

**NAVREF Annual Report  
May 2005 – April 2006**

**NAVREF Mission:** NAVREF's mission is to promote high quality management and communication among the VA-affiliated nonprofit research and education corporations and to pursue issues at the government level that are of interest to its members.

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Karen Sanders, MD  
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Malcolm Cox, MD  
Chief Academic Affiliations Officer (as of 3/2006)

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Barbara West, Executive Director  
Angela Murakami, Program Manager  
Rose Kobylinski, Meeting and Office Assistant

**In Appreciation**

NAVREF's success is highly dependent on generous contributions of time and expertise by its members. All NAVREF activities and accomplishments are made possible by the hard work of its board of directors and many others who are committed to the VA-affiliated nonprofit research and education foundations as well as the VA research and education programs. Individuals who contributed to the activities described below are too numerous to list. However, NAVREF wishes to express its gratitude to all.

## Top Four Accomplishments May 2005 – April 2006

1. NAVREF's main focus during the last year -- replacing clinical research agreements (CRAs) between NPCs and industry research sponsors with Cooperative Research and Development Agreements (CRADAs) – reflects a number of accomplishments, but nonetheless remains a work in progress. At this writing not all of the components necessary for implementing CRADAs are in place and the transition to CRADAs is just beginning. CRADAs will continue to be the major focus of NAVREF for the foreseeable future. In the meantime, milestones reached to date include:
  - Establishing a collaborative working relationship with the Technology Transfer Program (TTP) and the Office of General Counsel through the CRADA Work Group
  - Incorporating NPCs as “parties” in model VA CRADAs with recognition of their legitimacy in negotiating CRADAs and administering the research as well as the funds
  - Coordinating a two-day joint VA/NAVREF workshop on CRADAs, with particular responsibility for the session on CRADA basics
  - Completing the model Clinical Trial (CT) CRADA, guidelines and an implementation plan after extensive review of multiple drafts
  - Providing guidance on amending Cooperative Technology Administration Agreements (CTAAs) to accommodate CRADAs
  - Participating in multiple training sessions for NPC and VA personnel on CRADAs and CTAAs amendments
  - Developing a comprehensive CRADA web page on the R&D web site
  - Establishing contact with selected industry sponsors to educate them about CRADAs and initiate development of master CRADAs
2. In March 2006, NAVREF released its *NPC Self Assessment Tool* for member review. This is designed to serve as a means for NPCs to evaluate compliance in four main areas of typical NPC operations: programs, governance, finances and selected management topics. Along with items required under the NPC authorizing statute, VA policy reflected in VHA Handbooks 1200.17, 1400.2 and occasional VHA policy memos, or required by other oversight or regulatory organizations, this tool offers additional standards that reflect a higher, but not required, level of competence. During the coming year, NAVREF will enhance the tool by linking some of the standards to applicable statutes and regulations as well as guidance for meeting them.
3. Over the course of the last year, NAVREF re-built what has historically been a strong working relationship with VHA, particularly with ORD and OGC, that had been eroded due to VA staff transitions and vacancies as well as the fallout from the Friends Research Institute (FRI) investigation even though the FRI practices were unrelated to and different from the NPCs' standards for conducting business. A major focus of this effort was a proposal to develop a joint VHA/NAVREF vision for the NPCs with specific goals and objectives. Although VHA declined to participate in developing such a vision, the proposal was discussed during meetings with VHA, ORD, TTP, and OGC as well as a VISN director and a medical center director, and served to open a highly productive dialogue that has continued through subsequent interactions. NAVREF now attends meetings of the VA NPC Oversight Board as a guest and regularly comments on its agenda items.
4. During the last year, NAVREF conducted a number of activities designed to improve the quality and consistency of NPC financial reporting as well as compliance with federal requirements. These included drafting sections of the finance section of the Best Practices Program, refining guidance on completing IRS Form 990, working with a number of NPCs to make improvements in their Form 990 reporting, and arranging for the IRS to conduct a NAVREF teleconference on IRS requirements regarding education.

## Other Accomplishments and Ongoing Initiatives

### Policy Development

- Focused NAVREF policy development activities entirely on CRADAs. This entailed gaining an understanding of federal technology statutes and regulations as well as surveying how other agencies – DOD, HHS, Agriculture and NASA – and government affiliated nonprofits address technology transfer in sponsored research. Although the VA model Clinical Trial CRADA has been published, work continues on model Material Transfer CRADAs, CRADAs for PI-initiated clinical and basic research and related topics.
- Assisted NPCs in implementing policies developed last year on reimbursement for travel and mixed use items, joint VA/NPC employment, reimbursing VA for research related clinical services and transfers of funds. Staff answered numerous questions and reviewed drafts as NPCs tailored the policies to meet local needs.

### Member Communications and Services

- Responded to numerous email and phone questions from members, usually with a one-day turnaround time; used questions to prompt newsletter articles on timely topics and additional postings on the web site.
- Wrote and disseminated by email 11 newsletters and updates; posted on web site for future reference.
- Conducted four Best Practices Consultations and one three-day NPC visit to orient the new NPC executive director and a staff member.
- Broadened membership inclusiveness by involving the governmental affairs (GAC) and non-governmental grants (NGGC) board advisory committees in identifying and addressing issues relevant to the general membership. While the NGGC largely has been suspended due to the transition to CRADAs, GAC members have been particularly engaged in re-building relations with VHA and addressing issues related to administration of NIH grants.
- Researched cost effective medical malpractice insurance for NPCs as entities and identified possible solutions in policies offered by Lloyd's of London, One Beacon and Chubb that are undergoing review by an insurance consultant retained by NAVREF.
- Fostered the peer to peer sharing that has been a highly valued characteristic of the NPCs by enlisting experienced NPC executive directors to mentor several new directors. Also arranged for executive directors with experience in federal funds administration to advise NPCs considering taking on this responsibility.

### Governance

- Held four board of directors meetings, each hosted by a NAVREF member foundation to allow interaction between the host board and the NAVREF board. [NPCs interested in hosting a NAVREF board meeting should contact the NAVREF office.]
- Conducted ongoing governance training for the board that incorporated discussion of bylaws, long term planning and board member development.
- Reviewed and approved updated NAVREF board of directors, employee and financial policies.

### Advocacy and Public Policy

- Helped to achieve a \$19 million increase in the FY 2006 VA research appropriation. This represents restoration of the \$9 million cut in the administration's FY 2006 budget proposal for VA research and \$10 million in new funding.
- In response to OGC objections to NPCs supporting advocacy for increased funding for VA research, NAVREF scaled back its efforts in this area, shifting some to the Friends of VA Medical Care and Health Research (FOVA). The FOVA web site at [www.FriendsofVA.org](http://www.FriendsofVA.org) provides comprehensive information about advocacy for VA research and a means for both organizations and individuals to sign up for timely information.
- Collaborated closely with other members of FOVA to advocate a significant increase in the FY 2006 and FY 2007 appropriations for R&D. FOVA's ongoing joint efforts have included developing recommendations and supporting materials; meeting with key legislators and staff; testifying before the House appropriations subcommittee and generating support for a Senate Dear Colleague letter.
- Responded to inquiries about VA research funding, priority areas of research, recent achievements and VA policies in regard to women and minority participation in VA studies. Many of these were referred to ORD for responses and follow up.

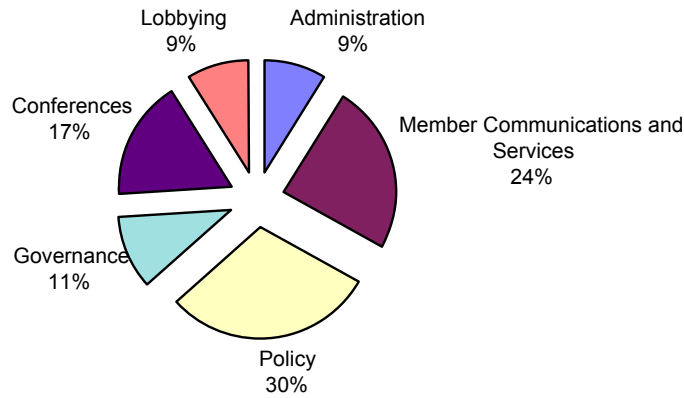
## **Conferences**

- Collaborated with VA to hold a two-day workshop on CRADAs that incorporated in-depth training on the basics of the CRADA statute. The program also included sessions by Technology Transfer Program staff and VA attorneys. The workshop led to formation of the CRADA Work Group which has subsequently been the focal point of progress in developing guidance on amending CTAs to accommodate CRADAs, model VA CRADAs for differing situations and relevant guidance.
- Conducted three membership conference calls including two membership calls without a structured agenda and one conference call on the IRS perspective on NPC support for education.
- Represented NAVREF in relations with outside organizations through participation in the Sustaining Members Conference of the Association of Medical Surgeons of the US (AMSUS), the Annual Conference of the National Council of University Research Administrators (NCURA) and the International Contracting and Negotiating Clinical Trials Conference.

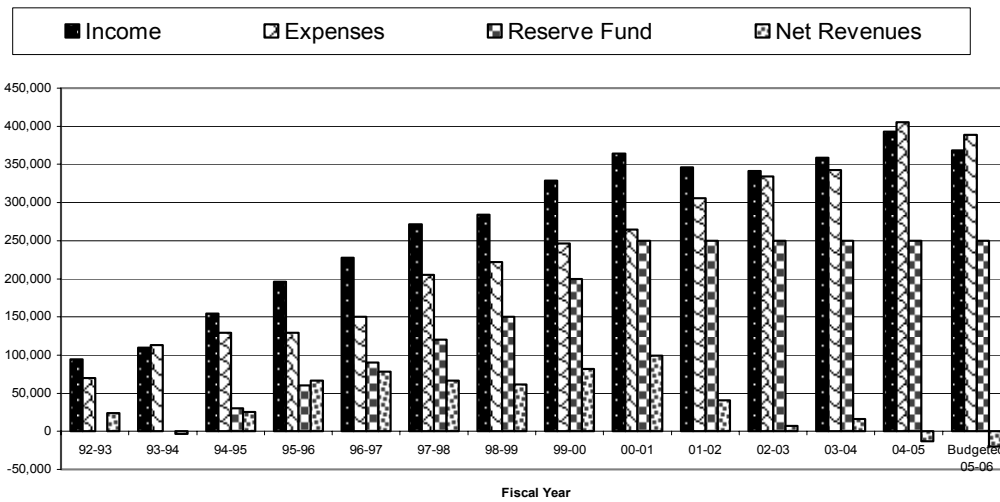
## **Administration**

- Moved to new office space in Chevy Chase, Maryland, to accommodate expanding the NAVREF staff and to improve access to downtown Washington. The new location is just two blocks away from the Friendship Heights Metro Station and two stops from NIH.
- Implemented the second stage of the first increase in NAVREF dues since its inception to support the new office and staff.

## NAVREF's Program Allocations FY05-06



NAVREF Income, Expenses, Reserve and Excess of Income over Expenses through FY05-06



\*FY05-06 Projected decline in revenues due to shifting 2006 Annual Conference from into FY06-07.

## NAVREF Dues Through FY05-06

