



Office of Research Oversight (ORO) Site Visit October 25-29, 2010

Presented by:

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Training Objectives

- About ORO
- Preparing for Site Visit
- VA HSR approvals/submissions
- VA-specific requirements related to HSR

About ORO

- Public law 108-170 created ORO in 2003
- Law mandates that ORO Director report directly to USH
- ORO advises USH on regulatory compliance and assurances related to human subjects and animal welfare, research safety and security, research information protection, research impropriety and research misconduct.
- ORO responsible for promoting understanding of and regulatory compliance with laws, regulations, directives that govern aspects of research – monitors, reviews, investigates compliance
- VA has Feds most comprehensive program of research compliance oversight; 5 regional and 1 central office

ORO Onsite Reviews

- To assess compliance with the laws, regulations, policies, and procedures governing research
- Conduct about 100 on-site reviews/year at VA facilities with research programs
 - 85% routine and not for cause
 - Issue written report and monitors implementation of remedial actions
- ORO findings reported to House and Senate Veterans Affairs Committees

ORO Site Visit NF/SGVHS

- Routine Review designed to assist VHA facilities in fulfilling compliance responsibilities – here to assess compliance with applicable requirements
- Focus: Human Research Protection Program, Research and Development Committee Function, and Research Information Protection Program
- 7 individuals - three teams conducting concurrent activities
- Onsite Activities: Information gathering through document reviews (R&D files/training records), interviews with key staff and groups, facility inspections

Preparing for Site Visit

- HRPP - Review AAHRPP Presentation available on VA website
- RIPP – ISO will be presenting information on research information security requirements
- Re-visit IRB and NF/SGVHS Research websites – be familiar with policies/procedures, processes for submissions, reporting
- Review IRB and VA forms used for VA research – designed to educate on VA requirements and help ensure that VA requirements are met
- Ensure that all required training is up-to-date and research scopes of practice on file
- Ensure that research information is stored and secured – per approved protocol and VA policy

IMPORTANT Reminders:
VA Approvals and
Submissions

VA Protocol Approvals

- Prior to beginning ANY research activities at the VAMC the following approvals MUST be in place:
 - UF Health Science Center IRB-01 (IRB)
 - Subcommittee for Research Safety
 - Information Security
 - Privacy
 - VA Research & Development Committee (R&D)
- No Research can begin without final R&D Approval and receipt of approval letter from ACOS/Research

Submission Information and Forms

All project submission forms can be found on the UF IRB-01 and VA Research websites, including instructions and frequently asked questions. Review the IRB-01 and NF/SGVHS website regularly for changes and updates.

Review Hidden Text in forms – provides important information on regulatory requirements

- ◉ UF IRB-01

- <http://irb.ufl.edu/irb01>

- ◉ NF/SGVHS Research Website

- <http://www.northflorida.va.gov/Research/indexResearchers.asp>

Ongoing Reporting to VA

- Following initial VA approval, ALL IRB actions must also be submitted to the VA HRPP Office
 - Continuing review (Annual Renewals/Periodic Reports required of all research including exempt)
 - Revisions (some may require re-review by safety, privacy, information security, pharmacy)
 - Adverse events/unanticipated problems (all 5 day reports should be submitted to IRB and VA simultaneously)
 - Deviations/regulatory non-compliance
 - Closure reports

IRB Forms and Addendum V

- IRB Forms were designed to educate investigators and solicit information the IRB needs in order to approve research under regulation
- Addendum V incorporates many VA HRPP requirements
 - Payments for subjects
 - *Research Involving Decisionally Impaired Subjects and requirements for Surrogate Consent*
 - *Research involving other vulnerable populations*
 - *Flagging medical record*
 - *Ensuring adequacy of resources*
 - *Enrolling non-veterans*
- **Strong Suggestion** – Review all IRB forms including Addendum V with Hidden Text. Hidden text provides essential background information you need to know to complete the forms and provide the IRB with the information they need to approve the research. Hidden text on Addendum V describes VA-specific requirements for conducting human subjects research

Addendum V

WITH HIDDEN TEXT

UF Institutional Review Board
UNIVERSITY of FLORIDA

Addendum V

VA Addendum

Make sure your Microsoft Word program is set to display "Hidden Text". This document contains helpful information, examples, and instructions that are only visible (and will never print) when the "Hidden Text" feature is enabled. *Hidden Text will be displayed, highlighted in yellow, bolded, and underlined.* Go to the "Tools" menu, "Options", on the "View" tab make sure "Hidden Text" has a check mark, and click "OK".

Study Title:

You indicated on your Introductory Questionnaire that your research will be conducted with the North Florida / South Georgia Veterans Health System (NF/SGVHS). VA involvement includes research (a) conducted as part of VA employment or affiliation, (b) conducted at or on VA facilities, (c) that utilizes VA resources, patients, or staff.

All studies conducted under the NF/SGVHS must also be submitted to: Research & Development (R&D) Committee for review and approval before conducting the study at that location. Additional details are available at:

<http://irb.ufl.edu/irb01/va.htm> and
<http://www1.va.gov/vsn8/hrs/research/committees.asp>

Please complete the following items, as appropriate.

1. Which NF/SG VHS facilities will be used?

<input type="checkbox"/> Inpatient	<input type="checkbox"/> Gainesville
<input type="checkbox"/> Outpatient	<input type="checkbox"/> Lake City
<input type="checkbox"/> Brain Rehabilitation Research Center (BRRC)	<input type="checkbox"/> Brain Institute VA
<input type="checkbox"/> Rehabilitation Outcomes Research Center (RORC)	
<input type="checkbox"/> Geriatric Research Education and Clinical Center (GRECC)	
<input type="checkbox"/> Other. Specify: <input type="text"/>	

2. Are you going to compensate or pay any veteran subjects enrolled in this project?
(This answer needs to be consistent with the answer provided in Question 19 of the Introductory Questionnaire.)

No. Go to Question 3.
 Yes. Answer items (a) through (c).

NOTE: VA policy prohibits paying human subjects to participate in research when the research is integrated with a patient's medical care and when it makes no special demands on the patient beyond those of usual medical care. (Reference: VHA Handbook 1200.5, Section 12)

(a) Please select all categories that apply:

1. The research is integrated with a patient's medical care.

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2. Are you going to compensate or pay any veteran subjects enrolled in this project?

No. Go to Question 3.
 Yes. Answer items (a) through (c).

(a) Please select all categories that apply:

1. The research is integrated with a patient's medical care.
-Does the research place any special demands on the patient beyond those of usual medical care?
 Yes. **CANNOT BE APPROVED BY THE IRB.**
 No.

2. The research is not directly intended to enhance the diagnosis or treatment of the medical condition for which the volunteer subject is being treated
-Is the standard of practice in affiliated non-VA institutions to pay subjects in this situation?
 No.
 Yes. Justify:

3. Multi-institutional study.
-Will subjects enrolled at collaborating non-VA institutions to be paid for the same participation in the same study at the same rate proposed?
 No.
 Yes.

Addendum V

WITH HIDDEN TEXT

FYI: Issues to be aware of when submitting to the VA R&D Committee

- Will non-veterans be entered into VA approved research studies? Only if there are insufficient veterans available to complete the study??
- If your study involves Tissue Banking... VHA Directive 2000-043... "Banking of Human Research Subjects, Specimens... November 6, 2000, requires that all human biological specimens and linked clinical data collected as part of research projects conducted by VA investigators in VA facilities or approved off-site locations will be maintained at either VA-sponsored tissue banks or VA (ORD) approved tissue banks. Sites that may not be acceptable for storage of tissue specimens include non-academic, for-profit institutions, such as pharmaceutical or biotech companies

Addendum V: NF/SG VHS
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- If your study will be conducted at sites that are not owned or leased by the VA (examples include Shands, Shands Jax, Brooks Rehab, private practices, etc.) you must submit a Waiver to the ORD and receive approval for your research to be conducted at these sites.
- Non-veterans may be entered into VA approved research studies only when there are insufficient veterans available to complete the study... All regulations pertaining to the participation of veterans as research subjects including requirements for indemnification in case of research related injury pertain to non-veteran subjects enrolled in VA approved research.
- Obtaining and using the records must be in compliance with all VHA regulations and with the Standards for Privacy of Individually Identifiable Health Information (45 CFR Parts 160-164).
- Persons not employed by the VA can be given access to medical and other VA records for R&D purposes only within the legal restrictions imposed by such laws as the Privacy Act of 1974 and the Privacy act of 1974 and 38 U.S.C.
- If someone other than the investigator conducts the interview and obtains consent, the investigator should formally delegate this responsibility and the person so delegated should have received appropriate training to perform this activity.
- The PI is responsible for informing Pharmacy Service that IRB and R&D Committee approval has been obtained. This must be through the use of VA Form 10-1229, Report of Subcommittee on Human Studies, to be sent to Pharmacy Service.
 - VA Form 10-9012, Investigational Drug Information Record, or superseding forms must be provided to the pharmacy by the PI as required in VHA Manual M-2, Part VII, Chapter 6, or superseding policy document.
 - In addition, a signed copy of VA Form 10-1086 must be sent to Pharmacy Service to document each subject's consent to participate in the study.

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Subject participation is limited to/involves only one encounter/event.

Subject participation is limited to/involves the use of questionnaire or previously collected biological specimens.

Identifying subjects as participants in the study could place them at greater than minimal risk (e.g. negatively affect their insurability, employability, reputation, or financial standing).

Addendum V: NF/SG VHS
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10. Please explain how you have the necessary resources to protect research participants:

(a) describe how you have adequate time to conduct and complete the research:

(b) describe how you have adequate number of qualified staff:

(c) describe how you have adequate facilities:

(e) describe how you have access to a population that will enable you to enroll enough subjects to complete the research:

(f) describe what medical or psychosocial resources are available to subjects if needed as a result of participating in this research:

11. Are you going to enroll non-veterans in the study?

No.

Yes. Are there insufficient veterans to complete the study?

Yes. Explain:

No. **CANNOT BE APPROVED BY THE IRB.**

VA Forms and VA Information

- Addendum V does not incorporate ALL VA requirements
- VA forms incorporate additional VA requirements
 - Coversheet – Required HRP/GCP, 201 Training and Conflict of Interest
 - Data Security Checklist and PI Certification – Requirements related to Information Security
 - Safety Evaluation Form - Requirement for review by Subcommittee for Research Safety
 - VA Form 10-9012 – Requirements for use of Investigational Drugs
 - Investigational Device Accountability Log and Guidance – Requirements for use of devices
- NF/SGVHS Research Website provides other important information
 - Description of procedures for submitting research to VA
 - Important information of VA specific policies - CPRS
 - Important contact information
 - Research Compliance Reporting Requirements
 - HRPP Manual and other policies and procedures

IMPORTANT Reminders:
VA-Specific Requirements

VA-specific requirements

- Flagging Medical Record
- Consent progress note is required (in med record or investigator file)
- Consent scanning into MR
- Create or update VA Health Record:
 - For all research subjects admitted as in-patients, treated as outpatients, or for whom research procedures or interventions are used in their medical care
 - When the research requires use of any clinical resources such as radiology, cardiology (e.g., EKG, stress test etc.), clinical laboratory, and pharmacy
 - The research intervention may lead to physical or psychological adverse events
 - Several different handbooks

VA-specific requirements

- **Researcher Contact with Veterans Recruitment**
 - initial contacts in person or by letter prior to phone contact
 - provide phone number or other means for veteran to verify validity of study
- **Restrict phone and other contacts with veterans to those procedures and data elements outlined in IRB approved protocol**
 - Researchers cannot request SSN

[CRADO/USH Memo 07/10/2006]

VA-specific requirements

Research Compliance Reporting

Investigators and members of VA research community **MUST** report to:

****IRB and NF/SGVHS ACOS/R****

Within 5 business days of discovery

- unanticipated problem involving risks to subjects or others in VA research
- unanticipated SAEs
- any apparent serious or continuing noncompliance with applicable human research protection requirements

Timeframes in IRB-01 Reporting Policy consistent with VA requirements

[VHA Handbook 1058.01]

VA-specific requirements

Research Compliance Reporting

REQUIREMENTS RELATED TO RESEARCH INFORMATION PROTECTION

Immediate Reporting:

- **Within 1 hour** of becoming aware of unauthorized access to VA sensitive information, (including unauthorized use, disclosure, transmission, removal, theft, or loss) related to research
- Report to: **Supervisor, the facility ISO, the facility PO and VA police**
- On VA Research Service Website and ISO Sharepoint

VA-specific requirements

VA Research Investigator Training

- All individuals involved in the conduct of VA research must complete annually:
 - Human Research Protection/GCP,
 - Privacy and Information Security – other VA required trainings
 - UF HIPAA for Researchers – every two years
- Information Security 201 – one time
- This must be verifiable for all individuals
 - Certificates of completion
- ALL required training **MUST** be current **BEFORE** VA approval will be granted!

VA-specific requirements

- Acknowledging VA in publications
 - Affiliation and Research Support
 - VA named first if
 - > 5/8 VA Time
 - > 50% VA funding
 - > 50% VA facilities used
- VA-funded research conducted outside of VA medical center or VA-leased space – Off-site waivers may be required - call research service for more details
- Privacy and release of information for research
- Record retention

Other Requirements

- Investigators are responsible for conduct of the research and for leadership and supervision of the research team
 - Function strictly in accordance with their VA-authorized credentials, privileges, and scopes of practice when involved in research
 - Are fully qualified to perform their research duties by virtue of their education, experience, and protocol-specific training

Keys to Success

- There are resources available to help you comply with VA HSR requirements
 - Research Service Office
 - Grant Specialists [RORC, BRRC, non-Centered]
 - Research Compliance Officer
 - IRB-01 Office
 - IRB and NF/SGVHS Websites
 - IRB and NF/SGVHS Forms/Instructions
- Attending to HRP, RIP and other VA requirements in the day to day conduct of your research is key

Questions?

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