Office of Research Oversight (ORO)
Education and Data Analytics (EDA)
Guidance on Reporting of Research Compliance Officer (RCO) Audit Results

1. Background

Revised Veterans Health Administration (VHA) Directive 1058, Office of Research Oversight, dated November 8, 2024, sets forth the Research Compliance Officer (RCO) responsibilities for reporting RCO audit results to research review committees (RRCs). The issuance of revised VHA Directive 1058, along with the concomitant rescission of VHA Directive 1058.01, provides VA medical facility personnel and RRCs 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 addressed within the timeframes specified in the revised directive. This document provides RCOs with guidance that will assist in understanding those reporting responsibilities and in updating RCO Audit Plans for reporting audit results to RRCs, including external RRCs. It also provides related policy references.

2. Pertinent Definitions in VHA Directive 1058

§8.e. Noncompliance. For purposes of the directive, noncompliance is any failure to adhere to applicable requirements for overseeing, reviewing, approving, or conducting VA research set forth in law, regulation, policy, or study agreements (such as reliance agreements, memoranda of understanding, data use agreements), including any failure to conduct research in accordance with a VA study protocol approved by a research review committee.

§8.c. Continuing Noncompliance. For purposes of the directive, continuing noncompliance means repeated instances of same or similar noncompliance with applicable laws, regulations, policies, agreements, or determinations of a research review committee or the prolonged persistence of noncompliance after its identification, awareness, or implementation of a corrective action intended to effectively resolve the noncompliance.

§8.m. Serious Noncompliance. For purposes of the directive, 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 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 Animal Care and Use Program (ACUP), Human Research Protection Program (HRPP), Research Safety and Security Program (RSSP), or research information security processes.

3. Reporting Audit Results

Audits with No Findings of Noncompliance

VHA Directive 1058 does not require the RCO to report the results of audits that do not identify noncompliance to the appropriate RRC or to the Research and Development Committee (R&DC); however, local policies may still require the RCO to report audits with no findings of noncompliance. The

RCO should refer to their local or RRC policy for requirements related to reporting of audits with no findings of noncompliance.

Audits Identifying Noncompliance

VHA Directive 1058 requires the RCO to report any audits identifying noncompliance to the relevant RRCs with primary oversight of the research or their respective research review committee coordinators (RRCCs), regardless of whether the RRC is operated by the VA medical facility or another entity. The RCO must report the results of audits identifying noncompliance promptly, within established timeframes as specified in local and/or RRC policy; however, reporting cannot exceed 30 calendar days after completion of the audit.

Audits Identifying Serious or Continuing Noncompliance

VHA Directive 1058 requires serious or continuing noncompliance to be reported to the Office of Research Oversight (ORO) within 60 calendar days after facility personnel first become aware of the event. If an RCO audit identifies noncompliance meeting the definition of serious and/or continuing noncompliance, the event is required to be reported to ORO within 60 days of awareness (i.e., date identified by the RCO) *if determined to be reportable to ORO.* While VHA Directive 1058 permits the RCO to report audit results with findings of noncompliance within 30 days of audit completion, in some instances, the RCO may need to report serious or continuing noncompliance found during the course of an audit to the RRC or the respective committee coordinator prior to completion of the audit to allow enough time to be reported to ORO within 60 days. The RCO should refer to their local or RRC policy for requirements related to reporting of serious or continuing noncompliance.

Reporting RCO Audits to the Research and Development Committee (R&DC)

Routine reporting of all audit reports to the R&DC is no longer required by VHA Directive 1058 if another committee provides primary oversight of the research; however, local policies may still require the RCO to report audit results to the R&DC. The RCO should refer to their local policy for requirements related to reporting of audits to the R&DC.

4. Soliciting Study Investigator Response

In accordance with VHA Directive 1058, the RCO must solicit the study investigator's response to preliminary audit findings. Prior to concluding that an audit result or other event represents noncompliance, the RCO must communicate with the investigator. This can be done through written or verbal communication with the investigator. The RCO should exercise due diligence to ensure that there is a reasonable basis upon which to conclude that the result or event in question represents noncompliance with applicable research requirements. In some cases, such due diligence may involve detailed consultation with the research team or RRC to seek clarification and/or confirm the results. For example, if the RCO identifies that an informed consent document (ICD) is not in the study file, rather than quickly concluding that informed consent was not obtained and notifying the Institutional Review Board (IRB) that noncompliance has occurred (i.e., failure to obtain required informed consent), the RCO should first reach out to the study team for an explanation (e.g., an incomplete file was inadvertently

provided to the RCO or the ICD was misfiled) and to ascertain whether the missing ICD can readily be provided.

5. Reporting Pathways

Audit results must be reported using methods and pathways mutually agreed upon by the RCO and RRCs. The RCO must ensure that timelines developed with any RRC do not exceed the requirements in VHA Directive 1058 to report the results of audits identifying noncompliance promptly but no later than 30 calendar days after completion of the audit.

The RCO may provide audit results directly to the appropriate RRC or RRCC in writing through an electronic platform account or other secure system. It is recommended that the RCO audit report be submitted directly by the RCO to the RRC or RRCC. Alternatively, the RCO may provide the audit results to the study Principal Investigator (PI) for submission to the RRC or RRCC through upload to the applicable electronic platform, for example, if the RCO does not have access to that platform. When relying on the PI to report the RCO audit report, the RCO must verify that the audit report has been appropriately submitted by the PI. There are pros and cons to this approach, as it provides the RCO more flexibility, but may be more labor intensive for the RCO to verify correct submission. Regardless of whether the RCO reports directly or relies on the PI to report the audit results, the RCO must ensure that that all RCO audits identifying noncompliance are reported within the timeframes required by local policies, not to exceed 30 calendar days after audit completion, and verify that the audit report was received by the applicable RRC or RRCC.

When relying on an external RRC, facilities must establish a Memorandum of Understanding (MOU) or Reliance Agreement with other VA facilities or external organization(s) providing RRC services. Some reliance agreements are established for use nationwide with an Office of Research and Development (ORD) Master Service Agreement or national MOU. National agreements have been established for IRBs such as the National Cancer Institute IRB, the National Institutes of Health (NIH) All of Us IRB, and commercial IRBs Advarra, WCG-WIRB, and Sterling. Each facility will also have a local RRC agreement and supplemental standard operating procedure that must be available to the RCOs because it may contain RCO specific responsibilities, reporting timelines, and agreed upon procedures for reporting audit results.

The RCO may establish accounts within the commercial IRB platforms in order to provide reportable audit results directly to the commercial IRB. To assist with communication, each VA medical facility has assigned one or more research staff to act as contact persons to the commercial IRBs. The RCO is encouraged to work with the facility contact(s) to establish procedures for reporting required RCO audit results to the commercial IRB that comply with the agreements in place.

For internal RRCs and external RRCs with reliance agreements not established nationally, the RCO should work with the VA-operated RRC, academically affiliated RRC, and other academic or Federal RRCs to discuss and establish agreed upon processes for audit reporting.

In addition to providing reports in writing, RCO audit findings may be presented in person at RRC meetings by invitation of a committee or as specified by local research committee or RCO audit plan.

6. RCO Audit Plan Pertaining to Audit Reporting

VHA Directive 1058 §2.h(3)(b) and (c) requires the development of a written audit plan that describes procedures for soliciting study investigators' responses to preliminary audit findings and procedures for reporting audit findings of noncompliance to relevant RRC with primary oversight of the research, or their respective RRCCs, promptly, but no later than 30 calendar days after completion of an audit with findings.

Methods for soliciting the PI's response to preliminary audit findings should be described in the RCO audit plan. Timeframes, methods, and pathways for reporting audit results to each applicable RRC should be explained in detail. Methods for reporting to each committee should be outlined. If reporting procedures differ by RRC, finding, or type of audit this should be specified. For example, in what circumstances the RCO will self-report and when, if ever, will the RCO rely on the PI to report the audit results to the RRC. A description of how the RCO will verify that the PI has submitted the report within the required timelines should be included. Procedures for verifying that audit reports have been received by the RRC or RRCC should be explained.

The audit plan should also describe any other role the RCO plays in the reporting process (e.g., RCO role in drafting reports to ORO, reporting to outside entities, any additional summary reports). The RCO should also review corresponding research and RRC standard operation procedures (SOPs) to ensure any reference to RCO reporting is aligned with the processes outlined in the RCO audit plan.

7. Other Events Reportable to ORO Under VHA Directive 1058

If the RCO becomes aware of other events reportable to ORO under VHA 1058 (see VHA Directive 1058 § 3), including those that should have been reported but weren't, they should notify the relevant RRC as soon as possible.

8. Pertinent References in VHA Directive 1058

VHA Directive 1058 §2.f(11). Ensuring that the VA medical facility RCO has ready access to research program and study documentation so that the VA medical facility RCO can effectively fulfill the responsibilities of the position, including access to documentation necessary to fulfill RCO research auditing requirements such as research review committee meeting minutes, study approval letters, approved study protocols, and investigator study documentation. ***NOTE:*** *In situations where the VA medical facility relies upon a non-VA research review committee, the VA medical facility Director must ensure that the agreement (such as an MOU, reliance agreement, or service agreement) to rely on the committee requires that the VA medical facility's RCO be provided access to the non-VA research review committee's records to the extent necessary for the RCO to fulfill research auditing requirements.*

VHA Directive 1058 §2.f(12). Ensuring that VA medical facility RCO audits are complete and timely, and that the results of those audits are reported as required by this directive. See paragraph 2.h.(4).

VHA Directive 1058 §2.h(3). Developing a written audit plan for performing informed consent and regulatory audits of approved study protocols and other post-approval monitoring activities as specified by ORO. ***NOTE:*** *Examples of audit plans can be found on ORO's SharePoint website at* https://dvagov.sharepoint.com/sites/VACOVHAORO/RCO/RCO/Forms/AllItems.aspx. *This is an internal VA website that is not available to the public.* The written audit plan must describe the VA medical facility RCO's auditing process, including:
(a) Procedures for planning and executing audits.
(b) Procedures for soliciting study investigators' responses to preliminary audit findings.
(c) Procedures for reporting audit findings of noncompliance to relevant research review committees or committee coordinators with primary oversight of the research promptly, but no later than 30 calendar days after completion of an audit with findings.

VHA Directive 1058 §2.h(4). Auditing VA medical facility research projects in accordance with the written audit plan specified in paragraph 2.h.(3), ensuring the accuracy of those audits, and ensuring the results of audits identifying noncompliance are promptly reported to relevant research review committees or committee coordinators with primary oversight of the research.

VHA Directive 1058 §2.i. VA personnel who become aware of the occurrence of research-related events described in paragraph 3 of this directive are responsible for promptly reporting the events to the appropriate VA medical facility point(s)-of-contact designated to receive such reports at the VA medical facility that approved the research. *NOTE: If VA personnel are unsure as to whom to report an event, they should report the event to the RCO at the VA medical facility that approved the research. VA personnel who choose to avail themselves of an anonymous reporting mechanism to report an event addressed in this directive are considered to have fulfilled their reporting obligation.*

VHA Directive 1058 §3.a. The events delineated in this paragraph, should they occur in VA research, must be reported by the VA medical facility Director promptly and within the timeframes specified in this paragraph to the appropriate ORO workgroup (see Appendix A, paragraph 3). ***NOTE:*** *The VA medical facility Director must implement processes within their respective VA medical facilities to ensure that the events covered by this directive are promptly reported to the VA medical facility Director so that the VA medical facility Director can submit required notifications to ORO within the timeframes specified. The timeframes specified in this directive for reporting events to ORO establish the maximum allowable time for reporting; once a reportable event is known to have occurred, it should be reported to ORO as soon as possible. Reporting requirements pertaining to research misconduct, as defined in paragraph 8.h. of this directive, are addressed separately in VHA Directive 1058.02.*