

**Department of
Veterans Affairs**

Memorandum

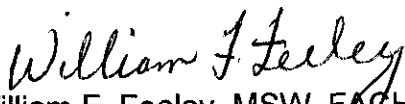
Date: **MAR 3 2009**

From: Deputy Under Secretary for Health for Operations and Management (10N)

Subj: Research Compliance Officer and Compliance and Business Integrity Officer Positions

To: Veterans Integrated Service Networks (VISN) Directors,
Veterans Affairs Medical Center (VAMC) Directors

1. The FY 2009 Executive Career Field (ECF) Performance Plan requires (under "Business Processes") that each VA research facility appoint a full-time Research Compliance Officer (RCO). RCOs are required to perform extensive dedicated auditing, monitoring, and reporting on the conduct of all VA research and to provide education to investigators and research staff regarding regulatory and policy requirements.
2. It is not the intent to make the RCO function part of the business compliance function. The Office of Research Oversight (ORO) Chief Officer and the Chief Compliance and Business Integrity (CBI) Office are in complete agreement with me that the RCO and the CBI Officer positions should not be combined.
3. The RCO and the CBI Officer perform key functions within your medical center. They are separate and distinct positions, each of which requires specific skill sets and experience. Each position is generally full time and must report to the medical center director.
4. The knowledge required of the RCO is detailed and requires experience in a broad range of research areas. Information regarding these requirements is provided in attachment A. Similarly, the expertise for the CBI Officer is detailed and requires experience in business compliance areas. Information regarding the CBI Officer is provided in attachment B.
5. If you have any questions regarding this information, I urge you to contact the representatives listed in the attachments for additional guidance and discussion.


William F. Feeley, MSW, FACHE

Attachments

cc: Chief Officer, Office of Research Oversight (10R)
Chief Compliance and Business Integrity Officer (10B3)
Chief Research and Development Officer (12)

Attachment A

Research Compliance Officer Requirements: Information from the Office of Research Oversight

1. What is the Office of Research Oversight that is participating in Research Oversight responsibilities?

The Office of Research Oversight (ORO)(10R) serves as the primary Veterans Health Administration (VHA) office for advising the Under Secretary for Health (USH), and conducting compliance oversight, relative to the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, and government wide debarment for research impropriety. In addition ORO provides an education program for Research Compliance Officers to promote clear understanding of Federal/VA requirements for research. The scope of the responsibility for ORO is codified in VHA Directive 1058, "Responsibilities of the Office of Research Oversight." (currently under revision). ORO serves a major role in helping to develop required standards for Research Compliance Officers required in VHA facilities with research.

2. What are the Research Compliance Officers' requirements?

At least one Research Compliance Officer is now required in each Veterans Health Administration (VHA) research facility. Requirements are specified in the FY 2009 Executive Career Field (ECF) Performance Plan. Note that the requirements are found in the Facility Director Performance Plan under "Business Processes." However, the intent is NOT to make this part of the business compliance function. The new RCO requirements include, for example, extensive dedicated auditing, monitoring, and reporting on the conduct of all VA research, the use of monitoring tools, non-member participation in research review committees, and providing education to investigators and research staff regarding regulatory and policy requirements.

More information is included on ORO's (10R) website at <http://vawwl.va.gov/oro/> entitled Requirement for Research Compliance Officers Due by End of Quarter 1, FY 2009.

3. Is the Research Compliance Officer a full time position?

The Research Compliance Officer (or lead Research Compliance Officer for facilities that have more than one) must be dedicated full time to research compliance and must report directly to the Facility Director in VA facilities. VHA will consider the possibility of a limited waiver for the Under Secretary for Health to permit part-time Research Compliance Officers at facilities with small research programs. Waivers will be considered on a case-by-case basis upon recommendation of the Office of Research and Development, ORO, and

approval of the Deputy Under Secretary for Health for Operations and Management, and the Principal Deputy Under Secretary for Health, and the Under Secretary for Health. Instructions on how a waiver for a full-time Research Compliance Officer is found in attachment C. Reporting to the Facility Director is still required if the Research Compliance Officer is full time or part-time.

4. Whom do I contact for additional information about the ORO and Research Compliance Officer general responsibilities?

Please contact ORO Central Office, Paula Waterman, Paula.Waterman@va.gov or Dr. Joan Porter, Joan.Porter@va.gov.

Attachment B

1. What is the role of the Compliance and Business Integrity (CBI) program?

The mission of the CBI Program provides internal oversight of VHA's revenue operations to:

- Uphold compliance with applicable laws, regulations, and standards
- Foster a culture of business integrity and quality
- Support the early detection, mitigation, and prevention of non-compliance practices
- Demonstrate our commitment to accountability, transparency, and stewardship

The CBI Office supports the CBI Program and VHA in several core ways. First, the Chief CBI Officer and the CBI office serve as the principal VHA function advising the Under Secretary for Health on matters related to compliance and business integrity. The CBI Office receives guidance from the Compliance Advisory Board (CAB) and provides routine updates on the program to VHA Executive Leadership and the Executive Committee of the National Leadership Board.

Second, the office acts in a custodial role for the program as a whole by providing guidance and targeted support to regional (VISN) and medical center-based (VAMC) CBI Officers. This support enhances local CBI Program initiatives in alignment with core national risks, priorities, and needs. Finally, the CBI Office partners actively with other VA and VHA business and ethics offices to work on joint risk management, strengthening of internal controls, mitigation activities, and enhancement of business and ethics quality.

2. What is the role of a CBI Officer?

Network and medical center CBI Officers are responsible for establishing and maintaining CBI Programs within their facilities in alignment with national directives and guidance. CBI Officers are accountable for programmatic elements and outcomes, advising leadership on CBI matters, and receiving guidance from a local multi-disciplinary Compliance Committee.

The CBI Officer position should be a full time position reporting to the network or medical center director. CBI Officers are sometimes assigned other collateral duties (non-conflicting with their core business compliance role) as defined by local leadership, systems requirements, and resources. Although other areas of the organization may benefit from the contribution of the CBI Officer's valuable expertise, collateral duties typically significantly impede a CBI Officer's ability to proactively strengthen their program and reduce business risks.

3. Whom do I contact for additional information about CBI?

Please contact the VA Central Office, CBI Office, Caitlin O'Brien, Chief CBI Officer, Nancy L. Howard, Deputy Chief CBI Officer or visit the CBI website at <http://vaww.cbi.va.gov>.

Attachment C

Please refer to the following documents on ORO's website for Waiver Information at <http://www1.va.gov/oro/page.cfm?pg=143> or follow the links below.

Other Requirements/Policies —

- [RCO Waiver Clarification and Designation of Full-Time "Acting" RCO](#) - (01/12/09)
The Deputy Under Secretary for Health for Operations and Management (10N) and the Chief Officer, Office of Research Oversight (10R) have issued guidance concerning the RCO waiver request and the designation of a full-time "acting" RCO.
- [Waiver for Hiring Full-Time Research Compliance Officer](#) - (01/09/09)
This memo has been signed by the Under Secretary for Health and outlines the waiver request requirements and procedures.

Note: March 5, 2009 - This document has been appended to include Attachment C that was left off the original document when it was sent out.