



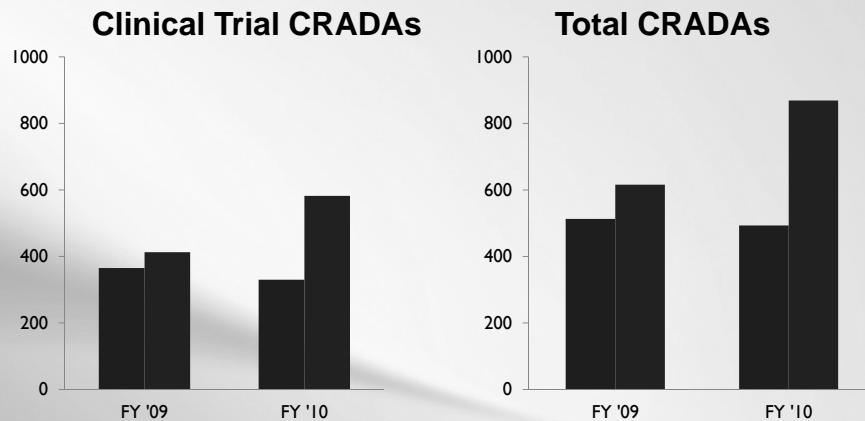
ORD NPPO Update To NAVREF September 2011

*Holly H Birdsall MD PhD
Acting Deputy CRADO*



85 Years of Discovery, Innovation, and Advancement

CRADAs are increasing



■ New that year ■ Total active



eCRADA is live



- Everyone should have a login and password
 - If not contact Jeff Moore
- Training is coming
- More than 100 CRADAs were not in the old registry when FY 2010 annual CRADA report was prepared.



Model CRADAs



- All Model CRADAs will be updated over next fiscal year
- The goal is to incorporate language to make the CRADAs easier to use



Regulatory burden must decrease



- Executive Order
- Priority from the Deputy Secretary
- Top issue identified by VA researchers and ACOS/Rs as impediment to conducting research
- Selected by ORD as the priority item for improvement based on external review of ORD outcomes and operations



Simplifying compliance



- Address Handbooks and Policies
- Develop Research Administrative Management System (RAMS)
 - Track personnel, projects, protocol reviews
 - On-line protocol submission (IRB etc)
 - Designed on basis of field input
 - Estimate go-live 2013



Some differences between FDA & ICH



- What IRB must review (specific list of documents, deviations)
- Primary physician must be notified
- Alternative treatments must be described along with their risks and benefits
- Must provide signed copy of consent
- Provides for broader access to medical records
- Local policy must be re-written



ICH - GCP



- FDA has not adopted it in its entirety
- VA cannot adopt in its entirety and then be bound to enforce it
- It is possible to monitor a study in accordance with ICH and CRADAs should continue to state that “VA adheres to ICH E6 where and as adopted by the FDA.”



Central IRB



- VA Office of Research & Development (ORD)-funded multi-site projects only
- 94 VA facilities have signed up
- First project reviewed August 2008
- 53 projects involving 503 sites (some of the 94 sites are participating in >1 project)



VA Central IRB Pros & Cons



- Investigator
 - Only has to submit to one IRB
 - But **does not** get automatic approval from IRB
- Local facility
 - Saves time for local IRB
 - But **does not** save time for local Research Office
- 30 day local site comment period
 - Allows for local input
 - But **prolongs** the time to final approval



History VA Oversight



Nonprofit Program Office (NPPO)

- Established in 2003 in the Office of Research and Development, Finance Division
- Formed in response to 2002 IG and GAO reviews of NPCs
- Responsible for compilation of the NPC Annual Report to Congress.
- Governance Training for VA Statutory Board Members



History VA Oversight



Nonprofit Oversight Board (NPOB)

- Established in 2004
- Meets quarterly to review the activities of VA Nonprofit Corporations for consistency with Departmental policy and interests and make recommendations to the Secretary and Deputy Secretary
- Comprised of high-level VA officials (Deputy Undersecretary for Health, Office of Academic Affairs, Finance, General Counsel, ORO)



2008 OIG recommendations



1. ...define the oversight authorities of the NPOB, CFO, and NPPO and update VHA Handbook 1200.17...
2. Strengthen NPPO procedures for following up on recommendations in independent audit reports .. and reviewing NPC submissions for the annual report to Congress.
3. ...define minimum control requirements for all NPCs and provide training to NPC Directors ...
4. ...procedures to perform substantive reviews of NPC financial and management controls to ensure NPCs fully comply with Federal laws, VHA policies, sponsor agreements, and control standards.
5. ...review, monitor, and enforce NPC compliance with conflict of interest laws and policies.



NPPO 2008-2010



- VA's Oversight and Review Function of the NPCs had to increase
- A Nonprofit Corporation Steering Committee was created
- The NPPO Administrator was hired September 2008



The first round of reviews



- Used a checklist approach
 - Provided evaluation criteria
 - NAVREF worked with NPPO to verify the documentation that would be expected
- 82 reviews completed in a four month period at the end of 2009 and two were completed in January 2010.



Second round of reviews



- Operations Oversight Questionnaire and the Internal Control Questionnaire provided to the Executive Director in advance
Questionnaires continue to be revised and shortened
- The NPPO routinely tests samples of various transactions and accounting records, such as CRADA reviews, grant reviews, credit card statements, policies and procedures, cash disbursements, bank reconciliations, payroll and IPAs.
- All NPCs will be reviewed triennially regardless of financial condition.



Out of cycle reviews



- problems or serious internal control weaknesses - reviewed on-site annually and monitored at least quarterly until resolved, then bi-annually
- Welcome to new EDs within 45 days and then on-site review when deemed appropriate
- NPCs that are starting-up, re-activating, merging or deactivating will be visited as needed
- NPCs with reported irregularities (e.g., as by whistleblowers) will be reviewed on-site immediately and have appropriate follow-up action taken
- NPCs requesting on-site visits



For Cause Reviews



- Approximately 10 For Cause Reviews (higher level reviews) were performed in FY 2010
- These reviews revealed internal control issues particularly in the small and small to mid-size NPCs
- Thus, our current three year reviews are on internal controls



NPPO 2011



- Comprehensive Oversight Plan approved by the NPOB.
- Developed “Tone at the Top” presentation
- Training on VHA Handbook 1200.17 after publication in December 2010
- Training with OGC on IPA’s
- Financial Training for small to mid-size NPCs



NPPO 2011 (cont'd)



- For Cause Reviews
- 31 Internal Control Reviews
- Activated NPPO Web Site
- Requested Paperwork Reduction Act approval :
 - Annual Report Template
 - Internal Controls Questionnaire
 - Operations Oversight Questionnaire
 - Audit Action Items



Results of NPC Reviews



- **Intergovernmental Personnel Act (IPA) Agreement Violations**
 - More than one Executive Director's Salary being paid by the VA through an IPA.
 - Other Inappropriate or Incomplete IPA Agreements
- **Internal Controls**
 - Bank Accounts/Reconciliations
 - Signers
 - Policies



Results of NPC Reviews



- A need for written policies on topics such as:**
- Control Environment
 - Financial Reporting
 - Budget Reporting
 - Cash Receipts
 - Accounts Receivable
 - Capital Assets
 - Purchasing, Accounts Payable and Cash Disbursements
 - Computer Security
 - Tax Compliance
 - Records Retention
 - Whistleblower Protection, Residual Fund Policies, etc.



Results of NPC Reviews



- **Administrative Budgets**
 - Approximately 50% of those reviewed did not have an administrative budget approved by the Board of Directors
- **Regularly Scheduled Board Meetings**
 - Many NPCs are having only one or two meetings per year
 - Recommend quarterly meetings



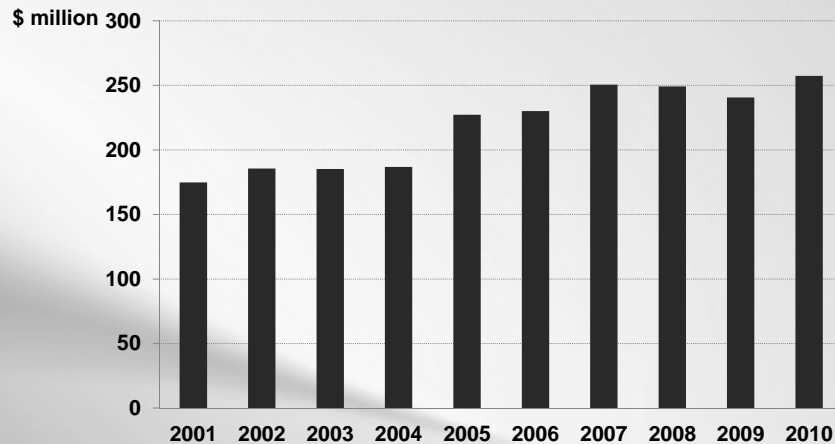
NPPO 2012 - 2013



- Analysis of the current Internal Control Questionnaire, the Operations Oversight Questionnaire will be completed
- Next third of the reviews will be scheduled 2012
- All remaining NPCs will be reviewed in 2013
- After a complete review of all NPCs in 2013, the NPPO will work with the NPOB to determine the ongoing need for reviews, the time frame, as well as the need for VA training, if applicable



Revenues are increasing



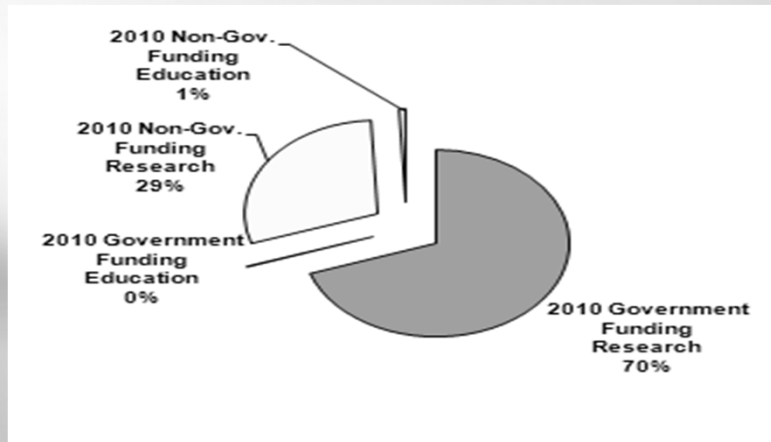
Revenue variances



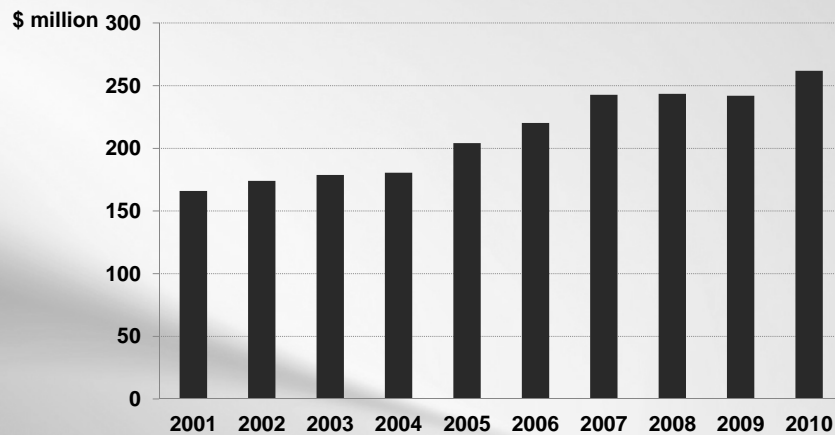
- 6.9% increase in NPC revenues
- Fifty-three NPCs reported an increase in overall revenues compared to 32 in 2009 and 43 in 2008.
- Non-Governmental funding decreased by 14.2% from \$88.6 million in 2009 to \$76 million on 2010
- Other revenue sources (such as interest income) decreased from \$6.6 million in 2009 to \$5.3 million in 2010.
- Funding from governmental agencies increased 21%, from \$145.5 million in 2009 to \$176.1 million in 2010



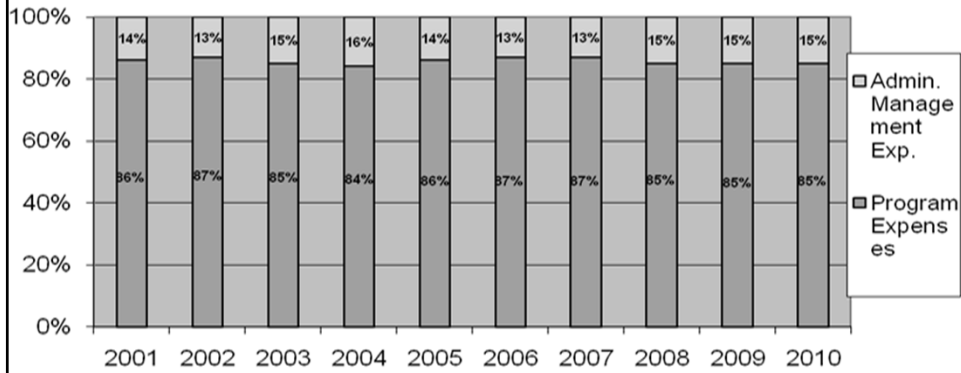
Revenue by Source



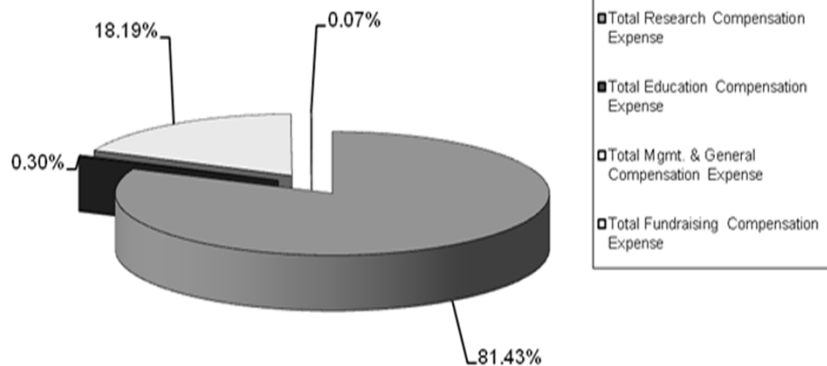
Expenditures are increasing



Overhead is stable at avg 15%



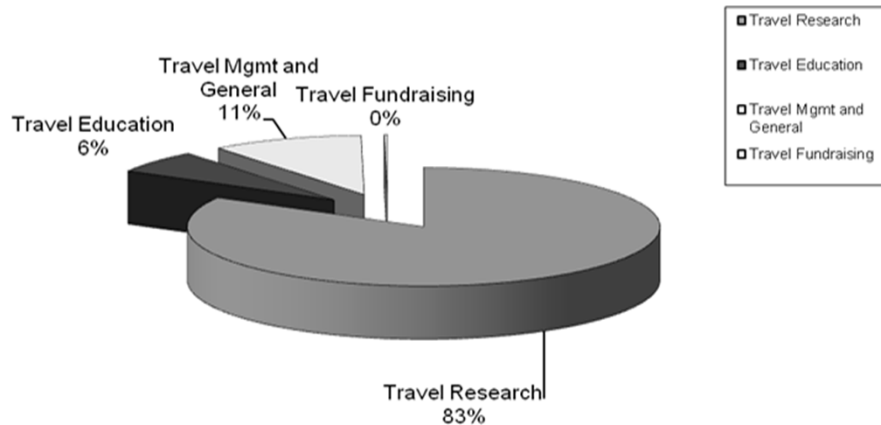
Compensation



77 NPCs reported compensation expense including benefits totaling \$144.1 million, a 12% increase over 2009



Travel



Seventy-five NPCs reported travel expenses totaling \$4.4 million, a 4.4% decrease from 2009



MATERIAL WEAKNESSES



- Only four NPCs had material weaknesses
- Type of Material Weaknesses
 - Inadequate Segregation of duties
 - Noncompliant accounting (cash vs. accrual)
 - Lack of comprehensive Internal Controls



Conclusions



- VA-affiliated NPCs make a substantial contribution to VA research and education missions
- Expertise in NPC governance and management is improving
- NPCs foster vibrant research environments at VA medical centers, enhancing VA's ability to recruit and retain clinician-investigators and other talented personnel who, in turn, apply their knowledge to state-of-the-art care for Veterans.



THANK YOU



Questions?

