



Research Compliance Oversight in the Department of Veterans Affairs

Karen M. Smith, PhD
Director, Midwestern Regional Office
Office of Research Oversight
Department of Veterans Affairs

Health Care Compliance Association
6500 Barrie Road, Suite 250, Minneapolis, MN 55435
888-580-8373 | www.hcca-info.org

```
graph TD; DVA[Department of Veterans Affairs] --- VBA[Veterans Benefits Administration]; DVA --- VHA((Veterans Health Administration)); DVA --- NCA[National Cemetery Administration];
```

- In 2007, VHA provided health care for 5.5 million veterans
- Care delivered at more than 1,400 sites, including
 - 157 VA medical centers
 - 895 community and facility based outpatient clinics
- VHA staff of 204,000
- More than 65% of all U.S. physicians trained in VA facilities
- 117 VA hospitals affiliated with 107 academic health systems
- ~115 VA medical centers conduct research

HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION
888-580-8373 | www.hcca-info.org

2

VA Research Accomplishments

- First effective therapies for tuberculosis
- Improvements in prosthetics
- The implantable cardiac pacemaker
- Advances in computed tomography (CT) scanner and Magnetic Resonance Imaging (MRI)
- Liver transplant
- The nicotine patch

VA Research Program Expenditures

- VA research appropriation is more than \$800 million per year for research and development (direct and administrative costs)
- VA facilities also carry out externally funded research sponsored by other government agencies and private sources
- Total research expenditure of around \$1.8 billion in 2008

What makes VA research attractive?

- Intramural funding
- Close academic relationships
- Large patient population
- Electronic medical record
- Data repositories

Challenge of Maintaining Compliance in Large National Health Care System

Late 1990s: Lessons of West Los Angeles VA Medical Center research shutdown

>>> Accreditation required for Human Research Protection Programs

>>> Establishment of national VA research oversight office

Office of Research Oversight (ORO) Mission

ORO is the primary office in VHA for overseeing the responsible conduct of research and investigations of alleged research misconduct and other research improprieties. ORO promotes and enhances the responsible conduct of research in conformance with all applicable laws, regulations, and policies.

- Human Research Protection
- Research Information Security and Privacy
- Laboratory Animal Welfare
- Research Safety and Security
- Research Misconduct
- Government-wide Debarment and Suspension
- Training Research Compliance Officers

ORO Organization: Central Office

ORO Central Office, Washington, DC

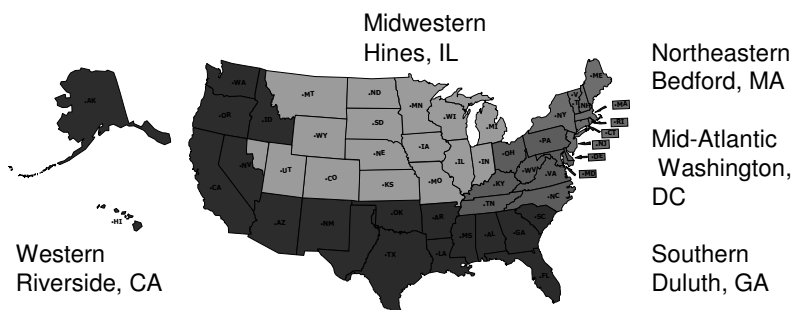
- Administration and liaison
- Policy formulation
- Subject matter experts
- Research misconduct and debarment
- Human research assurances

ORO Organization: Regional Offices

Regional Offices in 5 locations

- Oversight of compliance
- Liaison with VA facilities
- Site visits (routine and for-cause)
- Reports of noncompliance, unanticipated problems, adverse events

Map of ORO Regions



ORO Responsibilities

- Oversight of reports of noncompliance, problems
- Routine Reviews on site (~ 60/year)
- For-Cause Reviews on site
- Facility Directors' Certifications
- Human Research Assurances
- Training and Education

ORO Responsibilities

- Liaison
 - Within VA
 - With other government agencies
 - With academia and professional societies
- Policy development
- National quality assurance projects
- Technical assistance

ORO On Site Reviews

- Reviews in most of ORO's assigned topic areas (usually 1-2 topic areas per visit)
- Usually 2-5 site visitors, 2-5 days
- Site visits to each facility approximately every 2 years
- About 60 – 70 site visits/year
- Checklists posted on the ORO web site:
<http://www1.va.gov/oro/page.cfm?pg=139>
- Written report, remedial action plan, follow up until all issues are resolved

Human Research Protection in the VA

VA and the Common Rule

- 38 CFR 16 = 45 CFR 46, Subpart A
- VA policies conform to other Subparts, but are more restrictive

ORO collaborates with the Office for Human Research Protections to administer Federalwide Assurances (FWAs) for all VA entities conducting human research

VA follows FDA regulations as applicable

VA Handbooks impose additional requirements

Local Oversight of Human Research Protection Programs at VA Medical Facilities

- The Research & Development (R&D) Committee
- Reliance on affiliate IRBs
 - ~ 40% rely on an affiliate IRB
 - Relationships established through MOUs
- AAHRPP accreditation required
- Monitoring/auditing by local facility
- Research Compliance Officers
- Yearly training:
 - Human Subject Protection, Good Clinical Practice, Privacy, Information Security

Facility Director Research Oversight Certification and Checklist

Detailed checklist of facility director's specific responsibilities provided annually

Action plans with timelines

Monitoring of action plan implementation by ORO regional offices

Of the 2007 certifications, 57% reported need for an action plan. Common deficiencies:

- Annual assessments or reports not done
- Written operating procedures incomplete

Common Compliance Concerns Human Research Protection Program

- ✓ Initiating research without IRB and/or R&D Committee approval
- ✓ Enrolling subjects with absent or deficient informed consent
- ✓ Implementing unapproved protocol changes
- ✓ Inadequate procedures for reporting:
 - Serious / related / unexpected adverse events
 - Unanticipated problems involving risks to subjects/others
- ✓ Lack of procedures for conducting protocol and IRB audits

ORO Compliance Reports: Human Research Protection

“An FDA inspection found IRB did not follow its written procedures for reporting unanticipated problems; conducting initial and continuing reviews; and ensuring that unapproved changes do not occur.”

“PI obtained blood samples from 5-6 subjects without IRB approval and informed consent, shared PHI with individuals who were not part of IRB-approved research team, could not document consent for 120 of 266 subjects in other research.”

ORO Compliance Reports: Human Research Protection

“Facility suspended new enrollments on 4 studies where the PI had not completed investigator training, the co-investigator/resident had not completed credentialing, and improper consent documents were used for 175 of 201 subjects.”

“The sponsor-investigator of a protocol for the treatment use of an investigational drug failed to provide annual reports to the IRB and FDA.”

Common Compliance Concerns Privacy/Information Security

- ✓ Inadequate procedures for reporting breaches or losses to privacy officer and/or information security officer
- ✓ Unauthorized use / disclosure / loss of identifiable patient information
- ✓ Violations of VA information security requirements

ORO Compliance Reports: Information Security and Privacy

“A research assistant unknowingly dropped a piece of paper containing last names and last 4 digits of SSN of 5 prospective research subjects, and full names, VA ID numbers and completion dates of 3 enrolled subjects. The paper was found by a patient who turned it to the facility.”

“An unencrypted laptop was found connected to the VA network. Names and social security numbers of approximately 650 subjects were stored on this computer.”

ORO Compliance Reports: Information Security and Privacy

“Documents containing PHI (name, date of birth and SSN) of 5 subjects were lost.”

“More than 20 subjects received checks from a study administrator with ‘Shingle Study’ written on the envelopes, thus violating subjects’ privacy.”

“Facility reported that an investigator placed materials containing PHI in a recycling bin, constituting a security breach.”

Current VA Challenges in Protecting Human Subjects

Affiliate relationships

Research information security and privacy

Why Do So Many VAs Rely on Affiliate IRBs?

Overlap of faculty

Avoidance of dual IRB review

Availability of IRB expertise

Close relationships >> quality research programs

Challenges of Affiliate Relationships

- Additional requirements entailed by VA policy (including accreditation)
- Maintain knowledge base about VA policies
- Administrative burdens on IRBs
- Communication
- Division of responsibilities

Issues with Reliance on Affiliate IRBs: A Case Study

In 2007, the VA learned that FDA had terminated 3 collaborative studies involving a VA medical center, its university affiliate, and FDA.

The VA medical center relied on the IRBs of the affiliate for oversight of its human research.

Findings

VA facility audits identified serious deficiencies in a number of studies

University IRBs:

- Unresponsive to audit reports
- Not cognizant of VA requirements
- Failed to inform facility systemically of serious adverse events and noncompliance

Findings

VA Facility R&D Committee:

- Inadequate review of individual protocols
- Inadequate oversight of research program

Findings

VA Facility Research Administration:

Extreme reliance on affiliate

Inadequate written policies and procedures

Absence of infrastructure and internal controls for research

- Lack of complete protocol records in Research Service
- Deficient protocol inventory and tracking
- Lack of conflict of interest monitoring and management procedures
- Lack of enforcement of training requirements

VA Response

VA Under Secretary for Health required this facility to cease use of the university affiliate's IRBs and establish a VA IRB

ORO required the VA medical center to:

- Cease initiation of new studies
- Cease enrollment of subjects in existing research unless necessary for health of individual subject
- Transfer oversight to another VA IRB immediately
- Establish appropriate R&D Committee review and oversight procedures

ORO Review of Use of University IRBs

ORO's review of VA use of university IRBs is underway

- On-site reviews of effectiveness of university IRBs for VA research programs
- Strengthen annual Facility Director certification to include use of university IRBs
- Review accreditation standards and findings for VA use of university IRBs
- Review effectiveness of oversight by VA R&D Committees
- Develop and implement education programs addressing VA use of university IRBs

Maintaining Research Information Security: A Case Study

“On January 22, 2007, a Veterans Health Administration (VHA) Information Technology (IT) Specialist ... reported that a VA-owned external hard drive was missing... The missing external hard drive is believed to contain numerous research-related files containing personally identifiable information and/or **individually identifiable health information for over 250,000 veterans**, and information obtained from the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), on over **1.3 million medical providers**.”

“The vast majority of the data was not password-protected or encrypted.”

Report of VA Office of Inspector General,
<http://www.va.gov/oig/51/FY2007rpts/VAOIG-07-01083-157.pdf>

What the VA Learned

Electronic medical record

+

Related electronic data bases

>> Enormous data repositories

>> Potential for extremely valuable research

+

Lax information security procedures

>> Potential for disastrous information security breaches

VA Inspector General Findings

Inadequate information security controls to safeguard data stored on external hard drives

- Lack of encryption, password protection
- Lack of inventory/oversight of employee use of data

Inadequate physical office space security measures

- Doors that didn't close or lock properly

Inadequate assessment of the sensitivity level of research positions

- The IT specialist position was classified as "moderate risk"
- IT specialist had access to, obtained and stored data beyond the scope of his assignment

VA Inspector General Findings

Principal Investigator did not comply with conditions of IRB approvals and HIPAA waivers:

- More data was obtained than approved for the protocol
- Security measures described in protocol and waiver requests were not followed

Supervisory oversight of the research center was lacking

ORO Findings

- Facility leadership not involved in oversight of research
- Poor documentation of IRB deliberations and findings
- Research personnel did not complete required annual privacy training
- Failure to review or audit the research center to ensure compliance with applicable privacy requirements
- Inadequate Information or Data Security Plans
- Inadequate policies and procedures to ensure compliance with VA information security requirements for research

VA Response

Research was suspended at this and all similar research centers nationwide

All multi-site studies coordinated by these centers were suspended

Information security and privacy practices at these research centers were reviewed on-site by ORO and also by the VA Information and Technology Office of Compliance

All actions required to bring the research centers into full compliance with VA information security standards were completed before research was allowed to resume

VA Response

Additional policies, training, and oversight procedures were developed for research information security

ORO added research information security to the topics for which it carries out Routine Reviews

VA Information Security and Affiliate Relationships

Tightening of VA information security procedures makes collaboration with academic affiliates more difficult

- Off-site transfer and storage of sensitive information
- Use of non-VA computing equipment
- Management of “joint” projects
- Data ownership
- Statistical consulting
- Access to VA networks by university employees
- Email encryption

What's Next for VA Research Oversight?

- Increased training for Research Compliance Officers
- Audit the auditors
- Increased on site review of individual protocols and investigators

**Questions?
Comments?**

Contact information:

ORO Website: <http://www1.va.gov/oro/>

**Karen M. Smith, PhD
karen.smith7@va.gov
Midwestern Regional Office, ORO
Hines VA Hospital, 5th & Roosevelt
Building 1, Room B109 (578/10R)
Hines, IL 60141
708-202-7256
708-202-7250 (fax)**