Research Compliance Officer (RCO) Audit and Training Requirements
Version 2024 – 2025

1. **Introduction**. This document outlines RCO audit requirements for the June 1, 2024 - May 31, 2025, reporting period. At a minimum, RCO audits must be completed according to the requirements outlined in this document. The VHA Office of Research Oversight (ORO) official audit tools are available on the ORO website and RCO SharePoint site. RCOs are not required to use these specific tools or format. However, any tools used must include, at a minimum, all of the required information included in the audit tools. RCOs may to add additional audit elements they feel will be helpful for monitoring the quality, safety, and compliance of the facility's research program.

2. **Definitions**.
    a. **RCO audit**. RCO audits are audits **conducted, supervised, or verified** by the facility's lead RCO. Audits should be conducted by individuals with the requisite training to conduct audits and without apparent conflicts of interest in conducting the audits. RCO audits are completed when results have been confirmed with the Principal Investigator (PI) or study team and reported to all relevant research review committees.

    b. **Active study**. An "**active**" study is a study approved by and under continuing oversight from the Research and Development Committee (R&DC), Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Subcommittee on Research Safety (SRS), or other VA or VA-designated research oversight committee, regardless of whether the study is "open" or "closed" to accrual.

    c. **Completed study**. A "**completed**" study is a study for which oversight by all relevant research oversight committees (see Item 2.b above) has been concluded.

3. **Informed consent (IC) audits**. All human research studies (exempt and non-exempt) are required to receive at least one IC audit.
    a. Human research studies with required documentation of informed consent **AND/OR** required Health Insurance Portability and Accountability Act (HIPAA) authorization for the whole study or any portion of the study (e.g., studies requiring IC for only one arm of the study or only a certain phase of the study), are required to have annual IC audits (i.e., must be performed each year during the June 1–May 31 reporting period). This annual requirement applies whether any informed consent documents (ICDs) or HIPAA authorizations were obtained during the reporting period. A completed IC audit must include all administrative data on the IC audit tool and completion of all applicable audit tool elements for each signed ICD and/or HIPAA authorization reviewed as applicable.

    For studies where 1) the research is permanently closed to the enrollment of new subjects; *and* 2) all subjects have completed all research-related interactions or interventions; *and* 3) the research has progressed to the point that it involves only accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care; OR the remaining research activities are limited to data analysis, including

analysis of identifiable private information or identifiable biospecimens, subsequent IC audits are not required as long as the study has had at least one IC audit. For these studies, the RCO must *confirm and document* that the status of the study has not changed (i.e., still remains in long-term follow-up or data analysis only). This confirmation must be done annually and occur through a review of IRB records or protocol documents (e.g., review for any submitted amendments) and may also include communication with the PI. If the study status has changed from long-term follow-up or data analysis only, an IC audit must be conducted in the reporting period in which this was discovered, and subsequent annual IC audits must resume.

b. Exempt human research studies not requiring HIPAA authorization (i.e., not using PHI or with approved waivers of HIPAA authorization) require a one-time IC audit. The audit requirement is fulfilled by completing the administrative data section of the ORO informed consent audit tool (or local equivalent), including review of the required waiver of HIPAA authorization, as applicable. Subsequent IC audits of these studies are not required.

c. Non-exempt human research studies with approved waiver of IC or waiver of documentation of IC **AND** approved waiver of HIPAA authorization are required to have a one-time IC audit. The audit requirement is fulfilled by completing the administrative data section of the ORO informed consent audit tool (or local equivalent). Subsequent IC audits of these studies are not required.

d. **ICDs required to be audited**. The RCO must audit all research informed consent documents (ICD) required under 38 CFR 16.116 and 16.117 [and VHA Directive 1200.05(3) §§17 through 18]. Re-consents for research should also be audited and counted as a separate informed consent document. Regardless of how research protocols and parts of research protocols are tracked or labeled by an IRB or cooperative group, "sub-studies" also constitute research that requires specific IRB approval of the "sub-study" protocol and informed consent, and RCOs are required to audit those sub-studies, and ICDs as described above. If either HIPAA authorization or documentation of informed consent, but not both, has been waived by the IRB, the document that is not waived must be audited.

   Each ICD audited should have a separate line on the IC audit tool. For purposes of counting ICDs audited for the Facility Director's Certification of Research Compliance (FDC), each ICD audited should be counted separately—even if multiple ICDs applied to the same individual. Do not count an IC addendum as a separate document; an addendum is an addition/change to a study/sub-study and does not necessarily have to include all the required elements of IC.

   Consent forms that are required outside of the requirements of 38 CFR 16.116 and 16.117 (and VHA Directive 1200.05(3)) are NOT required by ORO to be audited by RCOs. Informed consents for medical procedures and consents for photography and voice

recording are examples among others that are not required by ORO guidance to be audited.

e. **Initial IC audits**. Initial IC audits must include all ICDs and HIPAA authorizations obtained since study initiation. This includes all documents signed, including those for screen failures, drop-outs, and reconsents. IC audits of newly approved studies must be conducted in the reporting period it became active, even if consent has not yet been obtained from any subjects.

f. **Subsequent IC audits**. For studies previously receiving an IC audit, the RCO must audit all new ICDs and HIPAA authorizations obtained since the previous audit. This includes all documents signed, including those for screen failures, drop-outs, and reconsents.

g. **Studies completed during the reporting period**. An IC audit must be conducted for any active study that is completed during the reporting period. If a study was previously audited during the reporting period, a supplemental IC audit must be completed before the end of the reporting period to capture any ICDs not previously audited prior to study completion. If no additional ICDs were obtained, then the audit already performed during the reporting period is sufficient and a supplemental audit for a completed study is not required.

h. **Million Veteran Program (MVP) IC audits**. The MVP is currently the only study that does not require 100% consent auditing. RCOs must audit all consent documents for at least 10% of the subjects enrolled during the audit cycle. This does not include enrollments through the MVP online consent process which are audited through a separate RCO review process.

i. **Deadline**. Required IC audits must be conducted at least annually and can be conducted at any point in each reporting period. There is no requirement to conduct a subsequent IC audit based on the anniversary date of the previous IC audit. IC audits must be conducted by May 31 of the reporting period, except for protocols approved (i.e., received final approval by the R&DC) after May 15 of the reporting period, or in rare extenuating circumstances. IC audits for such studies must be completed by June 30 to allow inclusion in the 2025 Facility Director Certification of Research Oversight.

4. **Regulatory audits – human subjects research.** Except as noted in 4.f, RCOs must conduct regulatory audits using ORO's Human Research Protection (HRP) audit tool (or equivalent) for all human subjects research studies (i.e., both exempt, and non-exempt) at least every 3 years (i.e., triennially). A completed HRP audit must include all applicable elements on the HRP audit tool. A complete HRP audit must include a review of both the IRB study file and the PI's records. IRB records may include the protocol history, ISSO and PO reviews, and research review

correspondence. PI records may include subject research records, electronic medical records, and research personnel training records.

a. **Records Reviewed.** ORO believes that a thorough HRP regulatory audit requires a reasonable awareness of the goals and methods of the research, as well as the manner of obtaining and documenting informed consent. Therefore, when performing an HRP regulatory audit, ORO expects the RCO auditor to achieve this awareness by reviewing the most recently approved informed consent document and HIPAA authorization, when required, and to review relevant parts of the approved research protocol. The RCO auditor may also wish to enhance their understanding of the research by having a conversation with the PI and/or study coordinator. Please note that ORO does NOT expect the RCO auditor to read the entire protocol, nor to duplicate the work of the IRB, the scientific reviewers, the ISSO or the PO. The RCO auditor should use professional judgment to determine when an adequate awareness, sufficient for the purposes of conducting the HRP regulatory audit, has been achieved.

   It is also important for the RCO auditing process to be transparent to the PI and study staff. Therefore, when performing audits, ORO expects the RCO auditor to explain the audit process in an in-person conversation, by telephone, or to include this information in an explanatory email. At the conclusion of the record review the RCO auditor is required to review the preliminary findings with the PI/staff and clarify any questions or apparent deficiencies. In cases where the RCO does not feel that a conversation is necessary, the RCO should still make an offer to discuss the audit process and findings with the PI and/or study staff if they desire.

b. **Deadline**. An initial HRP regulatory audit must be conducted within 3 years of the R&DC approval date. Subsequent HRP regulatory audits must occur within 3 years of the previous HRP regulatory audit.

c. **Exempt studies.** Exempt studies approved under the 2018 Common Rule Requirements are required to have HRP regulatory audits. Studies with previous HRP regulatory audits (previously exempted from *subsequent* HRP regulatory audits) must have their next HRP regulatory audit no later than May 31, 2027. Studies without a previous HRP regulatory audit must have HRP audits conducted in accordance with 4.b above. Exempt studies approved under the Pre-2018 Common Rule Requirements are not required to have regulatory audits.

d. **Studies with no activity.** If a human research study is opened and completed at a VA research facility without any research activity locally (enrolling any subjects or accessing any records) and before an HRP audit is done, then the requirement for an HRP audit may be satisfied in an abbreviated fashion by reviewing and completing the administrative data only of the HRP audit tool.

e. **Closure audits.** Closure HRP regulatory audits are not required for any studies that close within 3 years of the previous HRP regulatory audit. If no HRP regulatory audit has been done prior to closure, an HRP regulatory audit must be done within the reporting period in which the study closed.

f. **Studies in data analysis and/or long-term follow up.** For studies where 1) the research is permanently closed to the enrollment of new subjects[1]; *and* 2) all subjects have completed all research-related interactions or interventions; *and* 3) the research has progressed to the point that it involves only accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care; OR the remaining research activities are limited to data analysis, including analysis of identifiable private information or identifiable biospecimens, subsequent HRP audits are not required as long as the study has had at least one HRP regulatory audit. The RCO must *confirm and document* that the status of the study has not changed (i.e., still remains in long-term follow-up or data analysis only). This confirmation must occur through a review of IRB records or protocol documents (e.g., review for any submitted amendments) as well as communication with the PI and must occur within 3 years of the last HRP regulatory audit and every 3 years thereafter until the study closes. If the study status has changed from long-term follow-up or data analysis only, an HRP regulatory audit must be conducted in the reporting period in which this was discovered and subsequent HRP regulatory audits must resume as per section 4 of this document.

5. **Regulatory audits – animal research.** RCOs are required to conduct regulatory audits using ORO's Animal Welfare audit tool (or equivalent) for all animal research studies overseen by the IACUC that are active at any point during the reporting period. A completed animal welfare regulatory audit must include all applicable elements on the animal welfare audit tool. An animal welfare regulatory audit includes a review of the IACUC protocol file and research personnel training records, and other research records as needed.
   a. **Deadline.** An initial animal welfare audit must be conducted within 3 years of initial R&DC approval. Subsequent animal welfare audits must be conducted within 3 years of the previous animal welfare audit.

   b. **Studies with no activity.** If an approved VA animal research study is closed or expires without any animal research activities being initiated, then the requirement for an animal welfare audit may be satisfied in an abbreviated fashion by reviewing and completing the administrative data only on the first page of the Animal Welfare audit tool.

[1] Chart review/database studies are "permanently closed to the enrollment of new subjects" when the researchers will continue to collect long-term follow up data about the completed IRB-approved cohort but will not add data about other subjects. A chart review/database protocol is in data analysis when the remaining research activities do not include adding additional subjects or adding new data elements.

c. **Closure audits.** Closure animal welfare audits are not required for any animal studies that close within 3 years of the previous animal welfare audit. If no animal welfare regulatory audit has been done prior to closure, an animal welfare regulatory audit must be done within the reporting period in which the study closed.

6. **Regulatory audits – safety research.** Regulatory audits using ORO's Safety audit tool (or equivalent) are required for all research studies overseen by the SRS, active at any point during the reporting period. A completed safety regulatory audit must include all applicable elements on the safety audit tool. A safety audit includes a review of the SRS protocol file, including the research protocol safety survey (RPSS), identified study hazards and safety concerns, specialized required training, if any, research personnel training records, and may include other research records as needed.
    a. An initial safety audit must be conducted within 3 years of initial R&DC approval. Subsequent safety audits must be conducted within 3 years of the previous safety audit.

    b. VA research followed by the SRS generally falls into one or more of 3 categories: 1) Animal research followed by the IACUC and SRS, 2) certain human subjects research that involves exposure to blood or body fluids, human tissues, or other hazards (unless such research solely involves the collection and analysis of biospecimens by VA personnel within clinical areas and/or the performance of standard clinical procedures in clinical areas), or 3) bench or laboratory research that involves hazards or safety concerns. For safety research that is also followed by the IRB or the IACUC, the RCO may elect to perform the Research Safety audits in combination with the HRP or Animal Welfare audits.

    c. **Studies with no activity.** If an approved safety study is closed or expires without any research activities being initiated, then the requirement for a safety audit may be satisfied in an abbreviated fashion by reviewing and completing the administrative data only on the first page of the Safety audit tool.

    d. **Closure audits.** Closure safety audits are not required for any safety studies that close within 3 years of the previous safety audit. If no safety audit has been done prior to closure, a safety audit must be done within the reporting period in which the study closed.

7. **Research not required to be audited.**
    a. Any VA research study that is not human subjects research and is not overseen by the IRB, IACUC, or SRS does not require a regulatory audit.

    b. Expanded access protocols (whether emergency or non-emergency) and emergency use of a test article do not require any audits.

c. Human subject research studies approved by the R&DC prior to January 1, 2008, do NOT in most cases require an HRP regulatory audit. The exception to this "Grandfather rule" is those studies initially approved prior to January 1, 2008, that involve interaction or intervention with human subjects and remain open to enrollment.

   See ORO Guidance document "MODIFIED AUDIT REQUIREMENTS FOR HUMAN SUBJECTS RESEARCH INITIALLY APPROVED PRIOR TO JANUARY 1, 2008" dated November 15, 2012, available on the ORO website and Research Compliance and Technical Assistance SharePoint site.

d. Research followed by the SRS but initiated (i.e., approved for implementation by the R&DC as a VA study) prior to January 1, 2008, does NOT require a Research Safety regulatory audit.

8. **RCO training requirements**. In addition to conducting required audits, the RCO may serve as a non-voting consultant, as needed, to the facility's R&D Committee, IRB, IACUC, SRS, and other research review committees. The RCO may not serve as a voting or non-voting member of these committees. RCOs must complete and maintain the following Office of Research and Development (ORD) CITI training requirements: humans subjects training and animal welfare training (as applicable). RCOs are strongly encouraged to attend training webinars provided by ORO and ORD.

9. **RCO written audit plan or standard operating procedure (SOP)**. In accordance with VHA Directive 1058.01 §5.i.(1), RCO audits must be conducted in accordance with a written audit plan or SOP that describes the RCO's auditing process, to include: procedures for planning and executing audits, procedures for soliciting study investigators' responses to preliminary audit findings, and timelines for providing all audit results (regardless of findings) to the relevant research review committees, including the R&DC. The SOP or audit plan should address the RCO's procedures for each type of audit, including IC and regulatory audits as applicable to the facility. The SOP or auditing plan should address the source records that may need to be reviewed for auditing purposes and the roles of the RCO, the PI, and others in the audit process. The plan or SOP should describe how studies are planned for auditing during the year, how audits are scheduled and executed, as well as how progress toward accomplishing all required audits is monitored. It is also good practice to describe the RCO's audit record format(s) (electronic and/or hard copies), the locations where RCO records are maintained, and how security of records is assured.

10. **RCO Tracking of Active Research**. To effectively manage the RCO auditing program and to maintain awareness of what is required to be audited, RCOs are required to maintain a tracking inventory of all active research at the facility. Elements that must be included in the inventory include study ID, study title, principal investigator, the date of R&DC and each applicable research review committee approval, and dates of the most recently completed audits. Additional required elements for human subjects research include, exempt or nonexempt status, IRB-of-record and IRB-determined risk level for nonexempt studies, whether the study involves a required ICD and/or HIPAA authorization, and whether the study is subject to the Pre-2018 or 2018 Common Rule requirements. To assist the RCOs with this requirement, ORO has developed a sample tracking inventory available for use included in the embedded file below.

RCOs are free to customize the inventory to their program by adding additional elements or adding required elements to their current tracking mechanism. This inventory must be provided to ORO upon request for ORO compliance or technical assistance reviews. RCOs should periodically reconcile their inventory of active research with that of the research program. RCOs are encouraged to attend R&DC and research review committee meetings and review meeting minutes if available to maintain awareness of study changes and upcoming studies soon to be approved.

Note: RCOs are expected to provide the RCO written audit plan or SOP, protocol tracking records, and copies of completed audits upon request for ORO compliance or technical assistance reviews.

Active Studies and Audit History Tracking

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Summary of Changes:

2023-2024 Audit Requirements	2024-2025 Audit Requirements
Informed Consent Audits	
Annual IC audits required of all human studies (exempt and nonexempt).	Annual IC audits required of human studies requiring documented informed consent and/or HIPAA authorization.
Annual IC audit requirements includes exempt protocols *and* nonexempt studies with approved waivers of IC or documentation of IC AND waiver of HIPAA authorization.	One-time IC audit required for exempt protocols with waivers of HIPAA authorization (or not using PHI) and nonexempt studies with approved waiver of IC or documentation of IC AND waiver of HIPAA authorization.
Repeat IC audits not required for studies in long-term follow-up of clinical data only or data analysis only.	For studies in long-term follow-up of clinical data only or data analysis only, annual confirmation of study status is required and, if status is unchanged, no audit required.
Deadline for IC audits for reporting period is prior to submission of the FDC.	Deadline for IC audits for reporting period is May 31. Studies approved between May 15 and May 31, or other rare extenuating circumstances, need to be audited by June 30 to be included on the FDC.
HRP Regulatory Audits	
Triennial regulatory audits required of all nonexempt human studies; One-time regulatory audit required for exempt human studies approved under the 2018 Common Rule.	Triennial regulatory audits required of all nonexempt human studies and all exempt human studies approved under the 2018 Common Rule.
No regulatory audits required for exempt studies approved under the Pre-2018 Common Rule.	No regulatory audits required for exempt studies approved under the Pre-2018 Common Rule.
Repeat regulatory audits not required for studies in long-term follow-up of clinical data only or data analysis only.	For studies in long-term follow-up of clinical data only or data analysis only, triennial confirmation of study status is required and, if status is unchanged, no audit required.
SMART audits could be used in place of regulatory audit if all audit elements present.	Removed exception for SMART audits.
Animal Welfare Audits	
Initial audit deadline is based on the IACUC approval date.	Initial audit deadline is based on the R&DC approval date.
Safety Audits	
General Requirements	
	New requirement for tracking of active studies.
Training requirements based on R&DC member requirements.	Clarified that only CITI training is required.