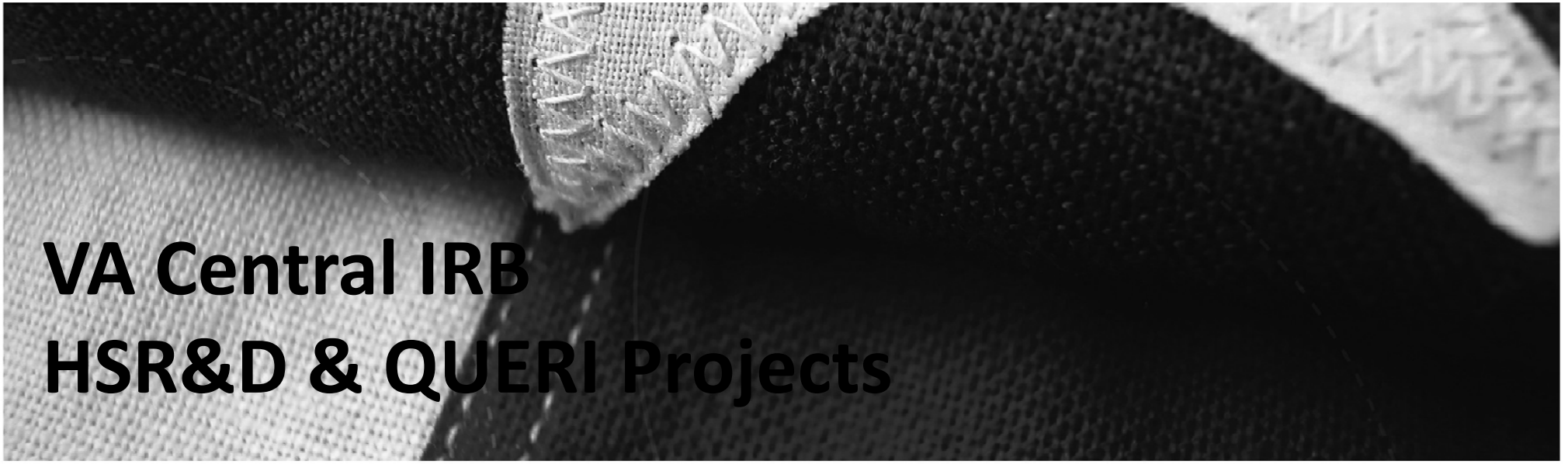

VA Central IRB
HSR&D & QUERI Projects

Cyber Seminar
Working with the VA Central IRB
November 7, 2012

Veterans Health Administration
Research & Development
Improving Veterans' Lives www.research.va.gov

VA PRIDE
Program for Research Integrity Development & Education

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

Presentation Outline

- What studies need to come to the VA Central IRB?
  - What is engagement in human subjects research?
  - How is engagement determined?
- What is the VA Central IRB process?
  - What are the responsibilities of the VA Central IRB?
  - What are the responsibilities of the local site?
- What causes delays in the VA Central IRB review process?
- Q & A

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What studies **must** come to the VA Central IRB?

- ORD-funded studies with more than one site engaged in the conduct of human subjects research

What does “engaged” mean?

- Engagement
  - VHA Handbook 1200.05, Paragraphs 50-51
  - Guidance from the Office for Human Research Protections (OHRP), October 16, 2008 http://www.dhhs.gov/ohrp/policy/engage08.html
- Multi-site studies
  - VHA Handbook 1200.05, Paragraph 52

Engaged* in Human Subjects Research

In general, a VA facility is “engaged” in human research when someone with an appointment at that facility **obtains** for the purposes of the research study

- Data about the subjects of the research through **intervention** or **interaction** with them
- **Identifiable private information** about the subjects of the research
- The **informed consent** of human subjects for the research
- **Funding** for the research

*VHA Handbook 1200.05, Paragraph 50

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Why is Engagement Important?

If a VA facility is engaged in human subjects research it must

- Hold a Federalwide Assurance (FWA)
- Have a local VA investigator for that study
- Have one of its IRBs of record approve the study
  - The VA Central IRB is one of the IRBs of record for 97 of the 109 VA facilities that can conduct human research

VHA Handbook 1200.05, Paragraph 50

Engagement Determinations Significance for HSR&D & QUERI Studies

- HSR&D & QUERI investigators can perform studies at other VA facilities that are **not** engaged without getting the other facilities' IRBs' approval – e.g., they can
  - Administer surveys or questionnaires to the other facilities' employees or patients
  - Hold focus groups of the other facilities' employees or patients
- Need to notify Director of non-engaged facility may disapprove.

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Who makes engagement determinations?

- If the PI's assessment is that only his/her site is engaged, the local IRB can confirm
- If the PI has any question about how many sites are engaged, the project should be sent to the VA Central IRB for a determination
- If it is not clear which sites are engaged, ORD and ORO work together to make a determination

What kind of information is needed to make an engagement determination?

- Who is the sponsor?
  - If funding comes through a Nonprofit or if study staff are hired by the Nonprofit, the Nonprofit is engaged
- What sites will be participating (e.g., which sites are providing vs. obtaining the data; where questionnaires or surveys will be administered)?

What kind of information is needed to make an engagement determination?

- Who is doing what?
  - Who **obtains informed consent**?
  - Who **interacts/intervenes**?
  - Who **provides** private identifiable information?
  - Who **obtains** private identifiable information?
  - Who **uses, studies, or analyzes** private identifiable information?
- Where are investigator & other research staff appointments?

VA Central IRB Process
Pre-submission Consultation

- Do I need to submit to the VA Central IRB?
- Engagement Determination
- Handling Multi-Phase Studies
- Contact VA Central IRB Administrator (Annette Anderson) or one of the co-Chairs

What if the study has multiple phases?

- Example:
  - Phase 1. Investigators at one VA facility to develop a national database
  - Phase 2. Investigators at 4 VA facilities will survey of employees at 20 VA facilities. Survey is to be based on analysis of Phase 1 data
  - Phase 3. Design of Phase 3 will depend on results of Phase 2

(VA Central IRB will review each phase sequentially so you don't have to switch IRBs after Phase 1 when more than one site becomes engaged in human subjects research)

PI/SC Application Review Process

- VA Central IRB Manager - administrative review
- Regulatory staff – regulatory review
- Two pathways:
  - Full Committee Review: Primary, Secondary, and Informed Consent Reviewers
  - Expedited Review: Single Reviewer with final review and approval by one of the VA Central IRB Co-Chairs

PI/SC Application Review Process

- VA Central IRB Privacy Officer & Information Security Officer (ISO) perform their reviews
- Reviewers can contact investigator directly for questions, or through VA Central IRB staff

Local Site Involvement

After the PI/SC application is **approved** by the VA Central IRB **contingent upon local site comment**, or **approved contingent upon minor modifications**, then two things occur simultaneously at the local level:

1. Local Site Review - A copy of the approved PI/SC Application packet is sent to each local site for review with a copy of the VA Central IRB approval letter
2. Local Site Investigator (LSI) Applications - LSIs can begin preparing LSI applications

1. Local Site Review

- Each local site designee has 15 days to provide comments to the VA Central IRB

  (NOTE: the local IRB does **not** perform a review; it has no role in review of studies sent to the VA Central IRB)

- Comments must be provided to the VA Central IRB by the individual designated by the local facility Director

2. LSI Application Process

- Each Local Site Investigator (LSI) prepares a Local Site Application based on PI/SC Application
- The ***PI/SC reviews*** all LSI Applications for consistency
  - The VA Central IRB will require a justification for **any** differences between the PI/SC & LSI Applications

Review of Local Site Comments

- VA Central IRB reviews all local site comments & determines if changes are needed - may result in
  - No changes, or
  - Changes in PI/SC Application (may or may not affect all LSI Applications), or
  - Changes in one LSI Application only (i.e., affects only local site making comment)

Final Approval by VA Central IRB

- The VA Central IRB grants final approval of the PI/SC Application once all local comments and other modifications have been addressed
- **Note: The PI/SC Application must be approved prior to approval of any LSI Applications**
- LSI Applications are then approved individually once all LSI conditions have been met

Continuing Review

- IRB approval expiration date for all sites in a given project is that of the PI/SC Application

  (i.e., all PI/SC and LSI applications for a project have continuing review at the same time)

- PI/SC is notified 90 to120 days prior to approval expiration date; PI/SC sets submission date for LSI
- LSI submits report to PI/SC by PI/SC deadline
- PI/SC submits a summary report and copies of all LSI reports to VA Central IRB by VA Central IRB deadline

Local Roles

- Medical Center Director designates a local site liaison and someone to provide comments to VA Central IRB
- Same role for VA Central IRB as for local IRB studies
  - R&D Committee
  - Research Compliance Officer
  - Local Research Office (e.g., training, credentialing, etc.)
- No role for VA Central IRB studies
  - Local IRB
  - Local Privacy Officer
- ISO – variable role depending on study

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What is THE Most Common Cause of Delays?

- Back and forth between IRB and study team because of unclear or insufficient information

Avoiding Delays in the IRB Review Process Complete IRB Applications

- Have a clear research question (i.e., hypothesis, purpose of the project)
- Provide detailed methodology
- Specify the sequence of events so the IRB reviewer can follow the flow of the project
- Ensure data categorized as de-identified are not still identifiable

Avoiding Delays in the IRB Review Process Complete IRB Applications

- Clearly delineate who is performing which research-related activities & where they will be performed
  - Use active voice, not passive, and be specific (e.g., “the Boston study coordinator will obtain informed consent,” **not “**informed consent will be obtained”)
  - **If you are designating someone as a “consultant,” “statistician,” “economist,” etc. provide a detailed description of his/her responsibilities**

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Avoiding Delays in the IRB Review Process Complete IRB Applications

- Clearly differentiate usual care from research activities or QA/QI activities
- Provide sufficient information for a waiver (e.g., of informed consent or HIPAA authorization)
- Provide sufficient information about a data repository (i.e., by providing information required by 1200.12)
- Indicate the local VA facilities involved
- Address IRB approval criteria

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IRB Approval Criteria

- Risks are minimized
- Risk/benefit balance is reasonable
- Selection of subjects is equitable
- Appropriate informed consent will be sought and documented
- Informed consent form has signature blocks/dates

IRB Approval Criteria

- Informed consent is consistent with protocol and HIPAA authorization
- Additional safeguards for vulnerable populations
- Data safety and monitoring plan
- Privacy and confidentiality protected
- VA information security requirements met
- Conflict of interest managed
- Investigators qualified and trained

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Preventing Delays in VA Central IRB Review of HSR&D & QUERI Projects

- More frequent communication among IRB staff & members & study teams; active monitoring of response times
- New protocol template for VA Central IRB applications; revise applications to more user-friendly for HSR&D studies
- Webinars with newly funded investigators & study coordinators to review IRB application process
- Other ideas?

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Next Steps

- Add individuals with HSR&D & QUERI expertise to the VA Central IRB (in progress)
- Implement new protocol template and IRB application to help prompt HSR&D & QUERI investigators to provide all necessary information
- Training for HSR&D & QUERI staff & investigators (e.g., webinars as needed)
- Provide guidance to be posted on HSR&D & VA Central IRB web sites (e.g., checklists, examples)

Next Steps

- Survey local facility staff & research teams for feedback on VA Central IRB
- Develop a mechanism for providing constructive criticism back & forth between study teams and the VA Central IRB staff & members, for example
  - Send comments and/or complaints directly to VA Central IRB staff, or
  - Send anonymously via HSR&D or QUERI staff

PLEASE NOTE: Vague criticism will not help us improve the process. We need to know exactly what is wrong as soon as you identify an issue, along with any ideas about how we can make it right

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QUESTIONS