**Office of Research Oversight**

**Research Compliance Officer (RCO)**

 **Technical Assistance and Self-Assessment Tool**

**October 2011**

**Revised July 2013**

This resource is provided by ORO for technical assistance to VA research facilities regarding the role of the RCO, in order to assist facilitiesin assessing their compliance with regulations and policies related to the role of the RCO, including but not limited to the VHA Handbook 1058.01 and guidance posted on the ORO website and the ORO Technical Assistance SharePoint site. It also emphasizes practices that help the RCO achieve success in their role. Please direct any questions you may have about the tool to ORO Central Office at ororcep@va.gov.

**SOURCES OF DOCUMENTATION/EVIDENCE:** Prior to conducting a self-assessment with this checklist, you may find it 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) 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.

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

|  |
| --- |
| **ORO Research Compliance Officer (RCO) Self-Assessment Tool** |
|  | **Element** | **Y** | **N** | **N/A** | **Reference** | **Notes** |
| 1 | The Medical Center Director has appointed one or more RCOs to conduct annual research informed consent audits and triennial regulatory audits, and to assist in facility assessments of regulatory compliance | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §6.c |       |
| 2 | The facility’s lead RCO reports directly to the Medical Center Director, and is responsible for developing and implementing a research compliance program. | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §6.c .(2)VHA Directive 1200 §4. (10)VHA Handbook 1200.05 §5.d.(2) |       |
| 3 | The RCO has a Position Description that accurately reflects their duties. | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §6.a-c |       |
| 4 | If the facility has not designated at least one full-time RCO, a waiver for a part-time RCO has been approved by the Undersecretary for Health. | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §6.c .(1) |       |
| 5 | No part of RCO activities are determined or managed by the Research Service, research investigators, or any other research personnel. | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §6.c .(2) |       |
| 6 | The facility has written standard operating procedures and/or an auditing plan that describes how the required RCO audits will be achieved. | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §6.c Guidance on ORO websiteGuidance on ORO Technical Assistance SharePoint site *“2013-14* ORO *Guidance for RCO research audit and training requirements”*  |       |
| 7 | The Medical Center Director provides adequate resources to support the research program and the required RCO audits. | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §6.a -.c VHA Directive 1200 §4.c.(4)VHA Handbook 1200.01 §5.a + .dVHA Handbook 1200.05 §5.d.(2) and .g |       |
| 8 | RCO informed consent document (ICD) audits are accomplished for all active human subjects research protocols annually, including 100% of ICDs. | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §6.c Guidance on ORO websiteGuidance on ORO Technical Assistance SharePoint site *“2013-14* ORO *Guidance for RCO research audit and training requirements”* |       |
| 9 | RCO regulatory audits are accomplished as required by ORO for research initiated after January 1, 2008. (approximately one-third of active studies annually) | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §6.c Guidance on ORO websiteGuidance on ORO Technical Assistance SharePoint site *“2013-14* ORO *Guidance for RCO research audit and training requirements”* |       |
| 10 | The RCO includes in audits all required aspects of the audit tools provided by ORO and revised annually. | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §6.c Guidance on ORO websiteGuidance on ORO Technical Assistance SharePoint site *“2013-14* ORO *Guidance for RCO research audit and training requirements”* |       |
| 11 | The results of RCO audits are reported to the relevant oversight committees and others as required by VHA Handbook 1058.01 and local SOPs | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §6.e | *Are ALL results, even normal audits, reported as required?* |
| 12 | Apparent serious or continuing non-compliance identified during the process of any systematic audit of human subjects research is reported by the RCO directly (without intermediaries) to the Medical Center Director within 5 days, in writing, with copies to the IRB, ACOS/R&D and R&DC. | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §7.h |      Note at least one recent example by identifying date reported to MCD |
| 13 | Within 5 business days of becoming aware of any apparent serious or continuing non-compliance other than during the process of any systematic audit, the RCO ensures that the apparent noncompliance has been reported in writing to the IRB. | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §7.e |      Note at least one recent example by noting date of IRB meeting where it was discussed |
| 14 | The RCO reports other non-compliance and reportable events consistent with the requirements of VHA Handbook 1058.01 and local SOPs. | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §7 - §12 |       |
| 15 | The RCO serves as a non-voting consultant, as needed, to the facility’s R&D Committee, IRB, IACUC, SRS, and other research committees. The RCO does not serve as a voting or non-voting member of these committees. The RCO attends meetings of these committees when requested by the committee or as specified by local SOPs. | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §6.c.(3)VHA Handbook 1200.05, §12.k |       |
| 16 | The RCO completes and maintains training required by voting members of the R&DC, IRB, IACUC, and SRS. | [ ]  | [ ]  | [ ]  | VHA Handbook 1058.01, §6.c Guidance on ORO websiteGuidance on ORO Technical Assistance SharePoint site *“2013-14* ORO *Guidance for RCO research audit and training requirements”* |       |

|  |
| --- |
| **While the characteristics described in this table are not mandated by VA requirements, ORO has found that these matters 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 | None1 ---5 Excellent | Notes |
| The RCO meets regularly and as needed with the Medical Center Director, and is able to communicate concerns in a timely manner without intermediaries. |  |  |
| The RCO and leadership of the Research Service have mutually supportive professional relationships and open, frank communication that encourages solutions to issues. |  |  |
| The RCO is able to reliably obtain from the Research Office accurate numbers and types of active VA research protocols, to effectively plan and accomplish required audits. |  |  |
| The RCO utilizes spreadsheets and electronic forms to efficiently accomplish required audits. |  |  |
| The RCO has adequate tracking systems to monitor progress towards audit goals, and provides progress reports as requested to the Medical Center Director. |  |  |

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