



COMMONWEALTH NEUROTRAUMA INITIATIVE (CNI) TRUST FUND Triennial Report October 1, 2020

The Code of Virginia § 51.5-12.3(C)(4), amended in 2008 by Senate Bill 494, requires the Commonwealth Neurotrauma Initiative (CNI) Trust Fund to “Report triennially on October 1, to the Governor and the General Assembly, aggregate data on the operations and funding of the Commonwealth Neurotrauma Initiative Trust Fund.”

***FOR STATE
FISCAL YEARS
2018, 2019,
2020***

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COMMONWEALTH NEUROTRAUMA INITIATIVE (CNI) TRUST FUND

October 1, 2020

Honorary Governor Ralph Northam
P.O. Box 1475
Richmond, VA 23218

RE: CNI Trust Fund Triennial Report

Honorary Governor Northam;

It is with great pleasure on behalf of the Commonwealth Neurotrauma Initiative Trust Fund Advisory Board that I share with you and the people of the Commonwealth of Virginia this Triennial Report on the logistics, activities and accomplishment of the CNI Trust Fund from July 1, 2017 to June 30, 2020. It has been and continues to be our privilege to support the efforts of the Commonwealth in helping to guide the use of the CNI Trust Fund to improve the lives and livelihood of the Virginians. As you will see, we have successfully stewarded the fund and leveraged the resources to a range of important and effective project and programs. Please do not hesitate to reach out to me and our board with any questions. I remain

Sincerely,

David X. Cifu, M.D.
Chair, CNI Trust Fund Advisory Board

Associate Dean of Innovation and System Integration
Herman J. Flax, MD Professor and Chair, Department of Physical Medicine and Rehabilitation
Virginia Commonwealth University School of Medicine

Senior TBI Specialist, U.S. Department of Veterans Affairs

Principal Investigator,
Long-term Impact of Military-relevant Brain Injury Consortium - Chronic Effects of
Neurotrauma Consortium (LIMBIC-CENC) <https://www.limbic-cenc.org/>

COMMONWEALTH NEUROTRAUMA INITIATIVE (CNI) TRUST FUND

TRIENNIAL REPORT FOR STATE FISCAL YEARS 2018, 2019, 2020 (JULY 1, 2017 THROUGH JUNE 30, 2020)

The Code of Virginia § 51.5-12.3(C)(4), amended in 2008 by Senate Bill 494, requires the Commonwealth Neurotrauma Initiative (CNI) Trust Fund to “Report triennially on October 1, to the Governor and the General Assembly, aggregate data on the operations and funding of the Commonwealth Neurotrauma Initiative Trust Fund.”

BACKGROUND/PURPOSE

On July 1, 1997, Senate Bill 1132 established the CNI in the Code of Virginia. This bill authorized the CNI Trust Fund as a special non-reverting fund and the CNI Advisory Board, a permanent collegial body affiliated with the State Board of Health. Effective July 1, 1998, Senate Bill 484 provided that moneys in the CNI Trust Fund “shall be used solely to support grants for Virginia-based organizations, institutions, and researchers.”

The 1998 Senate Bill 484 legislation also created a mechanism for funding the CNI Trust Fund. Moneys are deposited into the CNI Trust Fund pursuant to § 18.2-271.1 (E) of the Code of Virginia. If an individual’s privilege to drive is suspended, revoked, or disqualified, Virginia law (§§ 46.2-411, 18.2-271.1E, 46.2-333.1) requires the payment of the highest applicable fee to the Department of Motor Vehicles (DMV) prior to reinstatement of driving privileges. Currently, DMV license reinstatement fees, as relevant to the CNI Trust Fund, may be \$175 or \$220, depending on the type of suspension, revocation, or disqualification. In either case, the amount of \$25 of the total reinstatement fee “shall be transferred to the [CNI] Trust Fund.”

As stipulated in § 51.5-179 of the Code of Virginia, forty seven and a half percent (47.5%) of the trust fund is allocated for research on the mechanisms and treatment of neurotrauma and forty seven and a half percent (47.5%) is allocated for rehabilitative services. Five percent (5%) of the total fund amount per year is used for administrative costs. DARS funds any costs in excess of the five percent (5%) total.

PROGRAM ADMINISTRATION

As the result of a statutory Code change in 2004, the Virginia Department for Aging and Rehabilitative Services (DARS) now provides staffing of the Governor-appointed CNI Trust Fund Advisory Board as well as management of the CNI Trust Fund Grants Program.

Since 2016, a full-time Program Specialist provides administrative support for the fund and staff to the CNI Trust Fund Advisory Board.

CNI TRUST FUND ADVISORY BOARD

Per the Code of Virginia (§ 51.5-12.3), the CNI Advisory Board consists of seven governor-appointed members. With the exception of the commissioners of the Department of Health and DARS, who have no term limits and may appoint designees, members are appointed to four-year terms according to the following categories:

1. One person licensed to practice medicine in Virginia experienced with brain or spinal cord injury,
2. One person licensed by a health regulatory board within the Department of Health Professions with experience in brain or spinal cord injury rehabilitative programs or services,
3. One Virginian with traumatic spinal cord injury or a caretaker thereof,
4. One Virginian with traumatic brain injury or a caretaker thereof,
5. One citizen-at-large who shall not be an elected or appointed public official,
6. The Commissioner of the Department for Aging and Rehabilitative Services (or designee) [serves in ex-officio role],
7. The State Health Commissioner (or designee).

The only officer of the Advisory Board is the Chair who serves a one-year term. The current Chair is Dr. David X. Cifu, M.D. of Richmond. A full list of the current CNI Advisory Board members is included in the Appendix.

GRANT FUNDING

Per the Code of Virginia, 47.5% of the trust fund is allocated for research on the mechanisms and treatment of neurotrauma and 47.5% is allocated for rehabilitative services.

Between July 1, 2017 and June 30, 2020, a total of \$3,069,475 was paid to CNI Trust Fund Program grantees.

During the reporting period State Fiscal Year (SFY) 2018-2020:

- Four (4) Research grants were continued from the previous reporting period;
- A Request for Proposals (RFP) was issued for Community-Based Rehabilitative Programs and Services, and seven (7) proposals were submitted and four (4) awards made;
- One (1) grant was awarded by former DARS Commissioner James Rothrock per 22VAC30-50-120, which allows the DARS Commissioner to reallocate up to \$500,000 per biennium from unexpended balances in the CNI Trust Fund to fund new grant awards related to traumatic brain injury and spinal cord injuries; and
- Two (2) grants were awarded as a state-funded match for Virginia's federal traumatic brain injury (TBI) grants through the U.S. Administration for Community Living.

A summary of the grants funded is provided in the following tables. More detailed information about these grants is available on the DARS CNI website: <https://vacni.org/>.

RFP #17-002 GRANT AWARD PERIOD: April 1, 2017 – June 30, 2020

Research Grants

Researcher	Title	Summary
Virginia Commonwealth University Principal Investigator: Alex Valadka, MD <i>\$292,336 over 2 years</i>	“Comparative Evaluation of Mannitol and Hypertonic Saline in the Treatment of Experimental Traumatic Brain Injury.”	Compare the effects of mannitol and HTS at different concentrations on ICP, brain water content, inflammation, and early neuronal cell death immediately after experimental TBI. This study will also compare neuroprotective properties of mannitol and different concentration of HTS by determining functional recoveries and brain tissue preservation after experimental TBI.
Virginia Commonwealth University Principal Investigator: Kristy Dixon, PhD <i>\$450,000 over 3 years</i>	“PAIN-T Alleviation Immediately after Neurotrauma Mediated via TNFR1.”	Examine the extent of injury-induced hippocampal plasticity and its association with the development of pain, and determine whether this is TNFR1-mediated. Examine the mechanism as to how TNF induces hippocampal plasticity. The study will assess the efficacy of XPro1595 to alleviate pain and comorbid behaviors in mice following brain injury.
McGuire Research Institute Inc. Principal Investigator: George Gitchel, PhD <i>\$449,104 over 3 years</i>	“Targeted Transcranial Magnetic Stimulation for Cognitive Rehabilitation after Traumatic Brain Injury.”	Assess efficacy of right frontal rTMS for cognitive rehabilitation of attention and learning after TBI. In the short-term, this study is expected to provide needed information on the efficacy of a potential treatment for TBI-related cognitive dysfunction and encourage larger trials to be conducted.
Community Brain Injury Services (CBIS) Principal Investigator: Jason Young, MSW <i>\$448,419 over 3 years</i>	“Evaluating Brain Injury Clubhouses and their effects on Neurobehavioral Functioning and Participation.”	Implement a program level data collection system to standardize data concerning the injury and sociodemographic characteristics of people served, the level and duration of services provided, and outcomes generated by Virginia’s Acquired Brain Injury (ABI) Clubhouses. This project will also describe and evaluate the effectiveness of ABI Clubhouses in meeting Virginia’s citizens’ needs. This program will compare the persons treated, services provided, and the outcomes generated by Virginia’s ABI Clubhouses to 3 ABI Clubhouses in the US and Canada to identify strengths and opportunities for growth.

RFP #18-061 Grant Award Period: August 1, 2018 - July 31, 2021
Community-Based Rehabilitative Programs and Services Grants

Principle Investigator	Title	Summary
Virginia Commonwealth University Principal Investigator: Amy Armstrong, PhD <i>\$371,346 over 3 years</i>	“Enhancing Parenting Skills (EPS) of Civilians and Veterans with TBI and their Non-injured Partners.”	Enhance Parenting Skills (EPS) of civilians and veterans with Traumatic Brain Injury and their non-injured partners: A service-based program.
Virginia Commonwealth University Principal Investigator: Christine Groah, MEd <i>\$447,379 over 3 years</i>	“Project Achieve.”	Use Cognitive support technology to assist women veterans and service members with Traumatic Brain and/or Spinal Cord Injuries to achieve postsecondary education and careers.
Virginia Commonwealth University Principal Investigator: Melody Mickens, PhD / Zina Trost, PhD <i>\$443,808 over 3 years</i>	“Virginia Spinal Cord Injury Outreach and Services Clearinghouse.”	Create a registry for collecting and monitoring the characteristics of Virginians with SCI and their Outcomes.
Brain Injury Connections of the Shenandoah Valley Principal Investigator: Cynthia Noftsinger <i>\$260,246 over 3 years</i>	“Looking Out for Little Brains.”	Comprehensive pediatric case management to build the capacity of our local community to better respond to children (and their families and caregivers) who have sustained a brain injury, and support partner organizations who provide complementary resources.

Commissioner Grant for Community-Based Rehabilitative Programs and Services February 1, 2020 - January 30, 2022

Principle Investigator	Title	Summary
United Spinal Association of Virginia Principal Investigator: Richard Bagby, Executive Director <i>\$120,150 over 2 years</i>	“SCI/D Peer Mentor and Family Support Program”	Expand organizational capacity to build the Peer Mentor and Family Support Program in order to educate and empower those affected by spinal cord injury or disability; provide long-term practical and emotional support for individuals with a spinal cord injury and families as they move toward independence and healing.

Grants Made as Cash Match for Federal TBI Funding

Principle Investigator	Title	Summary
University of Virginia Principal Investigators: Jeffrey Barth, PhD & Donna Broshek, PhD <i>\$375,000 over 3 years</i> <i>Drew down \$750,000 in federal funds for the 2015 – 2018 DARS TBI Grant</i>	“Community Based Brain Injury Screening Initiative “	A formal review of existing literature and tools related to screening for brain injury, development of a brain injury screening tool for use by professionals, implementation of a pilot screening project at eight sites statewide, and a final analysis of the tool’s effectiveness.
Virginia Commonwealth University Co-Principal Investigators: Jeffrey Kreutzer, Ph.D. Jennifer Marwitz, M.A. <i>\$450,000 over 3 years</i> <i>Drew down \$900,000 in federal funds for the 2019 – 2021 DARS TBI grant</i>	“DARS / VCU Traumatic Brain Injury Model Systems Collaborative Grant”	Provide the foundation for a comprehensive Traumatic Brain Injury Data Plan for Virginia. Explore opioid use and misuse among Virginians with brain injury to better understand the nature and scope of opioid use and misuse among this population, information currently unavailable in Virginia.

COVID-19 IMPACT

During April, 2020, CNI Program Specialist Wanda Allen noted that the COVID-19 related restrictions might interfere with CNI Trust Fund Program grantee activities. She surveyed all active grantees to determine the extent of this interference. As a result, a no-cost three (3) month extension was allowed for each research grant, with closing dates of June 30, 2020. This allows them until September 30, 2020 to complete their work.

An RFP for research grants was issued in January 2020. Review of the applications by subject matter experts was delayed significantly due to the COVID-19 pandemic. In April, the decision was made to cancel this RFP because no grantee would be in a position to begin new research under the pandemic restrictions. The research RFP will be re-released in 2021, pending re-opening guidelines that will allow researchers to begin their projects.

FINANCIAL STATUS

The CNI Trust Fund receives revenue from DMV fees to reinstate a license after it has been suspended, revoked, or disqualified.

For the three-year reporting period SFY 18 – SFY 20:

- \$2,561,941 was transferred into the Trust from DMV, and
- \$3,069,475 was paid to active grantees.

<u>Expenses</u>	2018	2019	2020	Total
Grants	\$ 645,192	\$ 1,323,112	\$ 1,101,171	\$ 3,069,475
DARS Admin	\$ 41,300	\$ 42,426	\$ 40,683	\$ 124,409
DMV Admin	\$ 12,400	\$ 20,624	\$ 23,807	\$ 56,831
Total	\$ 698,892	\$ 1,386,162	\$ 1,165,661	\$ 3,250,715
<u>Revenue</u>				
DMV Fees	\$ 829,481	\$ 811,902	\$ 763,281	\$ 2,404,664
Interest	\$ 34,532	\$ 59,304	\$ 63,441	\$ 157,277
Total	\$ 864,013	\$ 871,206	\$ 826,722	\$ 2,561,941

NOTE: This includes only current year revenue and expenses and does not include the principal in the trust. The purpose of the trust is to create a reserve to allow for *consistent* funding of CNI projects regardless of DMV fees. In the previous triennial reporting period, DMV fees had decreased to the level that one RFP period was delayed. Since then, DMV fees increased to the level that grant making could continue and are only recently experiencing a mild downturn.

At the end of SFY 20, \$2,836,554 remains in the trust. Approximately \$720,489 will be paid in SFY 21.

PRESENTATIONS TO THE CNI TRUST FUND ADVISORY BOARD

During the reporting period, the CNI Trust Fund Advisory Board heard presentations from grantees as well as Virginia-based subject matter experts on brain injury.

Date	Grantee	Presentation
9/22/2017	Grantee Kirsty Dixon, PhD, VCU	Project Update: Pain-T alleviation immediately after Neurotrauma mediated via TNFR1
6/22/2018	Former CNI grantee Nora Fotuhi	Project Update: Concussion Superstars project
4/6/2018	David Cifu, MD, CNI Trust Fund Advisory Board Chair	Subject Matter Expert Presentation: Findings of the Chronic Effects of Neurotrauma Consortium (CENC) on Concussion in Veterans and Service Members
6/14/2018	Current Grantee Jason Young, MSW, Community Brain Injury Services; Ron Seel, PhD (Co-Investigator); Katie Strand, Clinical Research Coordinator (VCU)	Project Update: Evaluating Brain Injury Clubhouses and their effects on Neurobehavioral Functioning and Participation
12/17/2018	James Thomas, PT, PhD, VCU Director of the Motor Control Lab in the Department of Physical Therapy and the Virtual Reality Rehabilitation Lab at McGuire Veterans Hospital	Subject Matter Expert Presentation: Novel Applications of Virtual Reality (VR) Interventions for Rehabilitation
3/22/2019	Michael Friedlander, PhD, Executive Director, Fralin Biomedical Research Institute at Virginia Tech Carilion (VTC), VP for Health Sciences and Technology, Virginia Tech, Senior Dean for Research, VTC School of Medicine.	Subject Matter Expert Presentation: Innovations in Brain Research at the Fralin Biomedical Research Institute at Virginia Tech Carilion in Roanoke
9/20/2019	Current Grantee United Spinal Association of Virginia– Richard Bagby, Executive Director and Katie Sloan, Fundraising Chair & Board Member	Progress Report and Overview, SCI/D Peer Mentor and Family Support Program

PRODUCTS DEVELOPED FROM CNI FUNDED GRANTS

Virginia Commonwealth University,

Principal Investigator: Kristy Dixon, PhD

“PAIN-T Alleviation Immediately after Neurotrauma Mediated via TNFR1.”

Dr. Dixon has leveraged the initial \$450,000 CNI grant into \$4,758,204 additional research funds to develop therapies to improve outcomes in individuals with traumatic brain and spinal cord injury.

Invited Oral Presentations

National Capital Area TBI Symposium - Mar 2020

Title: SolTNF inhibitor attenuates inflammatory response to improve outcomes following TBI

Military Health System Research Symposium - Aug 2019

Title: XPro1595 improves hippocampal pathology and associated neurological outcomes following TBI (selected as only 1 of 8 invited TBI presentations for the whole symposium)

Patents

Provisional Patent Applications

- 1) Invention Disclosure Number: DIX-18-109
Patent Application Title: “Utilizing biologics to treat and prevent trauma-induced pathological and neurological outcomes”

- 2) Invention Disclosure Number: DIX-18-109
Patent Application Title: “Utilizing DN-TNF biologics acutely following trauma/ischemia to prevent deleterious pathological and neurological outcomes”

- 3) Invention Disclosure Number: DIX-19-089
Patent Application Title: “Use of XPro1595 to improve the pathophysiological and neurological outcomes following Gulf War Illness”

Full Patent Applications

- 1) Invention Disclosure Number: DIX-18-109
Patent Application Title: “Treatment of Traumatic Brain Injury”

Completed Research Support

Virginia Commonwealth University, Department of Surgery

Title: Novel TNFR1 non-opioid therapy to alleviate pain in chronic pancreatitis

Goal: Investigate the efficacy of the biologic XPro1595 to alleviate neuropathic pain in mouse models of acute and chronic pancreatitis.

\$25,000, 04/2017 – 03/2018

Ongoing Research Support

Department of Defense CDMRP GWIRP

Title: Novel solTNF inhibitor improves outcomes in a rat model of Gulf War Illness

Goal: Investigate the efficacy of the biologic XPro1595 to improve brain pathology and reverse cognitive impairment, depressive-like behavior, anxiety and pain in a rat model of Gulf War Illness.

\$776,137, 09/2020 – 08/2023

Department of Defense, BAA

Title: Treatment of traumatic brain injury (TBI) with customized poly-based low volume resuscitation (LVR)

Goal: Investigate efficacy of small PEG molecules to reduce the neuropathology of the brain following traumatic injury.

\$2,106,449, 09/2018 – 08/2021

Department of Defense, CDMRP SCIRP

Title: Treatment of spinal cord ischemia with cell impairment-based resuscitation
Investigate efficacy of small PEG molecules to reduce the neuropathology of the SC following injury.

Goal: Investigate efficacy of small PEG molecules to reduce the neuropathology of the SC following injury.

\$1,850,618, 09/2017 – 08/2020

Virginia Commonwealth University,

Principal Investigator: Jeffrey Kreutzer, Ph.D., Jennifer Marwitz, M.A., Co-Principal Investigators

“DARS / VCU Traumatic Brain Injury Model Systems Collaborative Grant.”

This grant serves as cash match for the DARS Federal Traumatic Brain Injury State Partnership Program grant 2017 – 2020, which draws down \$900,000 in federal grant funds during the grant period.

Manuscript submitted for review to the Archives of Physical Medicine and Rehabilitation with co-authors participating from the University of Washington, Craig Hospital, Brandeis University, and Mt. Sinai Medical Center: Scoping review of opioid use after traumatic brain injury

Published an informational article on opioids for the TBI Today Newsletter on October 30, 2019. Over 2,000 copies were distributed electronically, and 950 were sent by US mail.

***VCU Departments of Rehabilitation Counseling and Physical Medicine and Rehabilitation
Principal Investigator Christine Groah, MEd
“Enhancing Parenting Skills (EPS) of Civilians and Veterans with TBI and their Non-injured
Partners.”***

Newsletter Article: Evidence-based Parenting Skills (EPS) for Civilian and Veteran Families Following a Parent’s Traumatic Brain Injury

***Community Brain Injury Services (CBIS),
Principal Investigator: Jason Young, MSW
“Evaluating Brain Injury Clubhouses and their effects on Neurobehavioral Functioning and
Participation.”***

Manuscript in Process: CPQ data evaluating Brain Injury Clubhouses. Brain Injury Journal
Manuscript in Process: Neurobehavioral impacts of Clubhouse attendance. Journal of Head Trauma Rehabilitation.

Fact Sheet and Public Policy Guide on ABI Clubhouses published with the UMass Medical School

GRANTEE SUCCESS STORIES

***Brain Injury Connections of the Shenandoah Valley,
“Looking Out for Little Brains.”***

Janie is an 8-year-old little girl who sustained a traumatic brain injury as an infant. As a fourth grader who experiences seizures, cognitive and behavioral challenges, her parents and teachers are overwhelmed. Janie’s Case Manager has connected her with a wealth of services to support her special needs, keep her at home, and help the family cope.

The Case Manager worked with Janie’s school and IEP team to create a plan for her classroom success and behavior management. The Case Manager also connected Janie’s family with an outpatient Parent-Child Interaction Therapy Clinic to promote positive behavior facilitation at home and to strengthen family relationships. Additionally, the Case Manager connected Janie’s family to in-home behavior therapy for parent coaching at home.

To address Janie’s medical concerns, her Case Manager connected the family with and coordinated provider services with Pediatric Neurology and Developmental Pediatric Clinic. Janie is now experiencing academic and behavior improvements at school. Her physical health has stabilized and her relationships with family and peers have improved as well. Janie is just one of 10 children and their families Brain Injury Services of the Shenandoah Valley have helped using CNI funds to pilot their pediatric brain injury case management program.

***United Spinal (Richard Bagby)
“Peer Mentoring and Family Support Program”***

United Spinal Association of Virginia has experienced enormous growth in programming and capacity due in large part to the CNI Trust Fund Program grant.

Among their accomplishments:

- Transitioned from a 100% volunteer driven organization to a dedicated force by employing one full time staff member who represents the Spinal Cord Injury disabled population, and one part-time employee who represents the caregivers we serve.
- Peer and Family Mentoring now offered to nearly 100% of newly injured individuals and their families in the VCU system and Sheltering Arms.
- Formalized new partnerships with Norfolk General Hospital and Carillion Clinic.
- Offered support groups and educational/social opportunities for over 600 individuals throughout the Commonwealth in the past 3 years
- Received funding from the Craig Nielsen Foundation supplemented by the CNI grant, to implement the USAofVa Ramp Project. This pilot program allows accessibility to the home of newly injured individuals to mitigate unnecessary institutional placement where funds are the limiting barrier. To date has funded and coordinated the installation of 14 modular wheelchair ramps (\$41,937.40) for individuals prior to discharge in Appalachia, Tidewater, Northern Virginia, and Central Virginia. Funding will increase in order to serve many more in subsequent years.
- Partnered with Sportable, an adaptive sports organization, to source and deliver groceries, PPE, and medical supplies to our members in order to encourage safe practices/social distancing during the COVID pandemic. As of May 2020, they have delivered 150+ relief packages to our members.
- With Sen. Jennifer McClellan, supported the introduction of SB 287 Statewide Trauma Registry; spinal cord injuries. Virginia will now capture data on spinal cord injuries, which allow them to increase their outreach efforts and serve more people.

APPENDIX – CNI ADVISORY BOARD MEMBERS FY20

<p>David X. Cifu, MD, Chair Person licensed to practice medicine in Virginia experienced with brain or spinal cord injury</p>	Richmond, VA	July 2016 – June 2020 (1 st Term)
<p>Raighne "Renny" Delaney, Esq Virginian with traumatic brain injury or a caretaker thereof</p>	Arlington, VA	July 2016 – June 2020 (1 st Term)
<p>Scott Dickens Virginian with traumatic spinal cord injury or a caretaker thereof</p>	Richmond, VA	July 2017 – June 2021 (2 nd Term)
<p>David Reid, Psy.D Person licensed by a health regulatory board within the Department of Health Professions with experience in brain or spinal cord injury rehabilitative programs or services</p>	Charlottesville, VA	July 2017 – June 2021 (1 st Term)
<p>Patrik Sandas, Ph.D. Citizen-at-large who shall not be an elected or appointed public official</p>	Charlottesville, VA	July 2017 – June 2021 (2 nd Term)
<p>Kathryn Hayfield, Commissioner Virginia Department for Aging and Rehabilitative Services</p>	Henrico, VA	Ex-officio
<p>Heather Board, MPH Commissioner's Designee, Virginia Department of Health</p>	Richmond, VA	Standing Member