Department of Veterans Affairs

Memorandum

Date: FEB - 1 2005

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

Subj: Quality Assurance Project to Promote Research Compliance

To: VHA Facility Directors Using Affiliate Institutional Review Boards (IRBs)

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

1. The Office of Research Oversight (ORO) is now initiating the second phase of a Quality Assurance (QA) Project directed at evaluating the elements contained in the IRB minutes and certain procedural aspects of the IRB review. Our office recently completed its review of minutes for VHA facilities operating their own IRBs and now we are completing the review of those VHA facilities that rely on affiliate IRBs as their IRB of record.

2. The minutes of meetings of the IRBs of record for VHA facilities are key documents that support the review and approval of VHA research. They must be prepared in accordance with criteria found in federal regulations and policy in VHA Handbook 1200.5, "Requirements for the Protection of Human Subjects in Research," July 15, 2003.

3. We are conducting the quality assurance project as part of ORO's prospective oversight of human research protection in research. The approach provides an efficient data collection methodology through which both ORO and facilities can identify key deficiencies and best practices. ORO will provide feedback to individual facilities. At the completion of the project, the general trends observed in the composite findings will be summarized and circulated to all of the participants.

4. Each VHA facility that relies on an affiliate's IRB of record is asked to provide the following information to ORO:

   - Minutes from all IRB meetings (whether approved or not) occurring from December 2003 through April 2004. Include all appendices to the minutes. Where more than two IRBs from an affiliate review VA protocols, only submit minutes for the two IRBs that most frequently conduct VA protocol reviews.

   - A complete IRB roster of membership for each IRB that reviews VA research and was registered with the Office for Human Research Protections (OHRP) in the Department of Health and Human Services for the time period of December 2003 through April 2004. The roster should show each member's role (e.g., non-scientist, physician, psychologist, prisoner representative, unaffiliated member, alternate).

   These materials should be sent to your assigned ORO Regional Office either in hard copy or electronically through e-mail by March 4, 2005. A list of names and addresses

of ORO Regional Office staff is in the attachment. This information can also be found on ORO's website at http://www1.va.gov/oro/ or http://vaww1.va.gov/oro/.

5. ORO staff may contact your facility to clarify information in your documents. ORO will advise you immediately if any systemic fundamental compliance issues are apparent from document review.

6. If you have any questions, please contact your ORO Regional Office Director. We appreciate your assistance in carrying out this quality assurance project.

David A. Weber, PhD, FACNP

Attachment

cc: Acting Deputy Under Secretary for Health (10A)
Acting Chief Research and Development Officer (12)
Network Directors
ACOSs/R&D or Research Coordinators

OFFICE OF RESEARCH OVERSIGHT (ORO)
Regional Offices

ORO, MID-ATLANTIC REGION

50 Irving Street, N.W. (688/10R)
Washington, D.C. 20422
FAX: (202) 745-8538

VISNs 4, 5, 6, 9, 10

Director, Min-Fu Tsan	202-745-8544
Program Specialist, Sanitra McKenzie	202-745-8110
Deputy Director, Baochong (Ben) Gao	202-745-8687
Health Science Specialist, Kenneth Sung	202-745-8549

ORO, MIDWESTERN REGION

Building 1 (578/10R), Room B-103
5th & Roosevelt Avenues
Hines, IL 60141
FAX: (708) 202-7250

VISNs 11, 12, 15, 19, 23

Director, Karen M. Smith	708-202-7256
Program Specialist (vacant)	
Deputy Director, Cindy Paulsen	708-202-7251
Health Science Specialist, David Semlow	708-202-7266

ORO, NORTHEASTERN REGION

VAMC Bedford (518/10R)
200 Springs Road
Bedford, MA 01730
FAX: (781) 687-3858

VISNs 1, 2, 3

Director, Richard D'Augusta	781-687-3854
Program Specialist, Ovidia Dragoli	781-687-3850
Health Science Specialist, Curt Pospisil	781-687-3853
Health Science Specialist, Leslie Ann Cahill	781-687-3852

OFFICE OF RESEARCH OVERSIGHT (ORO)
Regional Offices

ORO, SOUTHERN REGION

1670 Clairmont Road (508/10R)
Decatur, GA 30033
FAX: (404) 417-2935

VISNs 7, 8, 16, 17

Director, David J. Miller	404-417-2933
Administrative Officer, Jane Roberts	404-417-2929
Deputy Director, Dale Conaway	404-417-2934
Health Science Specialist, Edward Cannady	404-417-2931

ORO, WESTERN REGION

P.O. Box 7360
Moreno Valley, CA 92552-7360

Express Delivery:
ORO, Western Region (605/10R)
5029 4th Street, Bldg. 2641
March ARB, CA 92518
FAX: (909) 801-5176

VISNs 18, 20, 21, 22

Director, Paul Hammond	909-801-5167
Administrative Officer, Susan Seiss	909-801-5164
Deputy Director, Alain Fymat	909-801-5168
Health Science Specialist, Lynn Willis	909-801-5169