Department of Veterans Affairs

Memorandum

Date: November 1, 2004

From: Chief Officer, Office of Research Oversight (ORO) (10R)

Subj: Announcement of ORO Initiation of Routine Reviews at VA Facilities Conducting Research

To: Directors of VA Facilities Conducting Research

1. ORO is initiating a program of Routine Reviews to prospectively and systematically review regulatory compliance at VA facilities (VA Medical Centers, VA Health Care Systems, and VA Medical and Regional Outpatient Clinics) conducting research.

2. The reviews will be consultative and directed at identifying issues of noncompliance and providing recommendations for correction as needed. Depending on the scope of and extent of noncompliance, action plans to make corrections may be required. If issues of noncompliance are identified that are harming patients or potentially are likely to harm patients, ORO would initiate a For Cause Review and seek appropriate immediate action. We hope not to see any problems of this type, however, we will promptly respond if they are identified. The on-site reviews are intended to review regulatory compliance in one or more of the following areas of research oversight: human subject protections, animal welfare, research safety, and research misconduct. Review questions will be based on current federal regulations, policies, and guidance.

3. ORO's Regional Office Directors will contact facilities to schedule the Routine Review site visits. Each ORO Regional Office will complete at least one Routine Review in CY 04. Directors of facilities to be visited this year have either been contacted or will be contacted shortly to schedule these reviews.

4. ORO will give feedback to each facility at the conclusion of its visit. A site visit report will be issued within 6 weeks of the visit. The report will include an assessment of good compliance practices, consultative suggestions, and, where needed, formal recommendations and actions required for the facilities to come into compliance with applicable laws, regulations, and policies.

5. ORO's Routine Review Program is directed at being collegial, interactive, and effective in helping assure that VA's research is in compliance with relevant regulations, policies, and guidance.

6. If interested, you may contact the ORO Regional Office to request that your facility be visited. Your full cooperation is appreciated, and our staff looks forward to working with you to achieve our mutual goals of regulatory compliance and excellence in VA research.

7. If you have questions about the ORO Routine Review Program, please contact your ORO Regional Office Director or contact me in Central Office. The postal and e-mail addresses, and telephone and fax numbers for each of these individuals are listed in an attachment.

David A. Weber, Ph.D., FACNP

Attachment

cc: ACOSs for R&D and Research Coordinators
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