VHA Directive 1058, Office of Research Oversight
Anticipated Frequently Asked Questions (FAQs)
November 19, 2024

Background Information:

Revised VHA Directive 1058 - Office of Research Oversight, dated November 8, 2024, sets forth the responsibilities of the VHA Office of Research Oversight (ORO); requires that certain research-related events be reported to ORO; establishes a requirement for VA medical facilities with research programs to appoint a VA medical facility Research Compliance Officer (RCO); and requires that each VA medical facility engaged in non-exempt human subjects research covered by the requirements of the Federal Policy for the Protection of Human Subjects hold a valid written assurance committing the facility to compliance with that Federal policy. ***NOTE:*** *This revised directive incorporates and/or streamlines content previously contained in VHA Directive 1058.01, Research Compliance Reporting Requirements, dated October 22, 2020, and VHA Directive 1058.03, Assurance of Protection for Human Subjects in Research, dated September 17, 2020, both of which were rescinded by the issuance of revised VHA Directive 1058.*

Major changes introduced by the issuance of this revised directive include:

- Previous versions of VHA Directive 1058.01 provided detailed processes for the reporting of VA research-related events to research review committees relied upon by VA medical facilities and the review of such events by those committees. As it pertains to research-related reportable events, the scope of revised VHA Directive 1058 (which incorporates content from rescinded VHA Directive 1058.01) has been narrowed to primarily address required notifications of those research-related events to ORO. The separate but related requirement for local VA medical facilities to review and address research-related events in conjunction with their responsibilities to provide continuing oversight of research is established in existing 1200 series directives issued by the VHA Office of Research & Development (ORD). The issuance of revised VHA Directive 1058, along with the concomitant rescission of VHA Directive 1058.01, provides VA medical facility personnel and research review committees with greater flexibility in establishing processes and timelines for the internal reporting and review of research-related events so long as those processes and timelines ensure that such events are subsequently reported to ORO within the timeframes specified in the revised directive. ***NOTE:*** *Events that were previously required to be reported to ORO under rescinded VHA Directive 1058.01 largely remain reportable to ORO under the revised directive.*
- The revised directive eliminates the previous policy requirement that VA medical facilities engaged in non-exempt human subjects research covered by the Federal Policy for the Protection of Human Subjects must hold a VA Federalwide Assurance (FWA) addendum approved by ORO. ***NOTE:*** *VA medical facilities engaged in non-exempt human subjects research covered by the requirements of the Federal Policy for the Protection of Human Subjects must continue to maintain a valid FWA on file with the U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP).*

Anticipated FAQs:

Q1. Do VA medical facility personnel seek **approval** from ORD, ORO, or both **to start a new Human Research Protections Program (HRPP)**?

A1. **ORD.** Per VHA Directive 1200.05(3) §5.f.(9), "[e]ach VA medical facility Director is responsible for … [r]equesting [ORD] approval when the VA facility wants to establish a new HRPP…." However, VA medical facility personnel are required to *notify* ORO of the establishment of an HRPP (as well as the establishment of an Animal Care and Use Program (ACUP) or Research Safety and Security Program (RSSP)) per VHA Directive 1058 §2.f(4).

Q2. If a VA medical facility is engaged in non-exempt human subjects research covered by the Federal Policy for the Protection of Human Subjects (*hereafter*, "the Common Rule"), which for VA is incorporated at 38 C.F.R. §16, does the facility still need to hold a valid, up-to-date **FWA approved by HHS OHRP**?

A2. **Yes.** Per VHA Directive 1058 §2.f.(2), "[t]he VA medical facility Director whose VA medical facility has a research program is responsible for … [e]nsuring that the VA medical facility holds a valid FWA approved by HHS-OHRP if the facility is engaged in non-exempt human subjects research covered by the requirements of the Federal Policy for the Protection of Human Subjects ("Common Rule"), which for VA is incorporated at 38 C.F.R. part 16." Further, per VHA Directive 1200.05(3) §5.f.(1), "[a]n FWA is required prior to conducting any [non-exempt] human subjects research subject to the [Common Rule]." ***NOTE:*** *The requirement to hold an FWA does not apply to VA medical facilities engaged solely in human subjects research that is exempt from the requirements of the Common Rule.*

Q3. What is the process for **obtaining, updating, or renewing an FWA approved by HHS-OHRP**?

A3. Information on obtaining, updating, or renewing an FWA approved by HHS OHRP is available at https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/index.html. ***NOTE:*** *The previous requirement in VHA national policy that ORO serve as an administrative intermediary between VA medical facilities and HHS OHRP for obtaining, updating, or renewing of an FWA has been eliminated.*

Q4. If a VA medical facility is engaged in non-exempt human subjects research covered by the Common Rule, does the facility still need to hold a **VA FWA Addendum** approved by ORO?

A4. **No.** The previous requirement in VHA Directive 1058.03 for VA medical facilities engaged in non-exempt human subjects research covered by the Common Rule to hold a VA FWA Addendum approved by ORO has been eliminated.

Q5. If a VA medical facility operates its own **Institutional Review Board (IRB)** for the review and oversight of non-exempt human subjects research covered by the Common Rule, must the IRB still be **registered with HHS OHRP**?

A5. **Yes.** Per VHA Directive 1200.05(3) §5.f.(8), "any IRB operated by the VA facility is established in accordance with the requirements of [VHA Directive 1200.05(3)] and registered … with the HHS OHRP."

Q6. What is the process for **registering an IRB** with HHS OHRP or **updating or renewing the registration for an IRB** currently registered with HHS OHRP?

A6. Information on registering an IRB with HHS OHRP, or updating or renewing an existing IRB registration with HHS OHRP, is available at https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-registration/index.html. ***NOTE:*** *The previous requirement in VHA national policy that ORO serve as an administrative intermediary between VA medical facilities and HHS OHRP for registration of IRB(s) operated by VA medical facilities has been eliminated.*

Q7. If a VA medical facility relies on an external IRB (i.e., an IRB not operated by the VA medical facility) for the review and oversight of non-exempt human subjects research covered by the Common Rule, must the **external IRB** still be **registered with HHS OHRP**?

A7. **Yes.** Per VHA Directive 1200.05(3) §5.f.(8)(d)2, "[w]hen [a VA medical] facility engages the services of another entity's IRB as its IRB of Record, the [VA medical facility Director] is responsible for … [e]nsuring that external IRBs of Record used by the VA facility hold current IRB registrations with … OHRP."

Q8. If a VA medical facility relies on an **external IRB** (i.e., an IRB not operated by the VA medical facility) for the review and oversight of the facility's non-exempt human subjects research covered by the Common Rule, must an IRB **reliance agreement** be executed detailing the arrangement and respective responsibilities?

A8. **Yes.** Per VHA Directive 1200.05(3) §5.f.(8)(d)1, "[w]hen [a VA medical] facility engages the services of another entity's IRB as its IRB of Record, the [VA medical facility Director] is responsible for … [e]stablishing and signing a Memorandum of Understanding (MOU) or Authorizing Agreement with other VA facilities or external organization(s) providing IRB services…." Further, per 38 C.F.R. §16.103(e), "[f]or nonexempt research involving human subjects covered by this policy (or exempt research for which limited IRB review takes place pursuant to §16.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8)) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol)."

Q9. Do VA medical facility personnel seek **approval** from ORD, ORO, or both **to change the facility's IRB(s) of record** (including engaging the services of an additional IRB)?

A9. **ORD.** Per VHA Directive 1200.05(3) §5.f.(9), "[e]ach VA medical facility Director is responsible for … [r]equesting [ORD] approval when the VA facility wants to … change its IRB(s) of Record…."

Q10. With ORO policy having been narrowed to focus on the reporting of **VA research-related reportable events (serious or continuing noncompliance, unanticipated problems, etc.)** to ORO rather than on how such events are reported and reviewed locally within a VA medical facility, are there still expectations that such events will get

reported to applicable research review committees operated or otherwise relied upon by VA medical facilities?

A10. **Yes.** VHA Directives 1200.05, 1200.07, and 1200.08, as well as other policies applicable to VHA research, establish an ongoing (continuing) oversight responsibility for research review committees for the research that the committees approved. A *select* (non-exhaustive) list of examples of policy provisions establishing such a responsibility include:

- Per VHA Directive 1200.05(3) §8.a.(4), "[t]he IRB must establish and follow written SOPs that include, but are not limited to, procedures for … [e]nsuring prompt reporting to the IRB [and] appropriate institutional officials … of: (i) any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB, and (ii) any suspension or termination of IRB approval." *See* also 38 CFR §16.108(a)(4).
- Per the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) (which per VHA Directive 1200.07 §2.b.(2) VA has agreed to abide by), "[t]he IACUC, through the Institutional Official, shall promptly provide … a full explanation of the circumstances and actions taken with respect to: a. any serious or continuing noncompliance with this [PHS] Policy; b. any serious deviation from the provisions of the [*Guide for the Care and Use of Laboratory Animals (Guide)*]; or c. any suspension of an activity by the IACUC." *See* also National Institutes of Health (NIH) Office for Laboratory Animal Welfare (OLAW) Notice #NOT-OD-05-034, "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals," dated February 24, 2005, available at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html.
- Per the *Guide*, "[t]he [Institutional Animal Care and Use Committee (IACUC)] is responsible for … ongoing assessment of animal care and use … and establishment of a mechanism for receipt and review of concerns involving the care and use of animals at the institution."
- Per VHA Directive 1200.08 §5.n.(8), "[t]he [Subcommittee on Research Safety] is responsible for … [e]nsuring that each of the following is evaluated, addressed, and reported … : (a) [a]ny human death that may be the result of work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area); (b) [a]ny serious accident, injury, illness, or exposure (other than those that result in death) that may be the result of work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area); (c) [a]ny intrusion, physical security breach, break-in, or other security violation that occurs in dedicated research areas; (d) [a]ny unplanned suspension or termination of research by the ACOS/R&D or another facility official due to concerns about research laboratory security; and (e) [a]ny other deficiency that substantively compromises the effectiveness of the facility's research laboratory security program."

Q11. Do **VA medical facilities need to implement local processes** to ensure that the VA medical facility Director is notified of events that are reportable to ORO?

A11. **Yes.** Per VHA Directive 1058 §2.f.(15)(a), "[t]he VA medical facility Director whose VA medical facility has a research program is responsible for … [i]mplementing processes

… to ensure that … [e]vents covered by [VHA Directive 1058] are promptly reported to the VA medical facility Director so that the VA medical facility Director, or designee, can submit required notifications to ORO within the timeframes specified in [the] directive."

Q12. How have the **timelines for notifying ORO of the occurrence of reportable research-related events** changed from rescinded VHA Directive 1058.01?

A12. The timelines in revised VHA Directive 1058 for notifying ORO of reportable events are largely set relative to when facility personnel first become aware of the event that is reportable to ORO. In contrast, the timelines in rescinded VHA Directive 1058.01 were largely based on when a research review committee made a determination that an event was reportable. The revised directive provides VA medical facility personnel and research review committees with greater flexibility in establishing processes and timelines for the internal reporting and review of research-related events so long as those processes and timelines ensure that such events are subsequently reported to ORO within the timeframes specified in the revised directive.

Q13. If a VA medical facility **Director designates another individual to submit required notifications of reportable events to ORO** on their behalf, is the Director still required to be notified of the events?

A13. **Yes.** Per the NOTE in VHA Directive 1058 §2.f.(15)(a), "[i]f the VA medical facility Director designates another individual to submit required notifications to ORO on their behalf, the VA medical facility Director must still be notified by VA medical facility personnel of the events covered by this directive and the actions taken or to be taken to mitigate the risks of, correct, or otherwise prevent reoccurrence of the underlying issues/causes of the events."

Q14. If the **deadline for notifying ORO of a reportable event** is approaching and facility personnel do not believe that they will be able to definitively determine prior to that deadline whether an event that occurred meets the criteria for reporting to ORO, should the VA medical facility Director be notified of the event and the event reported to ORO?

A14. **Yes.** Per the NOTE in VHA Directive 1058 §2.f.(15)(b), "[i]n some instances, it may be necessary for a VA medical facility Director, or designee, to submit an initial (preliminary) report to ORO to ensure compliance with the deadlines stipulated in this directive, followed by subsequent report(s) as needed to convey all relevant information." Further, per the NOTE in §1 of Appendix A of VHA Directive 1058, "[i]n some instances, it may be necessary for a VA medical facility Director to submit an initial report, which does not contain all of the information stipulated in … [the] appendix, to fulfill the requirements for prompt reporting to ORO within the deadlines stipulated in … the directive."

For example:
VHA Directive 1058 requires that the VA medical facility Director, or designee, notify ORO promptly, but no later than 60 calendar days after VA medical facility personnel first become aware, of the occurrence of an unanticipated problem involving risks to subjects or others (UPIRTSO). If 60 days after VA medical facility personnel first become aware of the event they have been unable to ascertain whether the event meets the criteria for required reporting to ORO (e.g., VA medical facility personnel

have been unable to determine whether the event was related or possibly related to research), the VA medical facility Director should be notified of the event and the Director (or designee) should submit an initial (preliminary) report to ORO. By submitting the initial (preliminary) report to ORO within 60 days after facility personnel became aware of the event, the VA medical facility Director will ensure compliance with the deadline for reporting the event to ORO if it is subsequently determined to be reportable. *If* an initial (preliminary) report to ORO is not submitted and the event is subsequently (i.e., >60 days after VA medical facility personnel became aware of the event) determined to be reportable to ORO, the facility would be out of compliance with respect to meeting the deadline for reporting the event to ORO.

Q15. What **information** should be **included in a notification** of the occurrence of a research-related reportable event sent **to ORO**?

A15. Paragraph 2 of Appendix A of VHA Directive 1058 addresses the minimum information that should be included in such notifications to ORO.

Q16. To whom in ORO are notifications of reportable events to be sent?

A16. The specific ORO workgroup to be notified of a reportable event is dependent on the nature of the event. Paragraph 3 of Appendix A of VHA Directive 1058 provides guidance as to the appropriate ORO workgroup to be notified. ***NOTE:*** *In some instances, where an event may be overseen by more than one ORO workgroup, VA medical facility personnel need only send the initial notification to one of the ORO workgroups with applicable oversight responsibilities.*

Q17. Where can the contact information of ORO workgroups be found?

A17. Contact information for ORO workgroups is available on ORO's website at https://www.va.gov/ORO/ORO_Contact_Information.asp.