



# VA Central IRB Updates

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# Overview

- FWA updates and MOU Amendments
- Changes to VA Central IRB SOPs
- Electronic Systems
- Reportable Events
- VA Central IRB Local Site Liaison and RCO Information Sheets
- VA Central IRB Annual Review Report
- Current Workload and Initiatives
- **Questions**

# FWA Updates and MOU Amendment Process

- Reminders:
  - Any time your facility updates its FWA, including adding a new component or changing the signatory official, including any changes in the NPC FWA, let us know
  - An MOU amendment will need to be submitted when the Institutional Official changes, either for the VA facility or for the NPC

# Changes to VA Central IRB SOPs

- ORD is in the process of becoming ISO 9001 compliant.
- The VA Central IRB is undergoing a conversion of all SOPs to ISO 9001 format; updating and changing/streamlining policies and procedures
- IRB staff is meeting weekly to review and revise SOPs and forms.
- Liaisons will be alerted when updated SOPs are posted to website going forward.

# Change to Local Site Comment Process

- Expedited Studies: Final IRB approval will no longer be pending 15 day comment period; Comments will still be solicited but only after approval
- Convened Review: Comments will be solicited as now if study approved pending minor modifications; in rare instance when there are no modifications, approval will be granted and then comments solicited
- If the IRB determines that changes are required, the PI will be asked to amend the study.

# Change to Local Site Comment Process

- The vast majority of sites have no comments and most comments received are questions or requests for clarification; some are suggestions which are referred to the PI.
- Less than 10% of studies have been modified due to local site comments.
- Change will allow funding to be released more quickly without compromising human subject safety.

# Electronic Systems - ACCESS

- Microsoft Access – MOU, FWA and Site Contact databases are up and running
  - New report listing VA Facilities and associated NPCs being posted to website
  - Annual site personnel update request will go out in March timeframe
  - PI Application tracking data next

*We hope to be able to provide useful reports to sites once all tracking data is entered into system, i.e., number of studies and status at each site.*

# Electronic Systems - SharePoint

- Main Site; Primary method for receiving and distributing documents to sites and study teams
  - Local site access for Liaison, RCO, R&D Committee Coordinator, and site designee for main site
- Reportable Event Site – Monitored daily and reports taken off site as they are processed
- Pending conversion to SharePoint 2010
- SharePoint is not a substitute for a regulatory binder

# Poll

- What version of SharePoint do you use at your site?
  - A. 2010
  - B. 2007
  - C. Don't use SharePoint
  - D. Don't know
  - E. Other

# Reportable Events

- Dual Reporting by the VA Central IRB
  - To VHA Central Office HRPP IO and ORO Central Office
  - To LSI, PI/SC, Sponsor, Local Medical Center Director
- VA Central IRB Liaison receives copies for Medical Center Director and other local staff and distributes
- Local MCD makes notifications to regional ORO Office, OHRP, and FDA (as applicable) with copies of notice to VA Central IRB

# Communicating Not Serious/Not Continuing Noncompliance and Unrelated SAEs/UAPs Determinations to Sites

The VA Central IRB currently posts SAE/UAP or Protocol Deviation Reports to SharePoint for a limited time. The local site liaison is copied on the email that contains the determination.

Question: Do we still need to post these reports?

- 1) Yes
- 2) No
- 3) Unsure

# VA Central IRB Local Site Liaison and RCO Information Sheets

- Local VA Central IRB Liaison Information Sheet provided to all new Liaisons
- Currently in draft for comment
  - Update of Local Site Liaison information sheet will be posted to SharePoint after meeting for comment
  - New draft RCO information will be forwarded to ORO Central Office for review and comment
- Will post final versions to SharePoint and website

# VHA Central Office HRPP Annual Review

- Include the VA Central IRB in the annual review of your local HRPP; Liaison Folder contains:
  - 2012 VHA Central Office HRPP Report on SharePoint
  - Current IRB Roster
- Allow at least one week lead time if you need supplemental information for your local review
- 2013 VHA Central Office HRPP Report being drafted.

# Preliminary 2013 Workload Data

- As of the end of CY2013, the VA Central IRB was actively overseeing or in the process of reviewing a total of 144 studies involving a little over **890** sites
- A total of 56 studies were submitted for initial review and 406 amendments to existing studies
- Approximately 406 amendments were received and processed (PI/SC and LSI), many with associated updates from local sites
- 695 Unanticipated SAE/UAPs Reports and 477 Reports of Protocol Deviations

# Preliminary 2013 Workload Data

- A total of 477 reports of protocol deviations or violations were received and processed – 7 resulted in reports to ORO of serious or continuing non-compliance
- 19 reportable event determinations made (8 related UAP/Unanticipated SAEs and 11 Serious Noncompliance with 3 enrollment suspensions)
- Fielded approximately 350 calls on the VA Central IRB toll free line

# Current Initiatives for 2014

- VA Central IRB Co-Chair starting work group to focus on types of studies that would benefit from review model
- Continued pursuit of fully electronic system
- Complete SOP ISO review and revision process
- Expand our educational outreach through more webinars, more frequent updates of our website, and fuller use of SharePoint and MS Access capabilities

# Contact Information

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For specific projects: Assigned IRB Manager (see next slide)

Other questions: [vacentralirb@va.gov](mailto:vacentralirb@va.gov) or 1-877-254-3130

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# Open Forum

Questions?