

**Department of  
Veterans Affairs**

# Memorandum

Date: September 17, 2007

From: Deputy Under Secretary for Health for Operations and Management (10N)  
Chief Officer, Office of Research Oversight (10R)

Subj: Encouraging Communications with the Office of Research Oversight (10R)

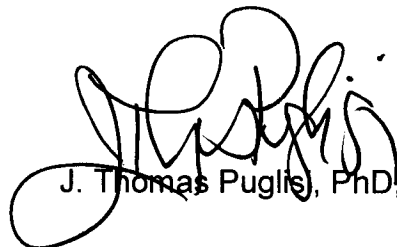
To: Network Directors

1. The Office of Research Oversight (10R) is responsible for oversight of compliance with all regulations and policies governing VHA research, including the protection of human subjects, laboratory animal welfare, research safety, research information security, research laboratory security, and research misconduct.
2. ORO's five Regional Offices (see attached) interact directly with VHA research facilities to provide technical assistance and otherwise facilitate local research oversight programs.
3. Developing ongoing lines of communication between network and facility leadership and the appropriate ORO Regional Office can be an important, proactive element in fostering research compliance and strengthening facility research oversight programs.
4. We encourage Network Directors to promote communication with ORO by inviting their ORO Regional Office Director to participate periodically in calls and meetings of their Network Leadership Council and Research Leadership.
5. ORO Regional Office Directors are anxious to assist networks and facilities in developing and maintaining strong research compliance programs. Please do not hesitate to contact ORO regularly, not only when problems arise, but on an ongoing basis to help ensure the best possible protections for veterans and staff involved in VA research.



William F. Feeley, MSW, FACHE

Attachment



J. Thomas Puglis, PhD, CIP

cc: Under Secretary for Health (10)  
Principal Deputy Under Secretary for Health (10A)  
Chief of Staff (10B)  
Chief Research and Development Officer (CRADO)(12)  
ORO Regional Office Directors

# **Office of Research Oversight (ORO)**

## **ORO CENTRAL OFFICE**

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## **MID-ATLANTIC REGIONAL OFFICE**

**VISNs 4, 5, 6, 9, 10**

Washington, DC VAMC

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## **MIDWESTERN REGIONAL OFFICE**

**VISNs 11, 12, 15, 19, 23**

Hines VAMC

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## **NORTHEASTERN REGIONAL OFFICE**

**VISNs 1, 2, 3**

**(also Hines VAMC)**

Bedford VAMC

Richard D'Augusta, RPh, MPA, Director: 781.687.3854  
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## **SOUTHERN REGIONAL OFFICE**

**VISNs 7, 8, 16, 17**

**(also WDC & Martinsburg VAMCs)**

VISN 7 Headquarters

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## **WESTERN REGIONAL OFFICE**

**VISNs 18, 20, 21, 22**

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**Office of Research Oversight  
Information Update  
September 12, 2007**

**ORO Checklists:** ORO's website now includes compliance oversight checklists for each of its areas of responsibility, including human research protections, laboratory animal welfare, research information security, research privacy, research laboratory safety, research laboratory security, Research and Development (R&D) Committee operations, Institutional Review Board (IRB) operations, Memoranda of Understanding (MOUs) for using an affiliate's IRB, and research misconduct. VHA research facilities will find these checklists useful for conducting self-assessments of their research oversight programs. These are the same checklists that ORO used when conducting on-site reviews of VHA research programs, and are accessible at <http://www1.va.gov/oro/page.cfm?pg=139>.

**Recruitment of Research Subjects:** VHA requirements for identifying and recruiting potential research subjects are more restrictive than those under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. Accessing patient records for recruitment into research requires prior Institutional Review Board (IRB) approval, IRB waiver of Privacy Rule Authorization, IRB waiver of informed consent, and Research and Development (R&D) Committee approval. These steps are required even when records of one's own patients are accessed for recruitment purposes. Additional information can be found on ORO's website at [http://www1.va.gov/oro/docs/Policy on Recruitment of Study Subjects-090507.doc](http://www1.va.gov/oro/docs/Policy%20on%20Recruitment%20of%20Study%20Subjects-090507.doc).