



ANNUAL REPORT

2019



SEATTLE INSTITUTE FOR BIOMEDICAL AND CLINICAL RESEARCH

ANNUAL MEMBERS MEETING

APRIL 19, 2010

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MISSION STATEMENT

Our mission is to facilitate the research and educational programs conducted at the VA Puget Sound Health Care System, Seattle and American Lake Divisions. SIBCR strives to provide outstanding support to VA staff in their research, education and training endeavors to foster progress in biomedical, clinical, rehabilitative and health care services programs that benefit the nation's veterans and the general public.



MESSAGE FROM THE PRESIDENT



The Board of Directors provides financial and management oversight for the Seattle Institute for Biomedical and Clinical Research. The Board's primary role is to assure that the Institute's assets are safeguarded and available to fulfill its mission. We are pleased to report that Clark Nuber, our independent auditors, had no findings and therefore reported no issues with the financial statements, operations, internal controls or financial management of the Institute for the year ended September 30, 2009.

SIBCR is committed to improving the research and educational programs at VA Puget Sound Health Care System. Our Executive Director, Eileen Lennon, PhD, and our knowledgeable staff have worked to ensure that we provide the best possible support to investigators in preparing grant applications and managing research and educational programs. We are pleased with SIBCR's growth, but recognize that further enhancing the research and education environment will require SIBCR to develop an even greater portfolio of sponsored programs, including acquiring more NIH and other federal awards. As we do this, we will have the opportunity to provide greater support to new investigators and new programs as they compete for independent research funding. Our Board of Directors works continuously toward this goal. SIBCR's dedicated support of a broad range of research and education serves our medical center's goal of providing outstanding patient care.

Thomas R. Martin, MD
President
Board of Directors

The Board of Directors and staff of Seattle Institute for Biomedical and Clinical Research are committed to the mission of facilitating the research programs and educational activities pursued by our members, who are staff at the VA Puget Sound Health Care System.

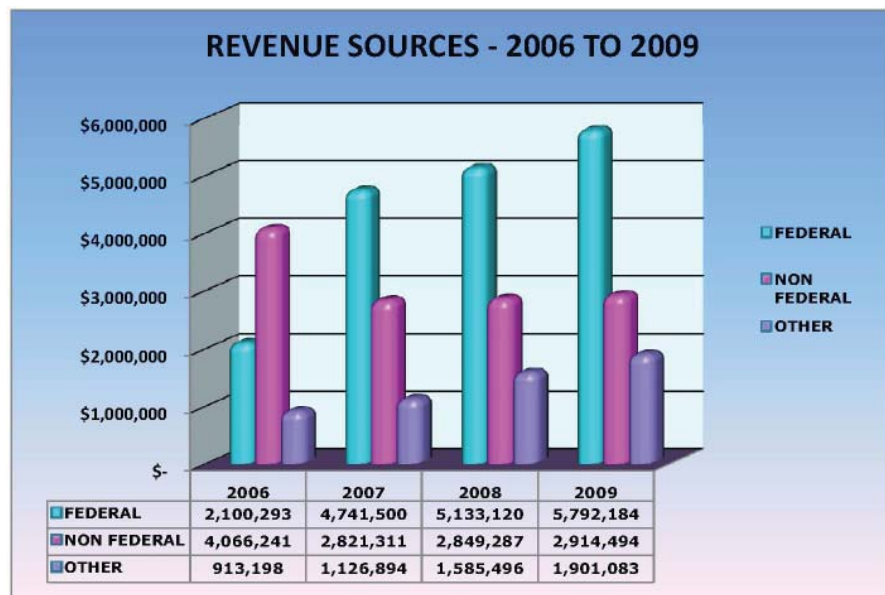
The 2009 fiscal year was truly a year of highs and lows. The VAPSHCS research program underwent an in-depth review by the Office of Research Oversight (ORO). Even though the review determined that there were no problems with human studies research activities, ORO did find administrative weaknesses. The reaction to these weaknesses turned out to have a significant impact on the community of VAPSHCS-based researchers and a negative effect on the sponsored research programs at SIBCR. The ensuing stoppage and re-review of most of the ongoing research projects created a hiatus in which funded projects were either temporarily suspended or their start dates were delayed. SIBCR supported R&D administration in dealing with the ORO compliance requirements by hiring temporary staff to assist with the re-reviews and by purchasing the MIRB database system for VAPSHCS.


FY2009 also had a high point for SIBCR. The long-awaited letter from the National Institutes of Health (NIH), Office of Extramural Research Administration, was received. Since May 2004, we have had an agreement with the University of Washington (UW) setting out the parameters of determining which entity is the appropriate administrator for federal awards. The remaining issue was approval from NIH to reimburse the UW for the effort of dual-appointed personnel on NIH grants conducted at the VA and administered by SIBCR. The UW and SIBCR worked together on receiving this approval for over three years. The letter that we received in July 2009 was formal approval from the NIH that SIBCR could submit and administer grants conducted at the VA which included investigator salary to be reimbursed through the UW. The investigators could be listed as personnel for SIBCR. Following the receipt of this letter, the SIBCR-UW implementation committee reformed and is meeting regularly to set up the necessary processes and templates to be used between the institutions.

In the latter part of FY2009, the NIH announced the availability of funding under the American Recovery and Reinvestment Act (ARRA), referred to as “stimulus funds”. This focused on new two year awards and supplements to existing awards. SIBCR received several awards under ARRA funding, including a U01, a P20 center grant, and several R01 supplements totaling \$3.7 million for the first year.

In addition to this good news, a number of SIBCR members successfully competed for sponsored research funded by NIH, DOD and voluntary health organizations or other nonprofits (VHO/NP). During FY2009, SIBCR submitted 53 grants to federal agencies and 18 to VHO/NP organizations. Of the federal applications, 13 have since been awarded (a 24.5% success rate); nine are NIH grants and four are funded by ARRA. Five of the VHO/NP applications were awarded (a 27.7% success rate). During FY2009 itself, SIBCR received award notices for a total of 18 federal and 8 VHO/NP grants.

The increase in federal funding is clearly depicted in the graph below. The increase started in FY2006, with an expected time lag after finalizing the agreement on grant submissions with UW in May 2004. The less obvious change in revenue in recent years is the decrease in pharmaceutical-sponsored clinical trials. This revenue, included within the non-federal source in the graph below, has dropped more than 75%. At one point this seemed to relate to the VA-wide introduction of the Cooperative Research and Development Agreement (CRADA) mechanism in 2007-08. However, that process is now working very well and CRADAs are in most cases being negotiated with actually less delay than clinical trial agreements in the past. While the timeline required to obtain compliance approvals can be an obstacle to any research project, it is a particular hazard for industry-sponsored clinical trials and seems to be a significant factor in the sharp decline in funding from this source. Currently, much of the non-federal revenue comes from investigator-initiated industry-funded studies, in which receipt of funding is not so dependent on adherence to the sponsor’s timeline.





The current Board of Directors is listed on page 11. There were several changes during the year. The VAPSHCS Director serves on the SIBCR Board as a statutory member. Stan Johnson left in August 2009 to be the Director at the San Diego VA, at which time DeWayne Hamlin served as the Acting Director and therefore SIBCR Board member. DeAnn Lestenkof is now serving as Acting Director. Gordon Starkebaum, MD stepped down as Chief of Staff, but was appointed to the Board as a non-statutory member and was elected Vice-President. William Campbell, MD, MBA became Chief of Staff in July 2009 and became a statutory member of the Board. Steven Kahn, MB, ChB stepped down as Associate Chief of Staff, R&D, in September and is no longer on the SIBCR Board. The Acting Associate Chief of Staff, R&D, Michael Chapko, PhD is his replacement on the SIBCR Board. Phillip Rakestraw, PhD was an active Board member through FY2009, but retired as of September 30, 2009. Ted Kohler, MD is the Acting Associate Chief of Staff, Education.

Ms. Marie Walters, Senior Grants and Contracts Manager, retired in November 2009. In order to provide a smooth transition, Ms. Danielle Belisle stepped into the position of Senior Grants and Contracts Manager and SIBCR recruited Ms. Alka Goyal as a Grants Specialist in July 2009. Ms. Goyal enjoyed an excellent relationship throughout the training period with Ms. Walters and was adept at learning the policy and processes to provide competent and collegial support to SIBCR members. The current staff (listed on page 12) also includes a new Program Assistant, Ms. Alice Victoria, who was hired in January 2010.

The table of members for FY2009 is found on page 13. New SIBCR members welcomed during the fiscal year were: Yoshio Hall, MD, Glenn Klute, PhD, Brian Kraemer, PhD, Karin Nelson, MD, MSHS and Steven Zeliadt, PhD, MPH.

EDUCATION AND TRAINING

Since the statutory authorization for administering education and training activities began in 1999, such activities have been a relatively small part of the SIBCR portfolio. In FY2009, the three continuing education programs were the small grant providing much appreciated assistance to a Hepatitis C patient and caregiver support group; funding for Social Work to defray costs of the Caregiver Conference and to provide educational training for social work staff; and the continuing competitive grant funding to the Multiple Sclerosis Center of Excellence for live national satellite broadcasts and case conferences on MS topics for MS patients, caregivers and clinicians.

SIBCR will submit requests for educational grants for members. Many of the pharmaceutical companies that fund programs have set up very specific application requirements. The method of requesting educational support by letter has been overtaken by a more formal application process, usually set up as an online application.



CLINICAL RESEARCH UNIT



The Clinical Research Unit was established 10 years ago to provide VA investigators with a well equipped, controlled and safe inpatient and outpatient setting for VA investigators to conduct clinical research studies. With its expertise in nursing and research administration, the unit is able to provide a variety of services in support of clinical research projects.

The unit has two full-time staff members: Susan Bigda, RN and Teresita Cornell. Susan Bigda is a Registered Nurse with extensive research and nursing experience. Teresita Cornell had experience in various medical specialty clinics in the areas of outpatient rehabilitation and urology prior to her position on the CRU. Both have been providing excellent clinical research support for over five years on the CRU.

Dr. Alvin Matsumoto is the Director of the CRU and heads the Advisory Committee. In addition to the CRU staff, the members of the Advisory Committee are Suzanne Craft, PhD, Charlie Keelin, Eileen Lennon, PhD, Elaine Peskind, MD, Andrew Saxon, MD, Kristina Utzschneider, MD and David Powell.

The CRU may be able to assist you in your clinical research program. If you are contemplating a new clinical research study, please check with the staff or any member of the Committee.



NAVREF



SIBCR is a member of the National Association of VA Research and Education Foundations (NAVREF). NAVREF promotes the interests of its member nonprofits and advocates for issues relevant to its members and the VA research program. It has been a vital force in maintaining the integrity of the nonprofit VA research foundations. Dr. Eileen Lennon, Executive Director of SIBCR, serves on the NAVREF Board of Directors as Vice-Chair as well as the liaison to the Government Affairs Committee and on NAVREF's Best Practices Consultation Program.

The effort to update and clarify the statute that authorized the VA-affiliated nonprofit corporations continued through 2009. Although the bill was passed by both the House and Senate, the bill was not conferenced before year-end and therefore did not come to a final vote. NAVREF has been assured that the bill will be carried over to this Congress and enacted soon.

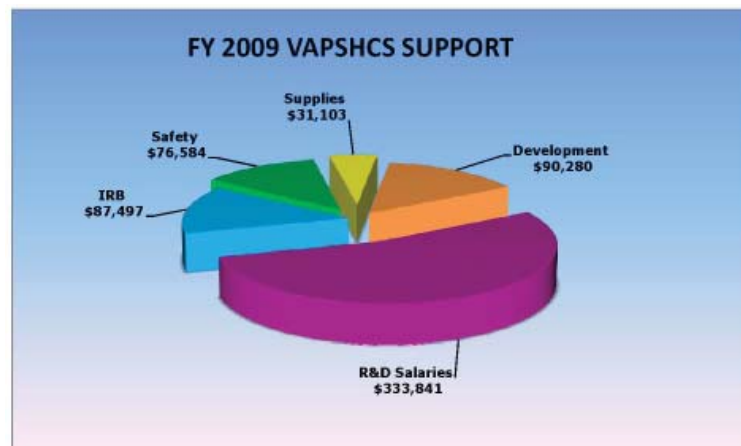
INTRAMURAL FUNDS PROGRAM

The recipients of SIBCR intramural funds who were highlighted at the annual meeting last year continued through FY2009. Dr. Lorrie Langdale received an intramural award in FY2009. A request for SIBCR support for the GRECC's prospective Associate Director for Research was approved by the Board of Directors. SIBCR will fund some core research equipment that is also needed for the Associate Director's research. Dr. William Banks started in this position as of March 2010.

The full intramural funds policy is on the SIBCR website. The priorities for intramural funds requests are: start-up funds for new investigators, funds for novel ideas or pilot projects for junior investigators, and development of new or novel projects within a member's existing program. Requests for assistance with recruitment efforts are also considered. The Board has established an Intramural Funds Committee (IFC) that reviews requests on an *ad hoc* basis. The IFC provides a recommendation to the Board who then makes the final funding decision.

RESEARCH SUPPORT

The SIBCR Board continues to support the R&D infrastructure at the VAPSHCS. The pie chart below shows the breakdown of support in FY2009.



FINANCIAL REPORT

SIBCR is audited annually by Clark Nuber, an independent auditing firm with significant expertise in nonprofit corporations. Clark Nuber also performs an A-133 audit as required by virtue of SIBCR having over \$500,000 in federal expenditures. Both the financial audit and the A-133 single audit for FY2009 are posted on the SIBCR website. The auditors meet annually with the Board of Directors and present the financial report.

The report for FY2009 was again the best result for an audit, an unqualified opinion and no findings on the single audit report.

The Institute negotiates an indirect cost rate and a fringe benefit rate annually with the Division of Cost Allocation (DCA), Department of Health and Human Services. These rates are subject to change when the DCA reviews our indirect and fringe benefit cost report, which is done within six months after the end of each fiscal year. SIBCR posts the current rates on the website.

The table below summarizes the statement of activities and the statement of financial position. The statement of activities compares the revenue and expenses for FY2009 to FY2008. As discussed previously, FY2009 did not have the growth previously expected, due to the ORO suspension. However, this effect should be short-lived and FY2010 is projected to have a significant increase in activity over last year. The statement of financial position points out SIBCR's strong financial position, with adequate cash reserves and minimal liabilities. Since the Institute is required by statute to invest in instruments guaranteed by the federal government, SIBCR may not achieve significant investment gains, but is protected from any investment losses.

Statement of Activities	2009	2008
Grants - Federal	\$ 5,792,184	\$ 5,133,120
Grants - Non Federal	2,914,494	2,849,287
Other Income	1,901,083	1,601,876
Total Support and Revenue	\$ 10,607,761	\$ 9,584,283
Program Expenses	8,521,354	8,175,888
Management, General and Administrative	1,098,406	1,078,477
Total Expenditures	9,619,760	9,254,365
Change in Net Assets from Operations	\$ 988,001	\$ 329,918
Statement of Financial Position	2009	2008
Assets		
Current Assets	\$ 3,506,244	\$ 2,528,338
Long Term Assets	9,845,583	9,454,761
Total Assets	\$ 13,351,827	\$ 11,983,099
Liabilities and Net Assets		
Liabilities	2,880,390	2,561,413
Net Assets	10,471,437	9,421,686
Total Liabilities and Net Assets	\$ 13,351,827	\$ 11,983,099



FY2010 PLANNED MOVE

In FY2009, it was planned for SIBCR to relocate to portable buildings outside Building 7. The IRB was also to be moved to a portable building outside Building 7 and R&D was to move into Building 7. These moves did not happen in FY2009. By the end of the calendar year, the significant problems presented by a move to portable buildings were becoming more obvious. SIBCR had already estimated some moving costs in the FY2009 budget and again in the FY2010 budget. At the time of this report, the plan has completely changed and it is expected that SIBCR will be obliged to move off-site, but will be allowed space in Building 7 for three people. This will allow human resources staff and grants managers daily access and other staff to be available on-site on a rotating basis. Also, SIBCR plans to update computer systems so that its staff, especially grants managers, can access programs and meet with members in VA offices without being confined to a single desktop office space. SIBCR will have to cover the cost of rental space in FY2010 and for subsequent years until we move back to the VAPSHCS campus.

CONCLUSION

SIBCR is poised to see significant growth in its federally-funded sponsored research. With the receipt of approval for reimbursing faculty salary, it is expected that more grants will now be submitted through SIBCR. By the end of FY2009, SIBCR received award notices for a number of federal grants. The impact of these awards will be seen in FY2010. Although funding levels at federal agencies, especially NIH, will obviously be a determining factor, we look forward to future growth. Though the future does hold challenges with some uncertainty on space and physical infrastructure, we can look forward to expanding and remaining committed to a robust environment for our research and education programs and to supporting the research infrastructure at the VAPSHCS.





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