *This chart does not cover other reportable situations (e.g., program changes, suspensions/terminations).*

[2]A **Systemic Deficiency** is a fundamental, underlying problem that jeopardizes the effectiveness of a VA medical facility's research protection system(s). VA personnel must report any **apparent systemic deficiency** of which they become aware that has a reasonable likelihood of substantially compromising the VA medical facility's research protection programs (Animal Care and Use Program (ACUP), Human Research Protection Program (HRPP) and Research Safety and Security Program (RSSP)) or information security processes, including persistent failure by any research review committee relied upon by the VA medical facility to adhere to the requirements governing VA research. (VHA Directive 1058.01 §3.p & §6.a)

[3]**Serious Noncompliance** is any failure to adhere to requirements for conducting research that may reasonably be regarded as:

(1) Presenting a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects or others, including their rights to privacy and confidentiality of identifiable private information;
(2) Presenting a genuine risk of substantive harm to the safety, rights, or welfare of research personnel who conduct research;
(3) Presenting a genuine risk of substantive harm to the health or welfare of animals used in research;
(4) Presenting a genuine risk of substantive reputational harm to VA; or
(5) Substantively compromising a VA medical facility's ACUP, HRPP, RSSP or research information security processes.

[4]**Continuing Noncompliance** means repeated instances of noncompliance with applicable laws, regulations, policies, agreements, or determinations of a research review committee or the prolonged persistence of noncompliance occurring after its identification, awareness, or implementation of a corrective action intended to effectively resolve the noncompliance. (VHA Directive 1058.01 §3.c & o, §7.c, §8, §9.c, §9.d, §10.c)

[5]**VA Animal Research Events Reportable to U.S. Department of Health and Human Services (HHS) National Institutes of Health Office of Laboratory Animal Welfare (NIH-OLAW).** VA personnel must ensure that the appropriate Institutional Animal Care and Use Committee (IACUC) of Record is notified in writing within five (5) business days after becoming aware of any event that is apparently reportable to HHS NIH-OLAW per NIH Notice No. NOT-OD-05-034, *Guidance on Prompt Reporting to OLAW under the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals*. See https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html. This includes serious or continuing noncompliance with the Animal Welfare Act and Regulations, PHS Policy on Humane Care and Use of Laboratory Animals, and IACUC-approved protocols, as well as unapproved departures from the *Guide for the Care and Use of Laboratory Animals*.
(VHA Directive 1058.01 §9.c)

[6]**Research Review Committee (RRC)** is any committee or subcommittee designated by a VA medical facility to review, approve and provide oversight of VA research. Research review committees include IACUCs, Institutional Biosafety Committees (IBCs), Institutional Review Boards (IRBs), Research & Development Committees (R&DCs), and Subcommittees on Research Safety (SRS), or the equivalents of any such committees, that are relied upon by a VA medical facility, regardless of whether the committees are operated by a VA or a non-VA entity. (VHA Directive 1058.01 §3.k)

[7]In circumstances where the apparent systemic deficiency does not pertain to the operation of a research review committee, the R&DC will delegate the review of the concern to the research review committee with primary programmatic oversight (i.e., to the IRB for HRPP-related systemic deficiencies, the IACUC for ACUP-related systemic deficiencies and the SRS for RSSP-related systemic deficiencies). Under such circumstances, the research review committee with primary programmatic oversight will fulfill the responsibilities described in VHA Directive 1058.01 §§6.b-d, as well as fulfill any other applicable requirements set forth in the directive. The outcome of the committee's review (if not reviewed by the R&DC) must be communicated to the R&DC. (VHA Directive 1058.01 §6.a)

[8]For animal research events including those reportable to NIH-OLAW, copy the IACUC's determinations to the Association for Assessment and Accreditation of Laboratory Animal Care International and the Office of Research and Development Chief Veterinary Medical Officer. (VHA Directive 1058.01 §9.a.(5), §9.b.(4), §9.c.(3), & §9.d.(3))

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