



## The Veterans Affairs research program: scientific and clinical excellence relevant to veterans' healthcare needs

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I am proud to have served as your president over the past year as this organization exemplifies the close-knit relationship amongst surgeons within the Veterans Affairs (VA) Healthcare System. The Association of Veterans Affairs Surgeons (AVAS; [www.vasurgeons.org](http://www.vasurgeons.org)) has been an important organization for VA surgeons to exchange ideas, for the

Council of Chiefs to meet and discuss issues germane to clinical care, and to present, discuss, and publish scientific research. Originally chartered in 1967 under the leadership of Lloyd Rogers, M.D., the first president of the AVAS, presentations are often done by younger investigators such as residents, fellows, and students, and as such, the association has been an excellent platform for educational opportunities for young investigators. Awards, which recognize outstanding resident presentations, originated in 1972 and several are given each year.

My association with the Department of Veterans Affairs ([www.va.gov](http://www.va.gov)) began with three electives done at the Long Beach VA Medical Center more than 25 years ago. Rotations in neurosurgery, gastroenterology, and thoracic surgery convinced me that the VA was an excellent source of interesting patients with whom I enjoyed my interactions as a senior medical student. There were also excellent role models, including Dr. Edward Stemmer, President of the AVAS in 1979–80, the same year in which I did my electives. He is Professor of Thoracic Surgery at the University of California-Irvine. Dr. Stemmer's lectures to us as both junior and senior medical students were stimulating and interesting, often with a wonderful historic flavor. I was able to participate in several complex thoracic and neurosurgical cases as a senior student, often first assisting, which thrilled me to no end. Dr. Stemmer was kind enough to write a letter of recommendation for my surgical residency for which I will be forever grateful. I then had the good fortune to be assigned to the VA hospital on July 1st of my intern year and was actually paid from the US Treasury for that year, which essentially began my formal 25-year relationship with the Department of Veterans Affairs, then known as the Veterans Administration.

My first operation occurred July 2nd, the second day of my internship, removing an abscessed vein with Dr. Don

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Fry as staff. Dr. Fry is past-president of our organization and has been a tremendous mentor to me over my career, stimulating thought into mechanisms of organ failure and a lifelong interest in infection. At the time, Dr. Neal Garrison had just returned from his military duty as ship's surgeon on the USS Eisenhower and Dr. Phil Harbrecht was the Chief of Surgery at the Louisville VA. This was an outstanding group of mentors, and I have continued to work closely with Dr. Garrison ever since. We share laboratory space in Building 19 adjacent to our VA, and there have been a total of nine VA merit review-funded investigators over the past 20 years in this building. At one point, there were six simultaneously VA-funded investigators working in this building. This atmosphere of collegiality, mentorship, and intellectual activity was perfect for a young surgeon-investigator to launch his career. All of these surgeon investigators had been recruited by Dr. Hiram Polk, who served as our Department Chairman for more than 33 years. I have been very fortunate to have Dr. Garrison and Dr. Polk as research and clinical mentors in my early years, and throughout my career, from which I benefited tremendously.

Mentorship is a key issue for young clinical investigators and was the subject of Dr. Neumayer's presidential address 2 years ago [1]. Clinical and research mentorship with the VA, particularly the surgical service, has been excellent over the years. Such mentorship requires a close affiliation between the VA Medical Center and the affiliated medical school as outlined by Dr. Rege in his presidential address last year [2]. Indeed, medical school affiliation originated shortly after World War II, when Public Law 293 was enacted in 1946, the so-called "Magna Carta" by General Paul Hawley. Omar Bradley was head of the VA from 1945 to 1947 when these critical affiliations occurred, which immediately increased the number of physicians able to care for veterans who had returned from the battlefields of World War II. It has been a long lasting relationship to this day, and the Academic Partnership Council, formerly the Dean's Committee, has been the key platform of communication between the VA and the university. The committee consists of the medical school Dean, the Medical Center Director, Department Chairs, and Service Chiefs in a monthly forum that is an excellent avenue of communication between the two entities. In 1989 the Veterans Administration was elevated to cabinet status, which is the second largest of the 15 cabinets and its name changed to Veterans Affairs to reflect a commitment to veterans.

The four missions of the VA are: patient care, research and education, backup medical care to the Department of Defense, and cemetery management. These are reflected in nine major programs within the VA, including medical care, medical research and support, disability compensation, pensions, education, housing programs, vocational rehabilitation, insurance, and burial. Thus, the first two missions of the VA are completely in line with those of the medical schools of the United States in that patient care, research, and education are the main focus. The Department of Vet-

erans Affairs is a large entity in which there are some 230,000 employees in 158 hospitals caring for approximately 5 million veterans. There are actually 25 million veterans alive and some 70 million people that are potentially eligible because of dependent status. Affiliations with 107 medical schools across the country are present. Overall, the number of veterans is declining, with approximately 4 million living World War II veterans, a number approximately equal to the number from the Gulf War and the present conflict in Iraq. The largest group, consisting of some 9 million from the Viet Nam era now entering their sixth decade of life, has increasingly sought health care in the VA healthcare system. The VA budget for 2005 will be some \$67 billion and this will increase to potentially over \$70 billion for the 2006 budget. Well over half is spent in discretionary funding and almost \$30 billion on direct medical care. Ten percent of this figure is actually collected from insurance.

The research program ([www1.va.gov/resdev/](http://www1.va.gov/resdev/)) within the VA is organized into four separate services, i.e., Biomedical Laboratory Research and Development (R&D), Clinical Science R&D, Health Services R&D (HSR&D), and Rehabilitation R&D (Fig. 1). The Chief Research and Development Officer reports to the Deputy Undersecretary, who in turn reports to the Undersecretary for Health. The Cooperative Studies Program is administered through the Clinical Science R&D service. The VA sponsors some 15,000 projects in 115 VA hospitals and overall, 75% of researchers are clinician investigators who spend a significant amount of their time providing patient care to veterans. This is in contrast to the National Institutes of Health, with a \$23 billion budget, in which 25% of funded applications are to M.D.s and 75% to basic scientists. This ratio is by design to provide funding for those clinicians who provide patient care to veterans as a priority. There are over 85 centers of excellence related to specific areas of disease and include the 44 research enhancement awards programs (REAPS) to train young investigators. The VHA Quality Enhancement Research Initiative (QUERI) under HSR&D has eight centers for colorectal cancer, diabetes mellitus, HIV/AIDS, ischemic heart disease, mental health, spinal cord injury and disorder, stroke, and substance abuse disorders. The mission of the QUERI program is to facilitate and support ongoing improvement in outcomes and in clinical care delivery. For the most part, surgeons have been most closely involved with the Biomedical Laboratory and Clinical Sciences R&D services, and the remainder of the discussion will focus on research performed under the auspices of these services. This is not meant to detract from the outstanding research performed under HSR&D and Rehabilitation Research, just to limit the scope of the discussion to programs most relevant to surgeons. In fact surgeons have begun to obtain funding from HSR&D, an example of which is "The study of mesh repair of ventral hernia: which rate is right?" with Dr. Mary Hawn as the principle investigator [3].

The Associate Chief of Staff for Research and Develop-

Table 1  
Veterans Affairs research portfolio: nine designated research areas

Military occupational and environmental exposures
Service related limb loss
Acute and traumatic injury
Aging
Mental illness
Diabetes
Cancer
Chronic disease
Special populations (blind, spinal injury)

ment, assisted by an administrative staff, is responsible for administration of programs at individual VA medical centers, and is a position that I have held at the Louisville VAMC for 15 years. Each VAMC research service either has its own internal research committees or participates in combined research committees, usually with the affiliated medical school. These committees are at the heart of the individual research programs in that they essentially adjudicate the research projects submitted for approval. The VA research committees consist of the R&D Committee that provides scientific review, the Human Studies Subcommittee, which ensures patient protection, the Animal Studies Subcommittee, which ensure appropriate treatment of animals, and the Biosafety subcommittee to ensure overall safety in the research program. Committee composition is governed by VA guidelines that ensure multidisciplinary input. All research performed in the VA must be categorized into one of nine designated areas to ensure that the overall portfolio is clinically relevant to disease that veterans are afflicted by (Table 1). There are also several centers of excellence across the country with special expertise in different disease areas that are particularly common in the veteran population. The fund allocation scheme is depicted in Table 2, and more than two thirds of funds are awarded to researcher-initiated projects.

Some highlights of clinical research accomplishments are listed in Table 3 and include a wide variety of disease areas that are germane to veterans' health. All of these accomplishments have been translated over to the private sector and have been accepted as standard medical care throughout the developed world. The VA has been actively engaged in sponsoring basic research since its inception, as part of the Vannevar Bush doctrine, and the quality of the research is reflected in publications in the highest impact journals. Three VA investigators have won the Nobel Prize. In 1977, the Nobel Prize was

Table 2  
Research funds allocation scheme

Researcher-initiated	68%
Multisite trials	13%
Career development	8%
Centers of excellence	7%
Special initiatives	3%
Service directed	1%

Table 3  
Highlights of VA research program

● 1946: Tuberculosis treatment, prosthetics, rehabilitation for the blind
● 1958: Implantable cardiac pacemaker
● 1960: Concepts leading to computed tomography scanner
● 1968: 1st liver transplant by Starzl
● 1984: Nicotine patch
● 1989: Computerized ventilator
● 1995: National Surgical Quality Improvement Program
● 1996: Insulin pump trial
● 2000: Colonoscopy for screening
● 2004: Inguinal hernia repair

shared by Andrew Schally from the New Orleans VA for discovery of hypothalamic releasing factors and Rosalind Yalow from the Bronx VA, who developed the radioimmune assay. In 1998, the award was given to Farud Murad, from the Palo Alto VA for his pioneering work with nitric oxide as endothelial-derived relaxing factor.

The VA Research Program has gained much of its notoriety from the Cooperative Studies Program, which began in 1946. The first cooperative study demonstrated the antibiotic efficacy of streptomycin against tuberculosis, as the disease was endemic in veterans at the time. The Cooperative Studies Program ([www.vacsp.gov/flashindex.cfm](http://www.vacsp.gov/flashindex.cfm)) was formalized in 1972 and then merged with the Cooperative Studies section of Health Services R&D in 1996. There are actually several stages in order to get a cooperative study up and running. At present, there are nine in the planning stage, five that have been approved but not yet funded, and two that have been funded but not yet started. There are 70 ongoing trials and literally hundreds of completed trials over the last 60 years. The Cooperative Studies Program has eight centers throughout the United States, including four with special expertise in biostatistical and data management coordination at Hines, Palo Alto, Perry Point, and West Haven, three epidemiologic research and information centers (ERIC) in Austin, Durham, and Seattle, and a major clinical research pharmacy coordinating center at Albuquerque. Cooperative Studies with special interest to, or which have been carried out by surgeons, include those in cardiac

Table 4  
Cooperative studies program: clinical trials in cardiac surgery

CSP #4—Coronary artery surgery I (1965–1975)
CSP #28—Coronary artery surgery II (1970–1992)
CSP #90—Prognosis and outcome following heart valve replacement (1975–1997)
CSP #207—Antiplatelet therapy after CABG (1983–1991)
CSP #385—Urgent revascularization in unstable angina (AWESOME, 1995–2000)
CSP #411—The coronary artery revascularization prophylaxis (CARP) trial (ongoing)
CSP #474—Radial artery vs saphenous vein grafts in CABG (ongoing)
CSP #517—Outcomes following myocardial revascularization: On and off cardiopulmonary bypass (ongoing)

CABG = coronary artery bypass graft.

Table 5

Cooperative studies program: clinical trials in vascular surgery

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CSP #43—Platelet aggregation in diabetes (1977–1986)
CSP #141—Comparative efficacy of vascular bypass materials in lower extremity revascularization (1983–1988)
CSP #167—Asymptomatic carotid stenosis (1983–1993)
CSP #199—Percutaneous transluminal angioplasty in the lower extremity (1983–1989)
CSP #309—The role of carotid endarterectomy in symptomatic carotid stenosis (1983–1993)
CSP #379—Aneurysm detection and management (ADAM, 1992–2000)
CSP #498—Open vs endovascular repair (OVER) trial for AAA (ongoing)

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surgery, vascular surgery, and other areas of surgery in general. Cooperative Studies that have either been completed or are ongoing in the area of cardiac surgery, which has spanned the last 40 years, are listed in Table 4. They demonstrate efficacy for coronary bypass, antiplatelet therapy and valve surgery [4–7]. Ongoing trials include coronary revascularization as prophylaxis, determination of the efficacy of radial artery versus saphenous vein graft, and the on- and off-pump myocardial revascularization study. At the 5-year follow-up point in the coronary artery revascularization trial, there was no difference in the mortality rate between the two groups, indicating that prophylactic revascularization is not warranted in patients with stable cardiac symptoms who are to undergo vascular procedures [8]. Symptomatic patients were excluded and more than 500 patients were randomized.

There have been several trials completed or ongoing in the area of vascular surgery, and these include carotid artery surgery, angioplasty, use of antiplatelet agents, peripheral bypass material, and the recently completed study on small aneurysm detection and management [9–13]. This trial has shown that the mortality rate for small aneurysms less than 5.5 cm is not improved with immediate surgery, and can be observed over time, with surgery reserved for those that grow rapidly or exceed 5.5 cm [14]. An ongoing trial, which compares open to endovascular vascular repair for abdominal aortic aneurysms (OVER trial), should provide very interesting data as to the efficacy of the technique of endo-

Table 6

Cooperative studies program: clinical trials in surgery

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CSP #142—Comparison of the peritoneo-venous shunt and medical treatment for ascites (1983–1988)
CSP #196—Spontaneous Pneumothorax (1983–1990)
CSP #221—Randomized clinical trial of TPN in malnourished surgical patients (1984–1991)
CSP #277—Medical and surgical therapies for GERD (1986–1997)
CSP #407—Prostate cancer intervention versus observation trial (PIVOT, 1986–1995)
CSP #456—Tension free inguinal hernia repair: open vs laparoscopic repair

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TPN = total parenteral nutrition; GERD = gastroesophageal reflux disease.

Table 7

Major risk factors for postoperative mortality

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- Serum albumin
  - Age
  - Emergency operation
  - ASA class
  - Disseminated cancer
- 

ASA = American Society of Anesthesiologists.

vascular stenting over a long period of time. These are listed in Table 5. Trials in various areas of surgery are listed in Table 6 [15–18]. These demonstrate the efficacy of a tetracycline in pleurodesis, a period of nutritional support prior to operative intervention in those patients with significant malnutrition, efficacy of Nissen fundoplication versus medical management for gastroesophageal reflux disease, and the PIVOT trial in which patients with prostate cancer were randomized to observation or radical prostatectomy. This area is still unclear and options include radiation therapy, surgery, or careful observation over time. Lastly, the tension-free inguinal hernia study, chaired by Dr. Leigh Neumayer, our past president, demonstrated a higher recurrence rate in those who underwent laparoscopic repair [19]. This is also a more expensive technique and these data showed that an open repair with mesh is the most cost-effective method of repair.

A highlight of VA research by surgeons is the National Surgical Quality Improvement Program headed up by Dr. Shukri Khuri and Jennifer Daley from the West Roxbury VA. The history behind the study, which was a challenge to VA by Congress, its inception and data accrual, establishment of the formal National Surgical Quality Improvement Program, and finally its transition to the private sector, has been one of the greatest successes in VA research. VA hospitals had become under increased scrutiny because of government reports demonstrating unadjusted comparative mortality rates that proved unfavorable to the VA. Congress passed Public Law 99-166, which mandated the VA gather data and compare mortality throughout their hospitals. The National VA Surgical Risk Study was then carried out from 1991 to 1993, in which almost 89,000 patients were accrued into a database. A risk stratification index was then developed by Dr. Khuri, utilizing the first half of the patient database and then validated using the second half of the

Table 8

The National Surgical Quality Improvement Program

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- 83,958 cases from 1991–1993 into database
  - Overall mortality rate of 3%, wound infection rate of 5%
  - Follow-up site visits resulted in decreased morbidity and mortality
  - Established factors for risk adjustment and expected mortality
  - Quarterly reports for all VA hospitals and means for quality improvement
  - Translated into private sector through the American College of Surgeons
  - Database for continued clinical research
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Table 9  
The Field Research Advisory Committee (FRAC)

- Central Office Administration (Chief R&D Officer, Deputy Chief R&D Officer, Directors of the 4 Research Services)
- 5 Associate Chief of staff for R&D (elected per region)
- Director of Rehab Center of Excellence
- Director of HSR&D Center of Excellence
- Cooperative studies chairman representative
- Career scientist program representative

database [20]. The overall mortality rate of 3% following all procedures was laudable and comparable to the private sector; however, there was variable mortality amongst individual VA hospitals. After structured visits to 44 VA hospitals, it was evident that hospitals' process of care was determined to be the major factor in quality of care [21]. This led to the development of a quarterly report and annual report of hospital clinical outcomes in surgical patients with incentives to improve the quality of care in those that were regarded as outliers. Multifactorial analysis showed that serum albumin, age, emergency operation, American Society of Anesthesiologists class, and disseminated cancer were the main risk factors in 30-day postoperative mortality (Table 7). These have remained remarkably consistent over time and in studies of private sector hospitals are equivalent. Overall, in the decade of the 1990s, there was a 27% decline in postoperative mortality, 45% decline in postoperative morbidity, and reduction in length of stay from 9 to 4 days despite a volume and complexity of major surgery that was unchanged (Table 8). Risk profiles of patients were also unchanged and patient satisfaction over this time in VA questionnaires improved. In a cost analysis study, Dimick has shown that implementation of the National Surgical Quality Improvement Program to the private sector can be cost effective because of the potential for reducing patient morbidity and its associated cost. In collaboration with the American College of Surgeons [22], 14 private and university medical centers have been included in an initial study to determine the applicability of the program to the private sector. This project has corroborated the conclusions made from the original National Surgical Risk Study data. The American College of Surgeons has used their own website to facilitate data accrual because of discrepancies between information transfer systems throughout this country. It is expected that virtually all hospitals in this country will eventually transition to use this risk stratification system for report cards to both hospitals and individual surgeons on an annual basis. This has literally been a 20-year project that is going to define the quality assurance of surgery throughout this country and highlights a program that was carried out in its inception through the VA by VA surgeons. The database has also been used to study the results of many individual procedures in the VA healthcare system and it has proven a tremendously valuable research archive. Cases continue to be added and the database is now well over a million.

Clinical research foundations in the VA were allowed to

be incorporated in the mid-1980s by an Act of Congress. These are similar to university research foundations in that they are nonprofit 501(c) corporations and have specifically been developed to separate research funds from general post funds. Investigators may direct funds into a clinical research foundation from sponsoring institutions, which are administered by an executive director and governed by a board of directors to carry out approved VA studies. These have been particularly useful for industry sponsored clinical trials in which the VA has participated widely in the last several decades. The foundations are a very efficient mechanism to allow appropriate reimbursement for conduct of such clinical trials yet will need to withstand increased scrutiny through auditing mechanisms to ensure that funds are dispersed appropriately.

Unfortunately, despite the thousands of investigators within the VA system who have conducted first-class clinical and scientific research of the highest ethical standard, there have been recent episodes of fraud and poor administration in the conduct of particular research programs. Several centers have been temporarily closed in order to fully investigate their research programs, which were highlighted in a recent headline article in The New York Times from February 6th. These unfortunate events have cast a tremendous shadow over what has otherwise been a world-class research program, but VA research service has responded vigorously. PRIDE, which stands for Program for Research, Integrity, Development and Education within the VA, was rapidly developed. A research stand down was conducted 2 years ago to fully investigate these matters and to ensure that those performing research were fully credentialed and properly trained. A compliance program has been developed under the auspices of PRIDE and is mandatory for all those performing any kind of human research on an annual basis. Secondly, the VA has contracted with the National Committee for Quality Assurance to accredit each and every research program throughout the nation, a process that is approximately halfway through. This will be completed by this year, and is evidence by an external accreditation body that individual research programs are in full compliance with VA research guidelines and that appropriate oversight exists. This will also ensure that the relevant committees, including the Animal Studies Subcommittee, Human Studies Subcommittee, and Research and Develop-

Table 10  
Merit Review Subcommittees' now combined for both Basic and Laboratory Science and Clinical Sciences R&D Services

Aging and clinical geriatrics	Infectious Diseases (A,B)
Cardiovascular studies (A,B)	Mental Health and Bipolar PTSD
Clinical Research Program	Mental Health Schizophrenia & Cog
Endocrinology (A,B)	Nephrology
Gastroenterology	Neurobiology (A–E)
General Medical Science	Oncology (A,B)
Hematology	Respiration
Immunology (A,B)	Surgery (A,B)

ment Committee are functioning appropriately and that those VAs with combined institutional review boards are having appropriate oversight of their research endeavors. Indeed, the Louisville VAMC itself has undergone site visits by the General Accounting Office, the former Office of Research Compliance and Assurance, the Federal Drug Administration, the Office of Inspector General, Association for Assessment and Accreditation of Laboratory Animal Care, the Joint Accreditation Committee on Hospitals, and finally the National Committee on Quality Assurance in the last five years.

One of the most important developments in the last decade has been the commission of the Field Research Advisory Committee (FRAC; Table 9). One year ago, Dr. Jonathan B. Perlin, M.D., Ph.D., who at the time was the Acting Chief of Research and Development Officer, and is now the White House nominee for Under Secretary for Health, held a national meeting in which all of the associate chiefs of staff for research were invited to express their input regarding the VA research program. The FRAC was developed out of this meeting and has been an effective avenue of communication between the field and central office with regard to budgetary allocation and structure of the overall research portfolio. The Merit Review program is now structured under both the Basic and Clinical Sciences services and the review boards reorganized into 26 separate subcommittees (Table 10). This program encompasses the majority of research funds allocated and is researcher initiated. The VA research program has recently encouraged investigator initiated clinical studies, and an individual investigator may now have both a basic and a clinical studies program funded through the Merit Review process. This is a new policy in response to calls for more clinical research to be done by VA investigators, and for these projects to be investigator-initiated [23]. An example of this is the prospective randomized trial of open versus laparoscopic ventral hernia repair, with Dr. Itani serving as principle investigator. The results of study, the second ever funded by the clinical sciences merit review program should be very interesting and timely as well [24]. Applications are triaged to



Fig. 2. Dr. Cheadle with Robley Rex, World War I Veteran and the oldest volunteer in the VA system. He exemplifies the spirit of those who have served their country and all volunteers within the VA.

the subcommittee with the most expertise to review the grant and often ad hoc reviewers have been used to aid this process. The percentage of funded proposals is set across the boards and varies from 18% to 25% in most years depending on the overall budget. The Merit Review Entry Program (MREP) is designed specifically for young investigators within 5 years of their formal training to compete for start up funds under the auspices of a close mentor relationship. The funding period is for 3 years with the goal of submission of a Merit Review application within that time frame. The career development program is variably geared to investigators at early, mid, and late stages of their careers. Upwards of 200 such awards are given out yearly to investigators across the country from all four the research services. Several other awards recognize outstanding research efforts for an entire career and include the Paul B. Magnuson Award, the William S. Middleton Award, and the Under Secretary's Award for Outstanding Achievement.

Members of the VA surgeon have both contributed to and benefited from the VA research program. Several AVAS members serve on surgery A and B subcommittees and have been successful in obtaining funding in both basic and clinical research. Several members have chaired the surgery subcommittee in the past. Dr. Clyde Barker, in a recent essay adapted from his Excelsior Society Lecture entitled "Is surgical science dead?," eloquently traced the highlights of research contributions by surgeons over the past century [25]. His conclusion, that surgical science, of course, is not dead, is perhaps best exemplified by those surgeons funded by the VA research program. Many VA surgeons continue to make seminal contributions in both the basic and clinical research arenas, as they have in the past. In fact one could argue that true clinician investigators, who practice on a regular basis, are best able to translate research into clinical practice. The VA healthcare system, our nation's largest, with its abundant patients and clinically relevant research portfolio has made immense contributions to

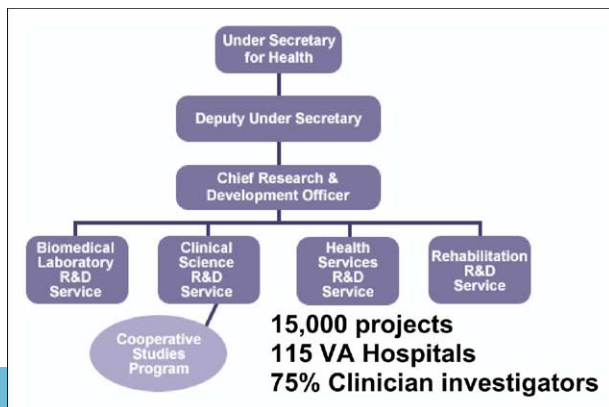


Fig. 1. Organization of the VA research program.

both veterans well being and to the general population as well. Patient care, education, and research are intimately tied together, and VA clinician investigators are a wonderful example of this ideal. The VA patient population is indeed a rewarding one for those of us who provide clinical care and the vast majority of veterans are very grateful for their care. Their spirit and camaraderie is best exemplified by the volunteer system throughout the nation and we at the Louisville VA are blessed to have Robley Rex, the oldest volunteer in the VA healthcare system and a surgical patient as well (Fig. 2). He is a World War I veteran who comes to our VAMC regularly with a wonderful positive attitude and helps make us proud of the work we do. Indeed I am proud to be a VA clinician investigator and to have served the AVAS and the VA research program in several roles. I am pleased that our organization continues to grow and to be an important means of communication to foster advances in knowledge that benefit the care of the veteran.

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