Summary of Major Policy Changes Introduced by the Issuance of
VHA Directive 1058 – Office of Research Oversight, dated November 8, 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Directive 1058.03, Assurance of Protection for Human Subjects in Research, dated September 17, 2020, both of which were rescinded by the issuance of revised VHA Directive 1058.*

Topic:	Description of Change:
Federalwide Assurances (FWAs)	It remains a requirement that VA medical facilities 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, must hold a valid FWA approved by the U.S. Department of Health and Human Service (HHS) Office for Human Research Protections (OHRP). *See* revised VHA Directive 1058 §2.f.(2). However, the previous requirement in *rescinded* VHA Directive 1058.03 that ORO serve as an administrative intermediary between VA medical facilities and HHS OHRP for obtaining, updating, or renewing FWAs has been eliminated. 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. Information on the status of a facility's FWA, including the status of a pending FWA update, is available at: https://ohrp.cit.nih.gov/search. ***NOTE:*** *Prior to seeking an FWA, VA medical facilities must secure approval from the VHA Office of Research & Development to establish a Human Research Protection Program (HRPP). See VHA Directive 1200.05(3) §5.f.(9).*
VA FWA Addendum	The previous requirement in *rescinded* VHA Directive 1058.03 for VA medical facilities engaged in non-exempt human subjects research covered by the Federal Policy for the Protection of Human Subjects ("Common Rule") to hold a VA FWA Addendum approved by ORO has been eliminated.

Topic:	Description of Change:
Institutional Review Board (IRB) Registrations	It remains a requirement that IRBs operated by VA medical facilities must be registered with HHS OHRP. *See VHA Directive 1200.05(3) §5.f.(8).* However, the previous requirement in *rescinded* VHA Directive 1058.03 that ORO serve as an administrative intermediary between VA medical facilities and HHS OHRP for the registration of IRB(s) operated by VA medical facilities has been eliminated. 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:*** *Prior to registering an IRB that will be internally operated by a VA medical facility, VA medical facilities must secure approval from the VHA Office of Research & Development. See VHA Directive 1200.05(3) §5.f.(9).*
Research-Related Reportable Events – Local Reporting and Review	*Rescinded* 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. 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. *See* revised VHA Directive 1058 §2.f.(15), §3, and Appendix A.
Research-Related Reportable Events – Notification of ORO	Events that were previously required to be reported to ORO under rescinded VHA Directive 1058.01 largely remain reportable to ORO under revised VHA Directive 1058. However, 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. *See* revised VHA Directive 1058 §2.f.(15), §3, and Appendix A.

Topic:	Description of Change:
RCO Responsibilities – Reporting of Audit Results to Research Review Committees	*Rescinded* VHA Directive 1058.01 required the results of all RCO audits – regardless of whether the audits identified noncompliance – to be reported to all relevant research review committees with oversight of the research, including VA medical facility Research & Development Committees (R&DCs); however, a timeframe for reporting those results was not specified. Revised VHA Directive 1058 (which incorporates content from rescinded VHA Directive 1058.01): • Only requires RCOs to report the results of those audits that identify noncompliance (i.e., it is no longer required to report the results of audits that do not identify noncompliance); • Allows the results of RCO audits that identify noncompliance to be reported to research review committees or the coordinators for those committees depending on the standard operating procedures of the applicable committee(s); • Only requires reporting to research review committees or the coordinators for those committees with primary oversight of the research (i.e., no longer requires the reporting of results to the R&DC if another committee, such as an IRB, Institutional Animal Care and Use Committee (IACUC), or Subcommittee on Research Safety (SRS), provides primary oversight of the research); and • Requires RCOs to report the results of audits that identify noncompliance to the research review committees with primary oversight of the research or the coordinators for those committees within 30 calendar days of completion of the audits. *See* revised VHA Directive 1058 §§2.h.(3) and (4).
RCO Responsibilities – Quality Assurance Review of Reportable Events	Revised VHA Directive 1058 establishes a new requirement for VA medical facility RCOs to annually conduct a quality assurance review to determine whether events covered by the directive were reported to ORO as required, including whether such events were reported within the specified timeframes. *See* revised VHA Directive 1058 §2.h.(6). ***NOTE:*** *Specific instructions and guidance on conducting these quality assurance reviews will be provided by ORO's Education and Data Analytics (EDA) Workgroup.*
VA Medical Facility Provisioning of Documents in Support of ORO's Oversight Activities	Revised VHA Directive 1058 incorporates in policy the longstanding expectation that VA medical facility Directors are responsible for ensuring that all applicable documents related to the review, approval, and ongoing oversight of VA research are *promptly* furnished to ORO in conjunction with ORO's oversight activities and, in the event that a VA medical facility relies on an external entity for the review, approval and oversight of the facility's research, it is the responsibility of VA medical facility personnel to obtain documents requested by ORO from the external entity. *See* revised VHA Directive 1058 §2.f.(18).