

June 11, 2010

## **OFFICE OF RESEARCH & DEVELOPMENT GUIDANCE THE RESEARCH COMPLIANCE OFFICER'S ROLE ON RESEARCH REVIEW COMMITTEES**

1. Recently a new policy (VHA Handbook 1058.01 published May 21, 2010) from the Office of Research Oversight (ORO) has re-defined the role of the Research Compliance Officer (RCO). In paragraph 4t the policy defines the role of the RCO as an individual whose primary responsibility is auditing and reviewing research projects. The definition indicates that the RCO does not serve as a voting or nonvoting member of research review committees. The RCO may attend meetings of specific committees when requested by the committee or as specified by local Standard Operating Procedures (SOP).

2. Review committees include the Research and Development (R&D) Committee, the Institutional Review Board (IRB), Subcommittee on Research Safety (SRS), and Institutional Animal Care and Use Committee (IACUC). Both the Office of Research and Development (ORD) and ORO understand that the RCO not serving as a non-voting member of the review committees is a change from previous ORO policies and differs from current ORD policies such as VHA Handbooks 1200.01 and 1200.05 that state the RCO may serve as a non-voting member.

3. Because this represents a major change in VHA policy, both ORO and the ORD discussed this issue and the appropriate wording for VHA Handbook 1058.01 as well as the draft VHA Handbooks 1200.01, 1200.05, and 1200.07. Both ORD and ORO did agree on the new wording, and this wording will be incorporated into the applicable new ORD handbooks.

The basis for this new wording includes such considerations as:

- Concerns related to conflict of interest or possible conflicts of interest between the role of the RCO on the review committees and the role of the RCO in auditing and reviewing research for compliance with applicable regulations/requirements.
- Preventing an appearance that the RCOs may be inadvertently or overtly influencing the decisions of the IRB and other review committees. This may occur if the RCO is overly assertive or the IRB is concerned about how the RCO will conduct an audit or what will be reported to the Medical Center Director (MCD) or ORO.

4. The current ORO policy allows the review committees to develop SOPs requesting the RCO's attendance at meetings when regulatory guidance is needed from the RCO. The intent of this part of the policy is to allow review committees the flexibility to develop RCO attendance policies that best meet the needs of the committee, as determined by the committee. ORO and ORD will be developing additional guidance related to these SOPs.