

OFFICE OF RESEARCH OVERSIGHT
Summary of Major Changes in Research Compliance Reporting Requirements under VHA
Directive 1058.01 (Dated October 22, 2020)

The revision of VHA Directive 1058.01, dated October 22, 2020, generally reduces the regulatory reporting burden of Department of Veterans Affairs (VA) medical facilities. This summary **only** lists **major** changes resulting from the revision. It is **not** a comprehensive list of **all** changes. Research facilities should review the Directive carefully to identify any modifications in local standard operating procedures (SOPs) that are needed to ensure compliance. **Facilities may decide to retain local requirements that exceed those required by the revised Directive** where such requirements are working well and serve the needs of the local oversight program.

1. Until instructed otherwise, VA facilities should continue to direct reports and questions to the responsible Office of Research Oversight (ORO) Workgroup as follows:
 - a. Research and Development Committee (R&DC) issues should be directed to the ORO Comprehensive Research Oversight Workgroup at OROCROW@VA.GOV
 - b. Human Research Protection Program issues should be directed to the ORO Human Research Protection Workgroup at OROHRP@VA.GOV
 - c. Research Compliance Officer (RCO) issues should be directed to ORO's Policy and Education Program (P&E) at OROPE@VA.GOV
 - d. Institutional Review Board (IRB) registration, IRB Memorandum of Understanding (MOU), and Federalwide Assurance (FWA) issues should be directed to ORO's P&E FWA staff at OROFWA@VA.GOV
 - e. Laboratory animal welfare, research safety, and research laboratory security issues should be directed to ORO's Research Safety and Animal Welfare program at ORORSAW@VA.GOV
 - f. Research information security issues should be directed to ORO's Research Information Security Workgroup at ORORISP@VA.GOV
 - g. Research Misconduct issues should be directed to the ORO Research Misconduct Officer at VHACOOROResearchMisconductProgram@va.gov.
2. New VHA publication guidelines resulted in the deletion of Directive links to the ORO SharePoint library that houses the RCO audit tools and related requirements. This information continues to be available at:
<https://dvagov.sharepoint.com/sites/VACOVHAORO/RCO/default.aspx> and
<https://www.va.gov/oro/>
3. Definitions:
 - a. **Adverse Event in Human Subjects Research** now includes the phrase "whether or not considered related to the subject's participation in research."
 - b. **Assurance of Compliance (Human Subjects) or Federalwide Assurance**: The revised definition includes the synonymous use of both terms and is more specific than the definition in the previous Handbook concerning the commitment the VA institution makes to the standards for the protection of human subjects when signing the Assurance.
 - c. **Continuing Noncompliance** has been expanded to include all areas of research noncompliance and also includes an additional component of previous noncompliance that has been identified but not appropriately remediated.
 - d. **Exempt Human Subjects Research** definition has been added.

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- e. **Exposure:** definition expanded to clarify that hazardous or toxic material includes the following biological materials: unfixed fluids, tissues, and cells derived from humans and other animal resources.
- i. **Research:** definition has been changed to be consistent with the definition found in the current 2018 Common Rule at 38 CFR 16.104 and to include research involving animals. Definition was also changed to be consistent with VHA Directive 1200.05 which considers clinical investigations defined under FDA regulations to be “research.”
- m. **Serious Accident, Injury, Illness or Exposure of a Human:** definition has been expanded to include illness or exposure. A new eligibility condition now includes time away from work or restricted work activities.
- o. **Serious Noncompliance** has been expanded to include the failure to adhere to requirements that may reasonably be regarded as presenting a genuine risk of substantive harm to animals used in research, risk of substantive reputational harm to VA, and substantively compromising the facility’s animal care and use program or research safety and security program.
- q. **Unanticipated Problem in Human Subjects Research Involving Risks to Subjects or Others (UPIRTSO)** has been added which includes a revision to the definition of “related” or “possibly related” to participation in research which differs from the definition in the previous Handbook.

The revised Directive at §5.g.(2) indicates that the VA medical facility Institutional Official is responsible for ensuring that SOPs or MOUs establishing the role of a non-VA operated research review committee for oversight of a VA medical facility’s research address the non-VA operated committee’s procedures for the review and reporting of events described in this Directive. If the procedures of a non-VA research review committee differ from, or the timeframes exceed, the requirements in this Directive, the VA medical facility must contact the Office of Research & Development (ORD) and the appropriate ORO Workgroup. If a non-VA operated research review committee is unable or unwilling to review an event requiring review under this Directive, the VA medical facility’s R&DC will either review the event or designate another applicable VA research review committee to review the event as would otherwise occur if the event were subject to review by a VA-operated research review committee under the requirements of this Directive.

The revised Directive at §5.g.(6) extends the required timeline for remedial action completion from 120 to 180 days.

The revised Directive at §5.g.(8)(a) allows the RCO to be directly supervised by VA medical facility senior leaders other than the Director. This Directive now allows the RCO to report directly to and be supervised by either the VA medical facility Director or a senior individual who reports directly to and is supervised by the VA medical facility Director and whose primary responsibilities at the VA medical facility pertain directly to compliance.

The revised Directive at §5.g.(8)(d) requires that the RCO have access to research program and study documentation in order to fulfill auditing responsibilities. This also includes ensuring that MOUs or other reliance agreements established to rely on a research review committee operated by a non-VA entity require that the RCO has access to regulatory documents and records to the extent necessary to fulfill research auditing requirements.

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The revised Directive at §6.a. adds a note that for systematic deficiencies that do not pertain to the operation of a research review committee, the R&DC will delegate the review of the concern to the committee with primary programmatic oversight.

The revised Directive at §7.a. requires that oral notification of deaths of human subjects participating in VA non-exempt human subjects research, that are both unexpected and related or possibly related to the research, must be provided to the IRB **and Associate Chief of Staff for Research (ACOS/R)** within one hour of discovery. The ACOS/R or designee must alert the medical facility Director and ORO within **1** business day after initial notification. Written notification to the IRB must be within 1 business day as well. The IRB Chair or qualified voting member must review within **1** business day to determine whether actions are warranted to eliminate immediate hazards to subjects, **and if so, to initiate those actions.** The IRB must review the written notification at the next convened meeting not to exceed 30 calendar days after the date of written notification. If the IRB cannot make a determination within 30 days, the facility Director, ACOS/R, **and RCO** must be notified in writing of this lack of a determination within 5 business days after the determination was due. The medical facility Director then has 5 business days to notify ORO.

The revised Directive at §7.b. indicates new reporting instructions for UPIRTSO as defined in §3.q. above. The IRB must be notified of the event in writing within 5 business days of discovery. The IRB has 5 business days to determine if actions are warranted to eliminate apparent immediate hazards to subjects, **and if so, to initiate them.** IRB review and determination timelines then follow the revised process described in §7.a. above.

The revised Directive at §7.c. requires written notification to the IRB within 5 business days after becoming aware of any apparent serious or continuing noncompliance with applicable laws, regulations, policies and agreements pertaining to non-exempt human subjects research; review at its next convened meeting (≤ 30 days); and determination and documentation (≤ 60 days) of whether serious or continuing noncompliance actually occurred, and what, if any, remedial actions are needed to resolve present or prevent future noncompliance. The IRB must notify the facility Director, **RCO**, and ACOS/R within 5 days of the determination.

The revised Directive at §8 describes specific procedures for reporting events occurring in Exempt research involving human subjects.

The revised Directive removed §§7.a. & b. from the previous Handbook concerning reporting related to animal deaths and theft, escape, or disappearance of animals.

The revised Directive at §9.a. & §10.a. harmonizes the processes for reporting and reviewing human deaths related to animal research to the Institutional Animal Care and Use Committee and human deaths related laboratory research to the Subcommittee on Research Safety.

The revised Directive at §7.c., §9.c., §9.d., & §10.c. harmonizes the reporting processes for reporting and reviewing apparent serious or continuing noncompliance in non-exempt human

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subjects research, VA animal research events reportable to National Institutes of Health Office of Laboratory Animal Welfare, other apparent serious or continuing noncompliance in animal research, and apparent serious or continuing noncompliance in lab research.

The revised Directive at §9.b. & §10.b. describes the same process as §7.b. for reporting and reviewing any human accident, injury, illness, or exposure in animal research and events reportable under applicable federal standards or involving human accident, injury, illness, or exposure in laboratory research.

The revised Directive at §9.c. revises external reporting requirements for animal research incidents.

The revised Directive at §11 was revised to harmonize reporting criteria for reportable incidents related to research information security and privacy with reporting criteria for serious or continuing noncompliance or unanticipated problems in human subjects research, animal research and laboratory research, as applicable.