

# The History of NAVREF

The National Association of Veterans' Research and Education Foundations (NAVREF) was the conception of a small group of dedicated Department of Veterans Affairs (VA) personnel who recognized in the early 1990s the need for a membership association committed to the interests of the VA-affiliated research and education nonprofits. The following is a brief history of formation of the organization that came into being to meet this need and its accomplishments during its first twenty years.

## The First Step – Authorization and Establishment of NPCs

In 1984 Richard Levine, MD, associate chief of Staff for Research and Development (R&D) at the Washington, DC, VA medical center (VAMC), founded the Institute for Clinical Research (ICR). His objective was to provide investigators at the Washington, DC, VAMC with a local entity – dedicated to their needs and familiar with VA requirements and processes - to administer research projects performed at the VAMC under funding provided by non-VA federal and private sector organizations. ICR also provided more general support for the VAMC's research and education programs, often in the form of much needed high speed Internet access lines (in lieu of dial upservice), copiers, and fax machines when these were problematic purchases for the VAMC. To accomplish similar purposes, the Chicago Association for Research and Education in Science (CARES) was established later in 1984 by Ron Flink, the administrative officer for R&D at the VAMC in Hines, Illinois.

ICR and CARES had been successfully supporting research at their respective facilities for several years when ICR came to the attention of the VA Office of the Inspector General (OIG). After an investigation, including a review of subpoenaed ICR records, OIG determined that the corporate records had been properly maintained, no misuse of funds was detected and no criminal statutes had been violated. However, after consultation with the VA Office of General Counsel, OIG concluded that ICR was illegally constituted because a federal agency and its employees are prohibited from establishing or operating a nonprofit without specific legislative authority [31 USC § 9102]. As a result, OIG recommended that all federal employees should sever their relations with ICR, and it advised informally that ICR should be shut down.

Anticipating this outcome, Dr. Levine approached Sonny Montgomery (D-MS), chairman of the House Committee on Veterans Affairs (HVAC), and Mack Fleming, the HVAC staff director, for assistance. Quickly persuaded that there was value in ICR, Chairman Montgomery convened a hearing on September 9, 1987, to explore the merits of giving VA authority to establish research and education nonprofits, and the committee subpoenaed Dr. Levine to be the main witness. In its own later testimony, even VA acknowledged that ICR had value, and subsequently, Dr. Levine became the



indefatigable driver for enactment of Public Law 100-322, title II, section 204(a).

This statute, later codified at 38 USC § 7361 *et seq.*, allowed the VA secretary to authorize the establishment of nonprofit institutions to serve as a “flexible funding mechanism” [38 U.S.C. 7362(a)] for the conduct of VA research at each medical center. While the enabling legislation was working its way through the various stages of legislative deliberation, Dr. Levine collaborated with Audley Hendricks, assistant general counsel for Professional Group III in the VA Office of General Counsel, to begin developing VA guidance on how to operationalize the anticipated new authority at the local level. Additionally, Dr. Levine and Robert Potts, the administrative officer for R&D at the Washington, DC, VAMC, held several educational seminars for individual VAMCs and at various national and regional VA research meetings about the potential opportunity this statute represented. As a result, within a few years of enactment on May 20, 1988, more than 90 VAMCs took advantage of the new VA authority and established the VA-affiliated nonprofit research corporations that came to be known as “NPCs” and that are the reason for the existence of NAVREF.



The trailblazing work of launching an NPC – writing and obtaining state approval of articles of incorporation, developing bylaws, forming an organizing committee and then a board of directors in compliance with the stipulations of the NPC authorizing statute, opening bank accounts, applying for exemption from federal taxation and all the other elements required

to set up a nonprofit business – typically fell to the administrative officer for R&D (AO/R), the research coordinator (RC) or the associate chief of staff for R&D (ACOS/R) at each VAMC that decided to establish an NPC.

Recognizing the advantages that NPCs offered to facility research programs, including local, on-site management of the extramurally funded research occurring in their facilities and control over the associated funds, these early founders took up the management of NPCs as a collateral duty among their many other VA responsibilities. Already colleagues administering VA research in multiple VA facilities, these individuals shared draft bylaws and IRS Form 1023 applications for exempt status; gave each other advice on setting up accounting systems and private sector human resources management; learned how to manage a board of directors; and much more. Additionally, Dr. Levine and Mr. Flink conducted sessions on establishing and managing NPCs during VA R&D conferences in 1990 and subsequently. However, in early 1991, these pioneering founders of NPCs came to recognize that a separate formal structure would be useful to accomplish three primary purposes including:

1. Offering expert advice on how to operate a nonprofit, and one affiliated with a VA in particular, as well as fostering peer to peer sharing;

2. Interfacing effectively with VA Central Office (VACO) on matters pertaining to NPCs; and
3. Lobbying to renew the already expired authority to establish new NPCs and for other modifications to the NPC authorizing statute as they may be needed, as well as advocating a robust federal appropriation for the Medical and Prosthetic Research account which funds the intramural VA research program.

## **Establishment of NAVREF – 1991-1993**

In 1991, a group of AO/Rs and ACOS/Rs set aside time to meet during a VA R&D conference held in Beaver Creek, Colorado, to discuss ideas for such a formal structure. After considering various possibilities, they decided to explore establishing a membership association of NPCs to be called the National Association of Veterans' Research and Education Corporations (NAVREC). Individuals participating in this discussion included Dr. Levine and Mr. Flink as well as:

- Dallas Cross, AO/R in Seattle, Washington, and executive director of the Seattle Institute for Biomedical and Clinical Research;
- Jeanette Evans-Hamilton, AO/R in Kansas City, Missouri, and Executive Director of the Midwest Biomedical Research Foundation; and
- Nancy Parks, AO/R in Augusta, Georgia and Executive Director of the Augusta Biomedical Research Corporation.

During subsequent phone conversations and meetings, they refined the concept of NAVREC as a voluntary membership association supported by dues paid by each NPC and decided that to the extent practical, the board should mirror NPC boards. As a result, the NAVREC board was set up to comprise individuals holding VAMC and NPC positions, as well as at least two external persons, with key VACO personnel serving as "liaisons." After consultation with attorneys, it was determined that NAVREC should seek exemption from federal taxes as an education organization under section 501(c)(3) of the IRS Code. Interestingly, notes from these meetings indicate that the founders decided that all NPCs should have access to information promulgated by NAVREC, its conferences and its services regardless of whether they were members. As a result, a high level of openness and sharing have characterized the association and its members since inception.

Dr. Levine took responsibility for coordinating with a Washington, DC, law firm, Williams & Connolly, for the incorporation of NAVREC in Washington, DC; drafting bylaws; and starting to develop the IRS Form 1023 application for exemption from federal taxes. Dues were set at 0.5% of annual revenues as reported on Line 12 of each NPC's IRS Form 990, with a cap of \$5,000. Within a short time, thirteen NPC executive directors committed to joining NAVREC upon formation and sent good faith dues payments to Dr. Levine to put toward start-up funding. Additionally, Paralyzed Veterans of America, the veterans service organization most actively supportive of VA research, made a \$10,000 contribution to help establish NAVREC.

To identify management for NAVREC, Dr. Levine set up meetings with two organizations known for their advocacy for the VA R&D program through the Friends of VA Medical Care and Health Research (FOVA), a lobbying coalition of about 80 national medical, specialty, patient advocacy and academic organizations committed to a well-funded VA research program. In early 1992, Dr. Levine, Ms. Evans-Hamilton, Ms. Parks and Mr. Flink met with Jim Terwilliger of the association management

firm SmithBucklin, and with Lynn Morrison and Barbara West of the lobbying firm Washington Health Advocates (WHA). Initially, WHA declined to take on NAVREC as a client because it was a lobbying firm focused on federal appropriations for medical research, not an association management company. However, Ms. Morrison later reconsidered, and she and Mr. Terwilliger were invited to make presentations before a larger group of NPC executive directors during a VA R&D conference held in May 1992 in Williamsburg, Virginia.

After consideration, WHA was selected to manage NAVREC and an agreement was reached with WHA to complete legal formation of NAVREC, to recruit members and to manage the resulting association including holding an annual conference and participating in lobbying activities. Ms. West was appointed executive director, a position she subsequently held for more than twenty years during which she was an astute and dedicated leader. Mr. Fuller, a long time VA advocate and former legislative analyst at Paralyzed Veterans of America, served as the Washington representative. Mr. Fuller left WHA shortly after the July 1, 1992, start date of WHA services, and Ms. West assumed responsibility for the advocacy work as well as full management of NAVREC within WHA. Among the initial priorities set by the organizers were 1) legally changing the name of the association to the National Association of Veterans' Research and Education **Foundations** to avoid the negative connotation of an acronym that sounded like "NAV wreck;" and 2) persuading Congress to extend the window of opportunity to establish new NPCs past the already expired deadline of September 30, 1990.

Under Ms. West's management, establishment of NAVREF proceeded quickly. Thanks to a concerted effort by some of the early founders of NPCs, encouragement by VA's chief R&D officer, Dennis Smith, MD, and announcements made during medical center directors' weekly national calls, most NPCs joined NAVREF before the end of 1992. All operational NPCs had become members during NAVREF's second year of operation. In January 1993, the IRS granted NAVREF exemption from federal taxes under section 501(c)(3) of the IRS Code. An initial board of directors was formed with Mr. Flink as chairman, and the board met for a full day on a quarterly basis. Initially, board meetings were often held in conjunction with VA meetings or Society for Research Administrators (SRA) conferences. Later, the board decided to ask its member NPCs to host NAVREF board meetings so that the NAVREF and host boards could become acquainted during their lunch break and could discuss informally issues of mutual interest. The first board elections were held in 1993.

NAVREF remained a client of WHA until the board determined that full time staff was required to manage the organization and meet its numerous objectives. In October 1994, NAVREF established an independent office with Ms. West as its full time executive director working out of her home in Bethesda, Maryland.

## **The First Ten Years**

NAVREF quickly became a vibrant membership organization. The "NAVREF Up-to-Date" newsletter was created and mailed to all NPCs on a bimonthly basis. NAVREF also facilitated numerous mentor relationships between experienced and new NPC executive directors, many of whom established lasting, mutually supportive bonds.

Programs developed by NAVREF included Best Practices Consultations which offered members the opportunity for self-assessment and peer-to-peer sharing of management and planning advice in a

non-judgmental format. The Biomedical Research and Education Foundation of Southern Arizona (BREFSA) in Tucson agreed to help NAVREF pilot-test this program in May 1996. After making a few minor changes in response to feedback from the BREFSA staff, it has remained one of NAVREF's most highly appreciated membership benefits.

NAVREF's membership insurance program was created to provide NPCs with the valuable service of designating a single broker to offer a full range of insurance coverages subject to NAVREF review of the policies offered. By working with a broker willing to become familiar with NPCs' unique relationship with VA, NAVREF gained an ally able to negotiate advantageous pricing on behalf of NPCs and special endorsements that accommodated their unusual working relationship with a federal agency and with federal investigators who typically are not NPC employees. With RCM&D as the broker currently designated for the NAVREF insurance program, there is universal agreement among the users of this ongoing membership benefit that it provides excellent service and high value.

Over time, NAVREF – and its website - became the “go to” resource for reliable, timely and practical management guidance on NPC operations. Drawing on the expertise and assistance of VA personnel, particularly those in the Office of General Counsel (OGC), VA Human Resources Management Service and the Office of Research and Development (ORD), as well as private sector lawyers, accountants, grants managers, and HR and insurance experts, NAVREF helped NPCs navigate the challenges of operating private sector small businesses aligned with a federal environment. Among the many, many conundrums on which NAVREF worked collegially and effectively with VA, other federal agencies and private sector entities were:

- Determining whether NPCs should obtain private sector workers' compensation coverage for all of their employees or should rely on Federal Employee Compensation Act benefits for those directly engaged in VA research or education;
- Navigating federal ethics requirements as applied to private sector employees;
- Obtaining WOC appointments for NPC employees working on VA research or education;
- Persuading NIH that NPCs may be grantee institutions in their own right with negotiated indirect cost rates; and
- Establishing that NPCs must obtain approval of their own Federalwide Assurances (FWAs) for human subjects protections.

Additionally, NAVREF worked with VA to develop successive versions of VHA Manual Chapter 17 (later Handbook 1200.17) which reflected VA's interpretation of the NPC authorizing statute and provided a few elements of operational guidance. NAVREF also obtained for all NPCs VA certification of their eligibility to engage in Intergovernmental Personnel Act (IPA) assignments with VA. The latter provided VAMCs with a highly cost-effective means to collaborate with NPCs to solve short term VA staffing needs.

The first NAVREF Annual Conference was held in June 1993 at the Washington Court Hotel. With about 85 attendees, the program featured a mix of VA and private sector speakers who offered guidance on a variety of operational topics specific to NPCs as well as those applicable to any small business such as labor law, insurance, and fundraising.

The 1993 conference also incorporated the inaugural NAVREF VA Research Capitol Hill Day which may have been the first large scale advocacy event ever dedicated entirely to the need for an increase in the VA Medical and Prosthetic Research appropriation. That year and in subsequent years until 2005, conference attendees received training on effective lobbying techniques and were briefed by key staff members of the House and Senate Committees on Veterans Affairs and the applicable appropriations subcommittees. They then dispersed across the Hill to make the case for increased VA research funding in over 100 meetings with their own legislators and staff members.

Some years NAVREF sponsored luncheons and receptions on the Hill to which conference attendees invited their own legislators. Several times, NAVREF used these events to present its "Champion of VA Research" award to particularly supportive members of Congress, including Senator Jay Rockefeller, III (WV), chair of the Senate Committee on Veterans Affairs, and Senator Barbara Mikulski (MD), chair of the appropriations subcommittee responsible for VA funding. In 1998, the tenth anniversary of passage of the initial NPC authorizing statute, Representative Sonny Montgomery (MS), chair of the House Committee on Veterans Affairs and the primary sponsor of the NPC enabling legislation, was made an "honorary VA researcher" and was presented with a mock VA badge and a lab coat embroidered with his name. Literally tickled pink by the recognition, he told attendees that just a few years before, NPCs had been "just an idea," but that "clearly, they were a very good idea."

The fact that so many individuals were willing to take annual leave in order to participate in these lobbying activities attests to their dedication to VA research. The effectiveness of these Hill days, letter writing campaigns and congressional sign on letters organized by NAVREF, and regular "legislative updates" encouraging NAVREF members and VA researchers to educate their elected officials about VA research and to engage with them at home and in Washington, DC, was evidenced by frequent increases in the annual appropriation and recovery of reduced funds in the years when administrations requested less funding for the VA R&D appropriation. NAVREF was compelled to discontinue its Hill Days and grassroots efforts in 2005 when the VA OGC objected to NPC participation in lobbying activities because they entailed VA personnel serving on the board appearing to advocate funding levels higher than the officially sanctioned funding levels provided in the administration's annual budget request. However, after 2005 Ms. West remained a leading advocate for VA research and continued to actively lobby on behalf of the annual VA research appropriation, primarily under the auspices of Ms. West's position on the Executive Committee of FOVA.

Other legislative achievements during NAVREF's first decade included working with Congress to make revisions to the NPC authorizing statute. These changes:

- Extended twice the "sunset clause" on establishing new NPCs [1996 – Public Law 104-262; 2003 – Public Law 108-170] To help VAMCs make good use of this renewed authority, in 1997, NAVREF held a two-day workshop in San Diego on how to establish a new NPC. Note: In 2010 Public Law 111-163 eliminated the sunset clause entirely; as a result, VA now has permanent authority to establish new NPCs.
- Added explicit authority for NPCs to administer educational activities of benefit to VA employees as well as veteran patients and their families [1999 – Public Law 106-117].

- Secured explicit eligibility for Federal Tort Claims Act protections for NPC employees [2003 – Public Law 108-170]
- Clarified the information NPCs were required to report to VA so that VA could in turn submit useful information about NPCs to Congress on an annual basis (1999 – Public Law 106-117)

Exemplary governance was an objective of NAVREF and it was most fortunate to have dedicated, experienced, well-connected and engaged chairs and board members during its formative years. The chairs included the aforementioned Mr. Flink, Mr. Cross, Ms. Parks and Ms. Evans-Hamilton as well as Antonio Laracuate, AO/R&D of the VAMC in Decatur, Georgia, and executive director of the Atlanta Research and Education Foundation. With the exception of Mr. Cross, who decided to retire from VA and the NPC shortly after his appointment as chairman, each chair served a two-year term.

## **NAVREF's Second Decade**

NAVREF's tradition of strong leadership continued during its second decade. Eileen Lennon, PhD, executive director of the Seattle Institute for Biomedical and Clinical Research, served two separate chair terms that bracketed the five years that Donna McCartney, executive director of the Palo Alto Institute for Research and Education, served as chair. After her second term as chair, Dr. Lennon was succeeded by Cindy Reutzel, executive director of the Chicago Association for Research and Education and Science (CARES) in 2012.

Two significant changes to NAVREF occurred in the early years of the new millennium. The first was hiring Angela Murakami as NAVREF's second fulltime employee. Ms. Murakami was previously employed by a Washington, DC, research institute and later worked for the Institute for Clinical Research, the NPC affiliated with the Washington, DC, VAMC. The second change was relocating the NAVREF office from Ms. West's home to commercial office space in Chevy Chase, Maryland. The move provided much-needed additional office space, including room for a third employee, and time-saving access to Metro for frequent meetings downtown and on Capitol Hill. In order to afford the rental expense, in 2004 NAVREF instituted its first dues increase. Perhaps as a result of showing members photographs depicting one staff member's desk located in Ms. West's laundry room and annual conference materials piled high in her living and dining rooms, there were no objections to the dues increase.

During its second decade, NAVREF's programs grew and matured along with its membership. After NAVREF discontinued its VA Research Hill Days, it began holding its annual conferences outside of Washington, DC, in alternate years in order to take advantage of the wealth of expert speakers located in such cities as Chicago and Seattle. Annual conferences and workshops offered in-depth training on operational matters, including several workshops on managing federal funds as more NPCs assumed responsibility for managing VA PIs' grants and sub awards from federal agencies, primarily from the National Institutes of Health (NIH) of the Department of Health and Human Services (DHHS) and from the Congressionally Directed Medical Research Program of the Department of Defense (CDMRP).

Concurrently, NAVREF continued to offer basic management guidance as the original VA executive directors were replaced with non-VA personnel. This included holding a special workshop in 2010 specifically for recently appointed executive directors. Other senior NPCs staff members – human

resource managers, chief financial and operations officers - were also invited to broaden their knowledge of NPCs and to support those who aspired to become executive directors.

Building on an NPC management checklist originally developed for Best Practices Consultations, in 2006 NAVREF created the NPC Self-Assessment Tool (S.A.T.) to help NPCs evaluate their compliance with the NPC authorizing statute, Handbook 1200.17, IRS and Department of Labor requirements, and to encourage NPCs to implement best practices. This was updated in 2010, in part to reflect the new NPC authorizing statute changes. In 2011 NAVREF developed concise, but comprehensive sample financial and operational policies and procedures for small-staff NPCs and disseminated them in early 2012. Adopting these, or using them as a cross-check of their own policies, has proven to be of great assistance to NPCs in avoiding negative findings during audits.

In 2003, VA created the Nonprofit Program Office (NPPO) and the Nonprofit Oversight Board in response to VA's Inspector General criticism that although NPCs appeared to be generally well-run, VA oversight was lacking. Accustomed to consulting with VA personnel in the offices directly responsible for issues that arose, NAVREF adjusted to working with these entities in pursuit of the mutual VA/NAVREF objective of well-run NPCs. In 2004, NAVREF collaborated with the NPPO and Gerry Zack, CPA, to develop a two-day training program that, along with an accompanying manual, was offered to NPC executive directors and board members five times in different locations around the country.

On April 1, 2005, OGC notified its attorneys that clinical trial agreements were no longer appropriate instruments for establishing terms and conditions of research collaborations (primarily clinical trials) with for-profit entities and that henceforth, NPCs must use Cooperative Research and Development Agreements (CRADAs). Notably, in 1996 Dr. Levine and Ms. West had met with OGC to suggest that NPCs might use CRADAs in lieu of clinical trial agreements, a suggestion that OGC declined at that time.

The April 1, 2005, announcement was not an April Fool's Day joke and the transition to CRADAs occupied much of NAVREF's staff time and resources during the next two years. A smooth and speedy transition was important because VA PIs and veteran patients participated in thousands of clinical trials each year; in some cases, an experimental drug was the patient's only hope for treatment. Additionally, the bulk of NPC revenues – and the support they in turn provided to VAMCs – were dependent on executing research agreements with pharmaceutical companies and device manufacturers. However, no NPC personnel, very few VA attorneys and virtually no industry sponsors were familiar with CRADAs in early 2005.

To support the transition, Ms. West and board members David Johnson, PhD, AO/R and executive director of the Baltimore Research and Education Foundation, and Mr. Laracuenta devoted considerable time to serving on an OGC and VA Technology Transfer Program (TTP) CRADA working group that met as often as weekly for nearly two years, initially under the leadership of Paul Hutter, assistant general counsel for Professional Staff Group IV. Mr. Hutter assigned responsibility for technology transfer and research matters, including CRADAs, to PSG III and after his promotion to general counsel, Associate General Counsel Renée Szybala was appointed to be the lead Office of General Counsel attorney advising on implementation of CRADAs. Decisions had to be made on such matters as who may sign CRADAs on behalf of VA and whether NPCs may enter into three-way CRADAs with VA and collaborators. Additionally, the working group drafted model CRADAs for



various research situations and developed - and advocated vigorously for - the concept of master CRADA templates.

In late 2005, NAVREF sponsored a two-day workshop in Santa Monica, California, and enlisted CRADA expert Robert Charles, a Department of Defense attorney associated with the US Army Medical Research and Materiel Command in Fort Detrick, Maryland, to educate NPC personnel and VA attorneys together about the CRADA statute and its requirements. After significant progress was made on model CRADAs, in 2008 NAVREF collaborated with TTP and OGC to hold a workshop to educate industry representatives about CRADAs and the VA research program. NAVREF also contributed significantly to the content of a new TTP website about CRADAs as well as development of CRADA review and approval procedure guidelines and a CRADA registry to facilitate execution of CRADAs and avoid duplication of effort. All of this work paid off mightily in fostering industry acceptance of CRADAs and mitigating - to the extent possible - the declines in the number of new VA/private sector clinical trials and in NPC revenues that resulted from the precipitous shift to CRADAs.

Clarifying and modernizing the NPC authorizing statute also dominated NAVREF's second decade. This three-year legislative effort entailed considerable effort by the NAVREF staff and board, including Donna McCartney testifying before the Senate Committee on Veterans Affairs on behalf of NAVREF's proposed modifications. Careful coordination with OGC and NPPO personnel was required to ensure that VA would testify in support of the NAVREF objectives.

After spending a year developing a detailed legislative proposal and supporting documentation, and then securing the agreement of the chairmen of the House and Senate Committees on Veterans Affairs, Bob Filner (D-CA) and Daniel Akaka (D-HI) respectively, to sponsor and introduce the NAVREF bill, it was rolled into a larger package for full House and Senate floor action in 2008. Unfortunately, that bill failed for reasons unrelated to the NPC provisions and the entire legislative process had to be repeated the following year. Final success and enactment were achieved when Public Law 111-163 was signed in May 2010. Notably, the final legislation was exactly what NAVREF proposed which is a testament to NAVREF's effectiveness in working with VA and congressional personnel to achieve its goals.

Key improvements reflected in the new statute included:

- The ability of two or more VAMCs to share one NPC – known as a “multi-medical center research corporation” or “multi-NPC” - without requiring all of the statutory VA directors from each site to serve on the board;
- Explicit broadening of the NPC authority to include providing support for functions related to VA research and education, as opposed to just VA-approved research and education, and for planning and development costs of projects;
- Clarification that NPCs are non-governmental entities and that NPCs may accept from VA reimbursement for salaries and benefits paid to NPC personnel assigned to VA under the IPA authority;
- A requirement that each NPC must establish its own conflict of interest policy, replacing the former inappropriate application of federal ethics rules to NPC employees and board members who were not salaried or VA WOC employees; and

- Granting OGC the ability to accept reimbursement from NPCs for services related to CRADAs as a means to increase OGC resources for timely CRADA reviews and approvals.

Following passage, NAVREF assisted in implementation of the new statute provisions by commenting on successive drafts of a new version of VHA Handbook 1200.17, working with OGC to develop a fee schedule for VA attorney services related to CRADAs, and assisting the first NPCs seeking to become multi-medical center NPCs. In this effort, as in the legislative effort, NAVREF staff relied on expert assistance from its volunteer board, particularly the chairs Ms. McCartney and Dr. Lennon.

NPCs entered a new era of VA oversight in 2008 with appointment of three VA employees to staff the Nonprofit Program Office (NPPO). This added a new dimension to NAVREF activities, specifically by monitoring the conduct of VA oversight and where needed, assisting NPCs in evaluating and putting in place appropriate management practices. NPCs cooperated fully in year 2009 NPPO “checklist” reviews of NPCs (modeled in part on the aforementioned NAVREF S.A.T.) to help the NPPO assess where deficiencies might lie. These reviews revealed few significant problems. However, VA used the results to frame plans to conduct triennial site visits of each NPC with the major focus on financial matters, including internal controls, and compliance with VA-specific matters such as IPA requirements. At NAVREF’s urging, OGC considered whether Paperwork Reduction Act (PRA) requirements applied to oversight questionnaires used by NPPO to evaluate NPCs and determined that, in fact, questions NPPO asked of 10 or more NPCs must undergo OMB review and approval. Consequently, the PRA afforded NAVREF the opportunity to submit to OMB substantive comments on successive versions of the NPPO documents during 2011 and 2012. In the end, many of NAVREF’s recommendations were reflected in the final OMB-approved documents with the result that the questionnaires were more concise, and the questions were clearer and more directly applicable to NPCs.

In early 2012, Ms. West notified the board of her decision to resign effective in January 2013 after more than 20 years as the NAVREF executive director. However, NAVREF was well-positioned to enter its third decade by the end of 2012. In addition to having a dedicated board of directors under the leadership of Ms. Reutzel, the board established a new set of strategic goals in tandem with bringing on new talent to guide the organization into the third decade.

## **The Third Decade aka The Transitional Years**

NAVREF’s third decade began under the leadership of Mr. Thomas E. Stripling as Executive Director and Ms. Angela Murakami as Associate Executive Director. Mr. Stripling, formerly of Paralyzed Veterans of America, was the PVA designee on the NAVREF Board of Directors for nearly a decade before becoming NAVREF’s second Executive Director in November of 2012. During Mr. Stripling’s tenure, NAVREF focused on stabilization and refocusing priorities toward membership benefits. This was the beginning of NAVREF’s transition to a more modern association member experience.

Throughout the ensuing period several structural changes took place - changes that ultimately helped NAVREF develop deeper institutional relationships. After a short time in her role, Ms. Angela Murakami stepped down to follow her passion in the musical arts which opened the door for the hiring of Mr. Hawk Tran, who joined the NAVREF team in 2014. Mr. Stripling departed NAVREF in June 2015, causing Ms. Cindy Reutzel to step down as board chair to assume duties as the Interim Executive Director.

After an exhaustive search with a recruitment firm, the board hired retired US Army Colonel, Mr. Rick Starrs, in January of 2016 to lead the Association. Mr. Starrs brought with him 26 years of leadership experience in the military health system ranging from leading troops in combat to working on Capitol Hill to overseeing the day-to-day operations of a multi-billion dollar military medical research, acquisition, and logistics enterprise. He had a background as a health services comptroller with extensive expertise in congressional affairs. His last assignment in the Army was as Chief of Staff for the US Army Medical Research and Materiel Command. Mr. Starrs not only brought a wealth of experience to NAVREF, but immediately implemented initiatives to better connect NAVREF leadership to its members.

Infused with a new Chief Executive Officer and fresh staff, NAVREF spent the Spring and Summer of 2016 engaging with members, learning the landscape, and recommitting itself to be a tireless advocate for VA research and the VA-affiliated nonprofits.

In a June testimony before the House Veterans Affairs Subcommittee on Oversight and Investigations, titled "VA and Academic Affiliates: Who Benefits." Ms. Nancy Watterson-Diorio, NAVREF board member and CEO of the Boston VA Research Institute, gave testimony that advocated on behalf of NPCs, requesting consideration of three recommendations: 1) Allow NPCs to pay investigators to the same extent as Academic Affiliates; 2) Provide NPCs right-of-first-refusal on administering all awards supporting VA research; and 3) Reduce the level of variability from site-to-site by creating general guidelines and decision trees that remove or reduce conflicts of interests among decision-makers.

Also in 2016, NAVREF launched into new partnerships, including an alliance with the Society for Clinical Research Sites (SCRS) that would provide all NAVREF members membership in the Society and access to SCRS mentoring, training, and networking. NAVREF would go on to establish partnerships with the Association of Clinical Research Professionals (ACRP), the Association of VA Hematology and Oncology (AVAHO), and several other like-minded organizations that would usher NAVREF into the next developmental stage. This notion of building relationships with stakeholders underscored the need for NAVREF to participate more actively in external events leading to NAVREF's first-time exhibition at the DIA Global Expo in Philadelphia, PA, an annual 4-day convening of the pharmaceutical and bio-medical industries. Exhibiting at DIA offered NAVREF the opportunity to highlight the benefits of working with VA research and introduce NAVREF and NPCs to a broad swath of the clinical trial community.

Mr. Starrs' first year with NAVREF proved to be a period of change and growth - both externally and internally. It was year in which NAVREF opened its arms to partnerships. It was a year in which NAVREF evolved from a physical office space to become a virtual organization. And it was also a year in which NAVREF reached out actively to all members to learn how to better develop and deliver the Association's services and educational programs.

Building on the recent positive changes, NAVREF entered 2017 in a strong position to grow. In March, NAVREF expanded its staff to include an in-house Clinical Trials Facilitator to support NAVREF's effort to bring more industry-sponsored clinical trials to veterans at VA medical centers. The newly created position was filled by Ms. Krissa Caroff, a former VA employee who brought more than a decade of expertise in regulatory affairs. In April, the board of directors traveled to Baltimore to hold a retreat that would help chart NAVREF's next steps. The board reaffirmed NAVREF's mission

Later in 2018, NAVREF was proud to host a gathering of the VA Associate Chiefs of Staff for Research (ACOS-Rs) at the 26th NAVREF Annual Conference. This was the first time in over 5 years this cohort had met in person as a group and it allowed for increased interaction and communication between NPC leaders and VA research leaders.

Moving into 2019, NAVREF continued to promote external engagement with VA research through the NPCs and launched development of a fundraising plan to further enhance support of the NPCs and profoundly impact veterans research and education programs. On October 24th, NAVREF hosted

a breakfast on Capitol Hill to celebrate individuals and organizations who have advanced the cause of veterans' health. The event also kicked-off NAVREF's fundraising effort with introduction of the NAVREF Accelerator Fund. The event included leaders from the Veterans Health Administration, biomedical research community, veterans service organizations, and congressional staff. NAVREF recognized three distinguished Members of Congress with its inaugural "Champions of Veterans Health" award—Senator Jon Tester, Representative Julia Brownley, and Representative (Dr.) Phil Roe. Each was presented with the new NAVREF Challenge Coin by NAVREF Chair Robin Rusconi. The VA Deputy Undersecretary for Health, Dr. Carolyn Clancy, attended and offered special remarks.

2019 was also a year of steady progress for the ACT for Veterans initiative. In February, NAVREF hosted a second ACT for Veterans summit at the Akin Gump offices in downtown Washington DC. This working event allowed the five ACT workgroups to come together, present their respective recommendations and products, and incorporate feedback from leadership. As the ACT initiative progressed across 2018 and 2019, it ultimately led in 2020 to the establishment of the new Partnered Research Program (PRP) within the Office of Research & Development. The PRP institutionalizes the goals of the ACT initiative and demonstrates VA's commitment to improving access to clinical trials at VA hospitals. NAVREF continues to play a key supporting role in the PRP by providing a clinical trial facilitator to interact with sponsors and sites.

NAVREF entered 2020—our 28th year—with great momentum. At the start of the year, Cohen Veterans Bioscience, a supporter of NAVREF activities for 3 years, became NAVREF's first Champion Level Sponsor, contributing a substantial financial donation to support NAVREF's critical role in the ACT for Veterans initiative.

As we approach the end of our third decade, NAVREF remains unwavering in its commitment to support our members and to provide our nation's veterans with cutting edge medical research.