**Office of Research Oversight (ORO)**

**Research Compliance Officer (RCO)**

 **Technical Assistance and Self-Assessment Tool**

**July 6, 2021**

This resource is provided by ORO for technical assistance to VA research facilities to assist facilitiesin assessing their compliance with regulations and policies related to the role of the RCO, including but not limited to the [VHA Directive 1058.01](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) and guidance posted on the [ORO website](https://www.va.gov/ORO/) and the [RCO section of the ORO SharePoint site](https://dvagov.sharepoint.com/sites/VACOVHAORO/RCO/default.aspx). For elements without a citation or reference, these practices are highly recommended but not required. This resource also emphasizes practices that help the RCO achieve success in their role. Please direct any questions you may have about this resource to ORO’s Policy and Education Workgroup at orope@va.gov.

**SOURCES OF DOCUMENTATION/EVIDENCE:** Prior to conducting a self-assessment with this checklist, it may be helpful to review documents including applicable facility and Research Service policies and procedures, particularly those describing the plan for successfully accomplishing required audits of research protocols, or ascribing other duties to the RCO. In addition, review of the approved Position Description(s) or Functional Statements of any/all RCOs, assistants, auditors, or other personnel involved in accomplishing the required audits is recommended.

**DIRECTIONS:** Check the Yes, No, or Not Applicable (N/A) box pertaining to each question; under the Notes column, cite the reference(s) to support your answer (e.g., auditing SOP section), describe any features of exceptional merit, or explain any deficiencies.

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| VA Facility: |       |
| Reviewer(s)[[1]](#footnote-1): |       |
| Review Date: |       |

| **ORO Research Compliance Officer (RCO) Self-Assessment Tool** |
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|  | **Element** | **Y** | **N** | **N/A** | **Reference** | **Notes** |
| 1. | The medical facility Director (MFD) has appointed at least one full-time RCO to conduct research informed consent and regulatory audits unless ORD and ORO jointly approve a waiver to permit appointing a part-time RCO. | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.g(8)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) |  |
| 2. | The facility’s RCO, or a lead RCO reports directly to and is supervised by either the MFD or other senior individual who reports directly to and is supervised by the MFD and whose primary responsibilities at the VA medical facility pertain directly to compliance.  | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.g(8)(a)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) |  |
| 3. | The RCO has direct access to the MFD for purposes of reporting research noncompliance and other research-related concerns. | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.g(8)(a](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082)) |  |
| 4. | RCO reports of noncompliance and other research-related concerns to the MFD are not routed “through” or subject to approval by any research staff or committee. | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.g(8)(a)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) |  |
| 5. | No RCO activities are determined or managed by the ACOS/R&D or any other individual or research review committee in the facility’s Research Service.  | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.g(8)(b)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) |  |
| 6. | The RCO has the necessary expertise, through education or experience, to fulfill the duties of the RCO position. | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.g(8)(c)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) |  |
| 7. | * 1. The RCO has ready access to research program and study documentation. This includes access to documentation (e.g., research review committee meeting minutes, study approval letters, investigator study documentation) necessary to fulfill requirements related to auditing of informed consents and study protocols.
 | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.g(8)(d)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) |  |
| 8. | When the facility relies on a research review committee operated by a non-VA entity the reliance agreements require that the RCO has access to the committee’s records to fulfill auditing requirements. | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.g(8)(d)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) |  |
| 9. | The RCO has access to non-VA operated research review committee’s records to the extent necessary for the RCO to fulfill auditing requirements. | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.g(8)(d)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) |  |
| 10. | * 1. All RCO appointments, resignations, or substantive change in duties are reported to ORO by the MFD within five (5) business days after the action takes effect.
 | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.g(8)(e)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) |  |
| 11. | The RCO has a position description or functional statement that accurately reflects their duties. | [ ]  | [ ]  | [ ]  | [VA Directive 5003 §3.c(3)](https://www.va.gov/vapubs/viewPublication.asp?Pub_ID=172&FType=2.) |  |
| 12.  | The facility has a written audit plan or standard operating procedure (SOP) that describes the RCO’s auditing process, including procedures for planning and executing the audits.  | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.i(1)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) Guidance on [ORO website](https://www.va.gov/ORO/) and the [RCO section of the ORO SharePoint site](https://dvagov.sharepoint.com/sites/VACOVHAORO/RCO/default.aspx)[*“*ORO *Guidance Regarding RCO Audit and Training Requirements”*](https://www.va.gov/ORO/Docs/RCO/2021_2022_ORO_Guidance_for_RCO_Research_Audit_and_Training_Requirements.pdf) |  |
| 13. | The RCO written audit plan or SOP includes procedures for soliciting the investigators’ responses to preliminary findings and timelines for providing all audit results (regardless of findings) to the relevant research review committees, including the R&DC.  | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.i(1)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) |  |
| 14. | The MFD provides adequate resources to support the research program and the required RCO audits. | [ ]  | [ ]  | [ ]  | [VHA Directive 1200.05(2) § 5.f(2)(a)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=8171) [VHA Directive 1058.01 § 5.g(1)(a).](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) |  |
| 15. | RCO informed consent (IC) audits are performed as required for active human subjects research protocols annually. | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.i(1)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082)Guidance on [ORO website](https://www.va.gov/ORO/)and the [RCO section of the ORO SharePoint site](https://dvagov.sharepoint.com/sites/VACOVHAORO/RCO/default.aspx) [*“*ORO *Guidance Regarding RCO Audit and Training Requirements”*](https://www.va.gov/ORO/Docs/RCO/2021_2022_ORO_Guidance_for_RCO_Research_Audit_and_Training_Requirements.pdf) |  |
| 16. | RCO triennial regulatory audits are performed on all required approved study protocols as specified by ORO. RCO audits must be conducted in accordance with a written audit plan. | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.i(1)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082)Guidance on [ORO website](https://www.va.gov/ORO/)and the [RCO section of the ORO SharePoint site](https://dvagov.sharepoint.com/sites/VACOVHAORO/RCO/default.aspx)[“ORO *Guidance Regarding RCO Audit and Training Requirements”*](https://www.va.gov/ORO/Docs/RCO/2021_2022_ORO_Guidance_for_RCO_Research_Audit_and_Training_Requirements.pdf) |  |
| 17. | The RCO includes in audits all required elements of the audit tools provided by ORO and revised annually.  | [ ]  | [ ]  | [ ]  | [“ORO *Guidance Regarding RCO Audit and Training Requirements”*](https://www.va.gov/ORO/Docs/RCO/2021_2022_ORO_Guidance_for_RCO_Research_Audit_and_Training_Requirements.pdf) |  |
| 18. | The results of RCO audits (regardless of findings) are reported to the relevant research review committees, including the R&DC and others as required by VHA Directive 1058.01 and local SOPs. | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.i(1)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) Local reporting SOPs  |  |
| 19. | Upon RCO discovery of any event reportable under VHA Directive 1058.01, the RCO reports the event according to the requirements of VHA Directive 1058.01 and local SOPs. | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) §5.lLocal reporting SOPs |  |
| 20. | The RCO informs the VA MFD and applicable research review committees about research compliance concerns. | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.i(2)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082) |  |
| 21. | Any additional research oversight duties assigned by the RCO’s supervisor do not conflict with or delay completion of the RCO’s research audit responsibilities.  | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.i(3)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082)  |  |
| 22. | The RCO serves as a non-voting consultant, as needed, to the facility’s R&D Committee, IRB, IACUC, SRS, and other research review committees. The RCO does not serve as a voting member of these committees. The RCO attends meetings of these committees when requested by the committee or as specified by local SOPs. | [ ]  | [ ]  | [ ]  | [VHA Directive 1058.01 §5.i(3)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=9082)[VHA Directive 1200.05(2) §7(h)](https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=8171) |  |

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| **While the characteristics described in this table are not mandated by VA requirements, ORO has found that these factors are strongly associated with a successful RCO audit program. ORO recommends a self-assessment of each of these areas when analyzing a facility’s RCO program and creating strategies for improvement.** |
|  | Success Characteristic | None 1---5 Excellent | Notes |
| 23. | The RCO meets regularly and as needed with the MFD |  |  |
| 24. | The RCO and leadership of the Research Service have mutually supportive professional relationships and open, frank communication that encourages solutions to issues. |  |  |
| 25. | The RCO is able to reliably access the facility electronic protocol tracking system to effectively plan and accomplish required audits. |  |  |
| 26. | The RCO reconciles their active protocol lists with information from the Research Service. |  |  |
| 27. | The RCO utilizes spreadsheets and electronic forms to efficiently accomplish required audits. |  |  |
| 28. | The RCO has adequate tracking systems to monitor progress towards audit goals and provides progress reports as requested to the MFD. |  |  |
| 29. | The RCO has a continuing education plan in place to maintain required knowledge and skills for the RCO role. |  |  |
| 30. | RCO routinely attends RCO bimonthly teleconferences and other ORO and ORD training opportunities. |  |  |
| 31 | RCO has established a mentorship or frequent effective communication with another facility or VISN RCO. |  |  |

1. Name and title. May include RCO, ACOS/R&D, AO/R&D, etc. [↑](#footnote-ref-1)