

TRANSLATION BUILDER

This newsletter is designed to provide a place for members of the APTC to share news, collaborate and network, and discover each other and the services we offer.

APT Center at a Glance

Happy New Year and welcome to 2018! It has been a very busy year here at the APTC. Check out some accomplishments and stats on our best and brightest below.

HIGHLIGHTS FROM 2017

Team Cleveland

- ◆ The Gold medal win at the Cybathlon brought international attention to VA technology, garnered over 40 news articles and interviews, and brought news reporters to Cleveland, including the Emmy-winning HBO VICE that featured this technological breakthrough in an episode titled “Black and Blue & Our Bionic Future.”

Emily Graczyk, MS, Matthew Schiefer, PhD, and Dustin Tyler, PhD

- ◆ Their article titled “[The neural basis of perceived intensity in natural and artificial touch](#)” was featured on the cover of Science Translational Medicine (STM), has been highlighted in 65 popular press articles, and viewed over 15,000 times on the STM website. CNN’s Great Big Story also featured this technology in “For Amputees, Reactivating the Sense of Touch” and has over 20,700 views. <https://youtu.be/lrn5HbQjkm8>

Pedram Mohseni, PhD, Evi Stavrou, MD, Michael Suster, PhD, and Umut Gurkan, PhD

- ◆ The ClotChip, a portable sensor that can assess the clotting ability of a person’s blood 95 times faster than existing methods, was licensed by Xatek Inc. and clinical trials have started at LSCVAMC.

Kristi Henzel, MD, PhD, Kevin Foglyano, MS, Frank Jacono, MD, and Ronald Triolo, PhD

- ◆ VA Innovator’s Network awarded the APTC five grants, one of which led to partnering with leading product and innovation firm, Nottingham Spirk. At the VA Innovation Demo Day, project progress was presented and Dr. Triolo’s was voted the Audience Favorite from over 90 VA innovations.

Jeffrey Capadona, PhD, and Dustin Tyler, PhD

- ◆ Both were inducted into the College of Fellows of the American Institute for Medical and Biological Engineering (AIMBE) at the National Academy of Sciences in Washington, D.C.

INFORMATION DISSEMINATION		
CORE INVESTIGATORS	Presentations/Posters	107
	Peer-reviewed Journal Articles	83
	Books/Chapters	12
GRANTS		
CORE INVESTIGATORS	New projects	15
	Total projects	64
INNOVATIONS		
ALL APTC	Patents Issued	6
	Patent Applications	34
	Invention Disclosures	23

Aasef Shaikh, MD, PhD, and Mark Walker, MD

Dr. Shaikh is the Director of the newly designated National VA Parkinson's Disease Consortium Center at LSCVAMC due to his tremendous clinical research (with Dr. Walker) and clinics related to Parkinson's Disease and movement disorders.

APTC Distinguished Lecture Series

APTC hosted experienced researchers focusing on research and rehabilitation efforts nationally who presented on mechanisms of human locomotion, prostheses and orthoses, devices to improve gait, and neurologically screening biologically-active surface coatings in 3D.

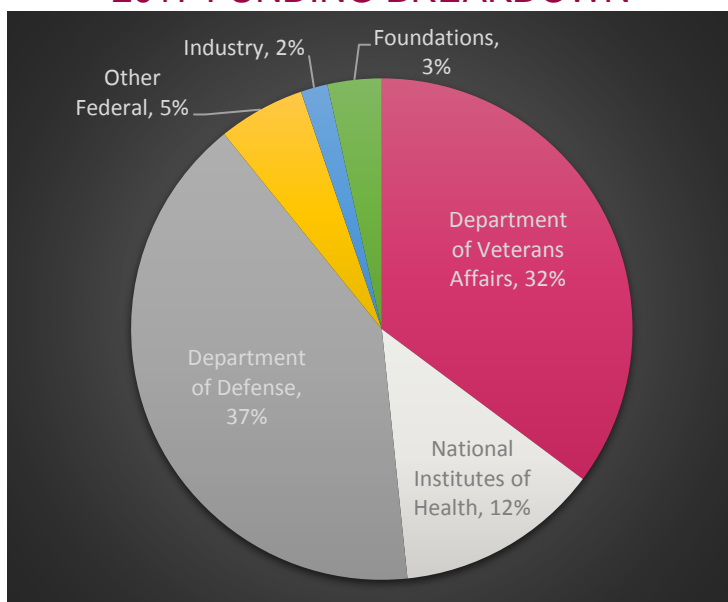
Jeffrey Capadona, PhD, Evon Ereifej, PhD, Matthew Schiefer (APT-SIP lead), PhD, Ronald Triolo, PhD

This was the inaugural year for the APT-Summer Internship Program for undergraduate STEM students. The 10-week program allowed four students to participate in cutting-edge biomedical research projects. All interns have continued working in their respective mentor's (listed above) lab. Three are now co-authors on APTC publications and another presented at the Biomedical Engineering Society 2017 conference.

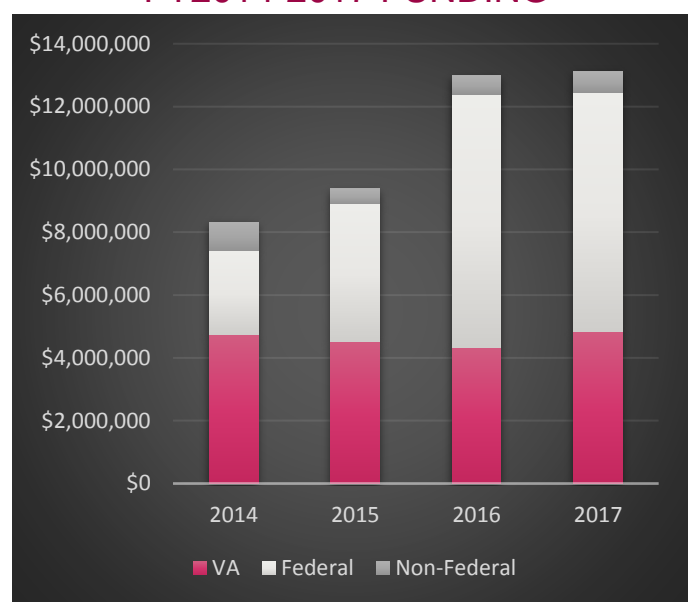
Research Funding

Since the APTC started, research funding has grown year after year. Looking back at the past few years, our Core Investigators have increased from 22 to 26 from 2014-2017. In that time, they increased their funding by 37% or \$4.8 million.

2017 FUNDING BREAKDOWN



FY2014-2017 FUNDING



Industry Collaborations

Currently, our Investigators are collaborating with many industrial companies, including Lubrizol, Parker-Hannifin, NeuroNexus, Novartis Institutes for Biomedical Research, Tepha Medical Devices, Medtronic, Koronis Biomedical Technologies, Lawrence Livermore National Laboratory, Ohio Willow Wood, Ottobock, Xatek Inc., and Nottingham Spirk. These relationships assist with development of designs, prototypes, packaging, and other technologies, as well as licensing new technologies and manufacturing devices.

Service to the Research Community

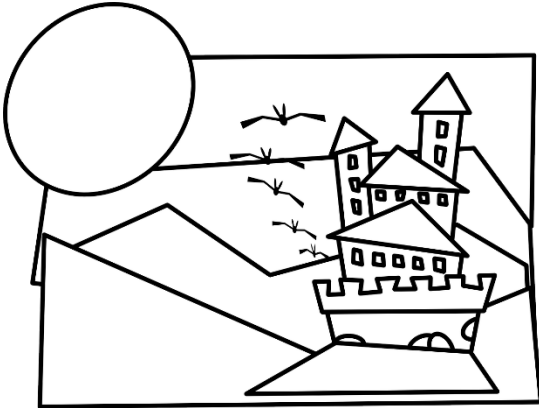
APTC Core Investigators contributed their time and expertise as editors (8) and on editorial boards (9) for 15 journals, and to 7 conferences as chair (1), co-chair (1), committee co-/chairs (2), abstract reviewers (3), and on the conference editorial board (1). They also review grant applications for VA RR&D Merit Reviews, SPIRE and other VA funding mechanisms, and serve as grant reviewers for NIH, NSF (Swiss), DoD, and other international and local organizations.

FDA & Quality Fast Facts

DESIGN INPUTS

Design input is the starting point for product design. A frequent complaint of engineers is that "there's never time to do it right, but there's always time to do it over." Within design controls, the use of input requirements assists with planning to prevent as much rework as possible. The requirements which form the design input establish a basis for performing subsequent design tasks and validating the design. Therefore, development of a solid foundation of requirements is the single most important design control activity to:

ENSURE YOUR INITIAL DESIGN MATCHES YOUR INTENDED OUTCOME

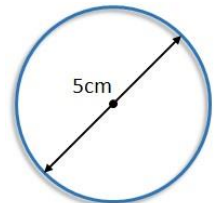


Design input requirements should be unambiguous. That is, each requirement should be able to be verified by an objective method of analysis, inspection, or testing. A qualified reviewer could then make a judgment whether the specified test method is representative of the conditions of use.

- ❖ Example of an insufficient requirement: "A catheter must be able to withstand repeated flexing."
- ❖ Example of a sufficient requirement: "A catheter should be formed into a 50 mm diameter coil and straightened out a total of 50 times with no evidence of cracking or deformity."

Quantitative limits should be expressed with a measurement tolerance, allowing 1) designers a basis for determining how accurate the manufacturing processes should be to produce compliant parts and 2) reviewers a basis for determining whether the parts will be suitable for the intended use.

- ❖ An incomplete specification is a *diameter of 5.0 cm*.
- ❖ A complete specification is a *diameter of 5.000 ± 0.005 cm*.



Environmental conditions should be properly characterized. For example, manufacturers frequently specify "laboratory" conditions for devices intended for use in the home. However, factors such as relative humidity, household temperatures, and altitude may adversely affect some kinds of medical equipment. If environmental conditions are fully specified, a qualified reviewer can decide whether the specified conditions are representative of the intended use.

Design input requirements should be self-consistent. It is not unusual for requirements to conflict with one another or with a referenced industry standard due to a simple oversight. Such conflicts should be resolved early in the development process.

WHERE DO I TURN FOR HELP?

Please contact Edward Panek at (216) 791-3800, ext. 6067, or Edward.panek@va.gov with questions or for assistance regarding your design inputs.

The APTC offers regulatory and quality support, including consulting services, to investigators at any point along their research and development continuums, from earliest concept to human trials. Developing a medical device with the ultimate goal of investigation via human studies? We provide a variety of resources to assist you.

NEWS

In remembrance of Professor Wen H. Ko



On Monday December 4, 2017, former APTC Investigator, Wen Hsiung Ko, PhD, passed peacefully at his Palo Alto home. At age 94, he lived a long and productive life. He was a Professor Emeritus of Electrical Engineering & Computer Science at Case Western Reserve University (CWRU) and an accomplished researcher with several future projects planned. Prof. Ko has more than 450 papers and 26 patents in the areas of solid state electronic devices, micro-sensors, control systems, biomedical telemetry systems, and medical devices. He was also a Fellow of both IEEE and AIMBE and received numerous awards and recognitions. APTC Investigator, Dr. Philip Feng (seated with Prof. Ko during a visit on January 22, 2017), stated that “Professor Ko has been a great inspiration for so many of us at

Case and beyond. He has helped and made a great positive impact on so many scholars/researchers in the Transducers and MEMS/NEMS communities – across the Pacific Ocean and worldwide.” He was surrounded by family in his last days, filled with good food and happy memorable moments. While his health had declined over the last 3 years with end-stage renal failure, his spirit and intellect continued to be strong and curious up to the end. To learn more about Prof. Ko’s amazing life, visit [Prof. Wen H. Ko in Memories](#), courtesy of CWRU.

A memorial service will be held on Saturday, January 27, 2018, starting at 10am, at the Amasa Stone Chapel at CWRU.

New patent: Methods for Treating Genitourinary Disorders

APTC Inventor: M. Damaser

Date of Patent: October 10, 2017

Patent No: US 9,782,440 B2

Abstract: One aspect of the present disclosure can include a therapeutic composition useful for treatment of a genitourinary disorder. The composition can be derived from a culture media having been in contact with a population of bone marrow-derived mesenchymal stem cells for a sufficient time period necessary to endow therapeutic activity in the culture media. The therapeutic property endowed to the culture media is the ability to promote structural and functional recovery of a dysfunctional organ or biological tissue associated with the genitourinary disorder.



Congratulations to [Dr. Musa Ausu](#) who was awarded a Travel Award to attend the [OpenSim Advanced User Workshop](#) at Stanford University in March 2018. This award, courtesy of the National Center for Simulation in Rehabilitation Research, will enable two of Dr. Ausu’s team members to interact with the OpenSim experts at Stanford University as well as advanced users at other institutions and make progress towards achieving the musculoskeletal modeling and simulation objectives of their research projects.



Gordon Research Conference

Beyond Feasibility - Bridging the Gap in Neuroelectronic Interfaces

March 25 - 30, 2018

Galveston, TX



Congratulations to [Dr. Jeffrey Capadona](#) who will co-Chair the inaugural **Gordon Research Conference on Neuroelectronic Interfaces**. This international event challenge the field to turn back to the drawing board of basic materials research armed with emerging fundamental neurosciences knowledge, and bring together a multi-disciplinary team of leading experts in cellular neuroscience, brain pathology, neuro-technology and materials science in order to discuss and eventually solve or discard the obstacles on the quest for a chronically useful and reliable neural interface.

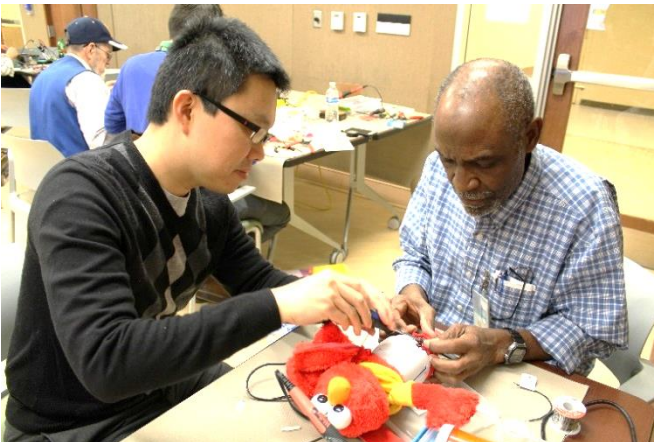
For those interested in attending, the application due date is February 25, 2018.

APPLY EARLY to ensure your spot!

Since its first official conference in 1931, Gordon Research Conferences have expanded to attract nearly 30,000 participants annually to one of over 300 conferences held around the world, but its vision and purpose remain the same - to build communities that provide an informal and important forum for the presentation and discussion of research at the frontiers of science.



Twenty-Seven Investigators and staff from the APTC, Research Service, and LSCVAMC volunteered at a workshop held by Replay for Kids. At the workshop, volunteers were shown how to adapt mainstream, battery-powered toys with external switches so that children with disabilities can use them. For more information about RePlay for Kids, visit their [website](#). This event was featured on the [front page of the Plain Dealer](#) on December 15, 2017.



This event is a collaboration with the APT Center, Replay for Kids, the Special Emphasis Program (SEP)-disAbilities, and CVAMCEA.

Influencing the next generation of Health Science majors

Kiley Armstrong, MS, a Biomedical Engineer and graduate student of Dr. Ronald Triolo, was invited to present at the **Women in Health Science Professions program** at her alma mater, St. Ursula Academy in Toledo, Ohio. Each month, the program's 10 high school juniors meet with women in health sciences to learn about the wide range of career options in the field. Kiley described her experiences in biomedical engineering, neuromuscular stimulation, and prosthetics and orthotics, and gave college advice. The students were unaware of the research being conducted at the APTC and Case Western Reserve University (CWRU) and **very excited to see a new aspect of the health science field**. Kiley was Valedictorian at St. Ursula Academy, on the women's varsity soccer team at CWRU, and is now pursuing a master's degree in Orthotics and Prosthetics at Northwestern University.

Good luck in your future endeavors, Kiley!



Life after the APTC and CWRU

Motion Study Lab and CWRU BME alumnus, Dr. Thomas Bulea, is part of a team developing assistive robotic exoskeletons for individuals with cerebral palsy (CP) at the NIH Medical Center. Check out how their exoskeleton is helping children with CP walk tall by changing their posture and assisting with knee extension.

<http://www.cnn.com/2017/11/08/health/cerebral-palsy-robotic-exoskeleton-teching/index.html>

Regeneratively Speaking featuring Dr. Margot Damaser

While at the Wake Forest Institute of Regenerative Medicine, [Dr. Margot Damaser](#) was interviewed for the Regeneratively Speaking® podcast. The podcast features interviews with guest researchers and the Institute's faculty covering the latest cutting-edge research on regenerative medicine. Listen to episode 33: Noncellular Regenerative Techniques for Pelvic Floor Disorders.

<https://regenerativelyspeaking.simplecast.fm/1ae98383>

RECENT PUBLICATIONS

Effect of exoskeletal joint constraint and passive resistance on metabolic energy expenditure: Implications for walking in paraplegia

PloS One, 2017

Authors: [Chang SR](#), [Kobetic R](#), [Triolo RJ](#)



This [article](#) studies the effects of exoskeletal constraints on metabolic energy expenditure were evaluated in able-bodied volunteers to gain insight into the demands of walking with a hybrid neuroprosthesis after paralysis.

ClotChip: A Microfluidic Dielectric Sensor for Point-of-Care Assessment of Hemostasis

IEEE Transactions on Biomedical Circuits and Systems, 2017

Authors: [Maji D](#), [Suster MA](#), [Kucukal E](#), [Sekhon UDS](#), [Sen Gupta A](#), [Gurkan UA](#), [Stavrou EX](#), [Mohseni P](#).



This [article](#) describes the design, fabrication, and testing of the ClotChip – a microfluidic sensor for dielectric spectroscopy of human whole blood during coagulation. This device has potential to be used at the point-of-care to assess the complete hemostatic process using a drop of blood.

Setting the pace: insights and advancements gained while preparing for an FES bike race



Journal of NeuroEngineering and Rehabilitation, 2017

Authors: [J McDaniel](#), [LM Lombardo](#), [KM Foglyano](#), [PD Marasco](#), [RJ Triolo](#)

Participation in the FES bike race during the Cybathlon led to modifications to stationary cycling used for rehabilitation and technological advances to develop an overground, outdoor cycling program for individuals with a spinal cord injury. This [article](#) details these advances and provides insights into the importance of regular exercise after a spinal cord injury.

✦ This article is also in a **featured thematic series in JNER** titled *Advances and challenges in the user evaluation and application of robotic assistive technologies: Insights from the first Cybathlon*. The selection of articles focuses on user-oriented developments in the field of assistive technologies related to the six disciplines of the Cybathlon.

<https://www.biomedcentral.com/collections/cybathlon>

The neural response properties and cortical organization of a rapidly adapting muscle sensory group response that overlaps with the frequencies that elicit the kinesthetic illusion

PloS One, 2017

Authors: [Marasco PD](#), [Bourbeau DJ](#), [Shell CE](#), [Granja-Vazquez R](#), [Ina JG](#).



Kinesthesia is a component of proprioception that is related to the sense of limb movement and essential for motor control. Vibrating the tendon of a limb muscle generates the perception that the limb is moving, even though it is immobile. This [article](#) explores the peripheral activity and cortical organization of a muscle sensory group response to mechanical vibration on kinesthesia.

UPCOMING GRANT DEADLINES

JANUARY

- 15 - CWRU CTP: CWRU Technology Validation & Start-up Fund Program **Pre-Proposal**
 - <https://case.edu/research/faculty-staff/tto/technology-validation-and-start-up-fund/>
- 16 - I-Corps@Ohio Program Proposals
 - <https://icorpsohio.org/apply/>
- 22 – CWRU Internet of Things (IoT): Internal Planning Grant Competition Proposals
 - <http://thedaily.case.edu/internal-campuswide-grants-available-researching-internet-things/>
- 26 – CDMRP: Accelerating Innovation in Military Medicine Research Award **Pre-Application**
 - <http://cdmrp.army.mil/funding/pa/FY17-DMRDP-AIMM.pdf>
- 26 – Taipei Medical University-CTSC Collaborative Pilot Program **Pre-Proposals** (target areas include TBI, stroke, dementia)
 - <http://casemed.case.edu/ctsc/funding/tmu.cfm>

FEBRUARY

- 1 - VA RRD: LOI for SPiRE Applications
- 5 - NIH: R01, U01 New Applications
- 9 - CDMRP: Accelerating Innovation in Military Medicine Application
 - <http://cdmrp.army.mil/funding/pa/FY17-DMRDP-AIMM.pdf>
- 12 - NIH: K New Applications
- 15 – Klingenstein Fellowship Awards in the Neurosciences Application
 - <http://www.klingfund.org/index.php>
- 16 - NIH: R21 New Applications
- 28 – Case-Coulter Translational Research Partnership (CCTRP) **Pre-Proposal**
 - <http://engineering.case.edu/ebme/Research/cctrp/CCTRPProposal>

MARCH

- 1 - VA BLRD/CSR, HSRD: RCS Applications
- 5 - NIH: R01, U01 Renewal, Resubmission, Revision Applications
- 10 - VA BLRD/CSR, HSRD: Merit, CDA, Pilot Applications
- 12 - NIH: K Renewal, Resubmission, Revision Applications
- 12 - VA RRD: SPiRE Applications
- 16 - NIH: R21 Renewal, Resubmission, Revision Applications

LINKS TO STANDARD ANNOUNCEMENTS

https://grants.nih.gov/grants/guide/parent_announcements.htm
<http://vaww.research.va.gov/funding/rfa.cfm>

ADDITIONAL FUNDING OPPORTUNITIES

Bridge Funding: A clinician with a BLR&D Merit Award that expired on or after October 1, 2016 and has not secured another VA award can apply for up to \$30K for 6 months.

https://www.research.va.gov/services/blrd/clinician_bridge.cfm

Funding opportunities aggregated by CWRU. <https://case.edu/research/faculty-staff/funding-ops/>

APTC now offers Business Plan templates to help with Transition Plans required in grant applications, such as the NIH. Contact Ed Panek at Edward.panek@va.gov for more details.

Have something to share? Send YOUR good news and professional accomplishments to Rebecca Polito at rpolito@aptcenter.org to include in a future Translation Builder.