

# 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 2019! 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 2018

#### Progress on the microfluidic artificial lung

- ◆ Dr. Joseph Potkay and team are building a 3D-printed, wearable, **microfluidic artificial lung** that will be compatible with living tissue and is capable of short- and long-term respiratory support. An article featured in [VA Research Currents](#) in August and has been covered by numerous media outlets that have been shared to Facebook over 500 times, along with a [news story](#) viewed over 2,200 times on Facebook. Dr. Potkay received a NIH R21 grant earlier this year to develop a control system for the lung, and a NIH R01 titled *Human-Scale Microfluidic Artificial Lung* will start in April.

#### Discoveries in wound healing and inflammatory disease

- ◆ Dr. Evi Stavrou, Dr. Umut Gurkan, et al published an article titled [Factor XII and uPAR Upregulate Neutrophil Functions to Influence Wound Healing](#) that was featured on the cover of The Journal of Clinical Investigation (JCI) and has been viewed almost 8,500 times on JCI and Pubmed Central. Their findings identify the axis of the Factor XII and its receptor uPAR as a driver of neutrophil-mediated inflammation, highlighting a potential target for inflammatory disease and inhibiting wound healing.

#### Restoring natural sensation in subjects with prosthetic arms

- ◆ Dr. Paul Marasco and team's article, titled [Illusory Movement Perception Improves Motor Control for Prosthetic Hands](#), detailed how the use of vibrations "turned on" specific neural pathways and allowed subjects with prosthetic arms to feel as if their fingers and hands were moving and were an integrated part of their own body. This was published in Science Translational Medicine (STM) and has been highlighted in 57 popular press articles and viewed over 19,600 times on the STM website.
- ◆ Outcomes of the first known study of how amputees use advanced sensory-enabled prostheses outside the laboratory included reports of a greater sense of psychosocial well-being and more regular use of a sensory-enabled hand compared to traditional prostheses. Led by Dr. Dustin Tyler, results of this home-use trial were published in [Scientific Reports](#) and has been covered extensively by several national media outlets.

## Inaugural Gordon Research Conference on Neuroelectronic Interfaces

- This wildly successful event, Co-Chaired by Dr. Jeff Capadona, challenged the international field to turn back to the drawing board of basic materials research and brought together a multi-disciplinary team of leading experts in cellular neuroscience, brain pathology, neuro-technology, and materials science to discuss and eventually resolve obstacles to a chronically useful and reliable neural interface.

## Wen H Ko Summer Internship Program

- In 2018, the APTC hosted 5 interns, all of whom have continued working with the APTC. One is a co-author on a manuscript published in *Micromachines* by two of our investigators, and two had abstracts accepted for the Biomedical Engineering Society conference and the IEEE Signal Processing in Medicine and Biology Symposium.

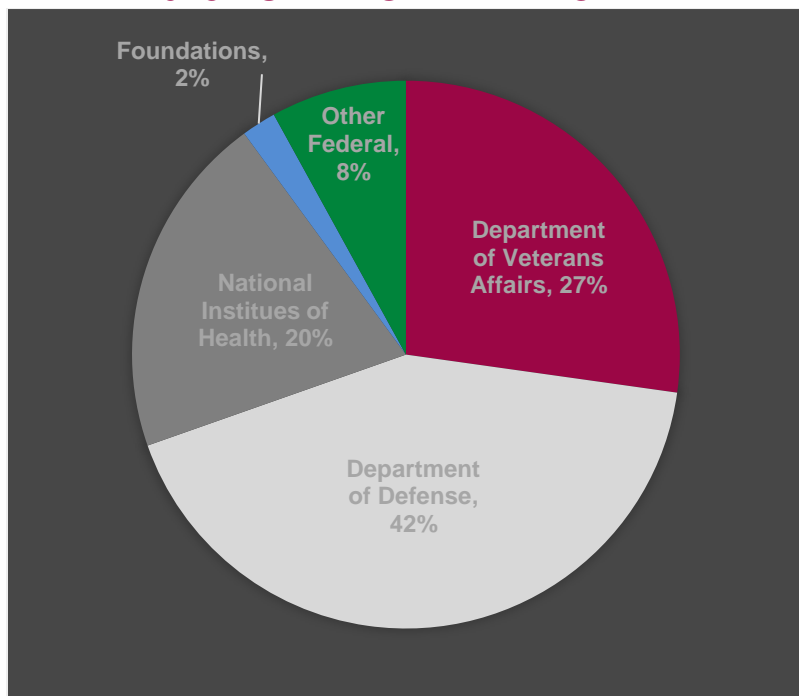
## Did you know?

A new service line for disabled Veterans was developed using insights and advancements from the stimulation bike race at the Cybathlon to take advantage of the health benefits of this unique exercise and recreational modality. Veterans with lower limb paralysis can now participate in surface stimulation bike riding.

## Research Funding

Since the APTC started, research funding has grown year after year. Although our Core Investigators decreased from 26 to 20 this year, their funding increased \$13 million to \$14.6 million.

### 2018 FUNDING BREAKDOWN



INFORMATION DISSEMINATION		
CORE INVESTIGATORS	Presentations/Posters	113
	Peer-reviewed Journal Articles	72
	Books/Chapters	8
	GRANTS	
	New projects	13
	Total projects	62
INNOVATIONS		
ALL APTC	Patents Issued	8
	Patent Applications	29
	Invention Disclosures	25

## FDA & Quality Fast Facts

### Sponsor-Investigator Responsibilities After FDA IDE Approval

Congratulations! You have just received FDA approval of your Investigational Device Exemption (IDE) application and you may begin your research (assuming you have also received IRB approval). With the approval comes reporting obligations. Full reporting details are [located on the FDA website](#) and summarized below (greatly abbreviated).

## General Duties (21 CFR 812.40)

- ✦ Submitting the IDE application to FDA
- ✦ Obtaining both FDA and IRB approvals for the investigation and submitting certification (letter) of IRB approval to FDA before shipping the device to any investigator
- ✦ Obtaining FDA approval and IRB approval for a supplemental application before beginning that portion of the investigation
- ✦ Selecting qualified investigators
- ✦ Ensuring proper monitoring
- ✦ Ensuring patient informed consent is obtained

Investigators are responsible for ensuring that investigational devices are made available only to persons who are legally authorized to receive them (see 21 CFR 812.110(c)).

## Supplemental Applications [21 CFR 812.35(a) and (b)]

Supplements are required to be submitted to, and approved by, FDA in the following situations:

- ✦ Changes in the investigational plan: FDA (and IRB) approval is required for any change that may affect the scientific soundness of the investigation or the rights, safety, or welfare of the subjects. The change in the investigational plan may not be implemented until FDA (and IRB, if required) approval is obtained.
- ✦ Addition of new institutions: The investigation at the new institution(s) may not begin until both FDA and IRB approval(s) are obtained, and certification of IRB approval is submitted to FDA.

## Maintaining Records [21 CFR 812.140(b)]

A sponsor-investigator shall maintain accurate, complete, and current records relating to an investigation.

- ✦ Correspondence (including reports) with another sponsor, monitor, investigators, and the IRB or FDA
- ✦ Records of shipment
- ✦ Records of disposition
- ✦ Signed investigator agreements
- ✦ Adverse device effects (whether anticipated or unanticipated) and complaints
- ✦ Any other records that FDA requires by regulation or by specific requirement for a category of investigation or a particular investigation

## Submitting Reports [21 CFR 812.150(b)]

A sponsor-investigator shall prepare and submit the following complete, accurate, and timely reports:

- ✦ Unanticipated adverse device effects (with evaluation) to FDA, all IRBs, and investigators within 10 working days after notification by the investigator. Subsequent reports on the effect may be required by FDA. *The local IRB might have a shorter reporting timeline that must also be met.*
- ✦ Withdrawal of IRB or FDA approval
- ✦ Current investigator list (FDA may grant a waiver allowing the sponsor to submit a current list to FDA annually as part of the annual progress report, in lieu of every six months.)
- ✦ Annual progress report (see format for IDE progress report)
- ✦ Recall and device disposition (within 30 working days after the request was made)
- ✦ Final report
- ✦ Use of device without obtaining patient informed consent
- ✦ Significant risk determinations by the IRB when proposed to be nonsignificant risk
- ✦ Other reports requested by the IRB or FDA

## WHERE DO I TURN FOR HELP?

Please contact Jen Wall, PAHM, CCRP, at (216) 791-3800 ext. 3578 or [Jennifer.wall@va.gov](mailto:Jennifer.wall@va.gov) with questions or for assistance regarding your application and next steps.

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.

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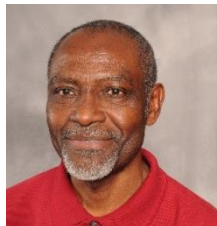
# NEWS

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Mr. Brett Scharringhausen, Deputy Chief, Science and Technology Division & Command Science Advisor for the **United States Central Command (USCENTCOM)**, to the Commander, and Chief, Discovery & Integration, visited with Dr. Dustin Tyler on January 18, 2019 to learn about Dr. Tyler's work with sensory-enabled prosthetics as part of the DARPA Hand Proprioception and Touch Interfaces (HAPTIX) program.



Congratulations to [Brian Cmolik, MD, FACS](#), the new Chief of Staff for the VA Northeastern Ohio Health Care System. Dr. Cmolik is a cardiothoracic surgeon and was promoted to Chief, Surgery Service in 2013. He is board certified in general surgery and cardiothoracic surgery, and an Associate Professor at Case Western Reserve School of Medicine.



Congratulations to [Musa Audu, PhD](#), who has been promoted to Full Professor of Biomedical Engineering at Case Western Reserve University. Dr. Audu has been an investigator in the APTC since 2007, working on projects in the areas of human musculoskeletal modeling, control of standing and seated balance, and neuroprostheses for intervention after spinal cord injury and other movement disorders.



Congratulations to [Hamid Charkhkar, PhD](#), who has been promoted to Senior Research Associate in the department of Biomedical Engineering at Case Western Reserve University. Dr. Charkhkar is also an investigator in the APTC. He is working with Dr. Ron Triolo to restore natural sensation to lower limb amputees by delivering electrical stimulation to the peripheral nervous system.

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## SHOUT OUT to Dr. Margot Damaser and Dr. Hui Zhu

Their article in American Journal of Physiology Renal Physiology (AJPRP) titled [Mesenchymal stem cells and their secretome partially restore nerve and urethral function in a dual muscle and nerve injury stress urinary incontinence model](#) was among the **top 10 cited articles** in AJPRP of 2015!







Participation more than doubled at this year's RePlay for Kids adaptive toy workshop with 52 staff and Veterans volunteering to adapt mainstream, battery-powered toys with external switches so that children with disabilities can use them. [Fox 8 Cleveland](#) covered the event, interviewing some of the volunteers. For more information about RePlay for Kids, visit their [website](#).



## New Patent Awarded

### Implantable Pressure Sensor

**Inventors:** MS Damaser, S Majerus, PC Fletter, SL Garverick, WH Ko, P Zaszczurynski

**Date of Patent:** December 4, 2018

**Patent No:** US 10,143,391 B2

**Abstract:** Systems and methods are provided for in vivo measurement of pressure. An implantable sensor assembly includes a pressure sensor configured to provide an analog signal representing pressure and a signal conditioning component configured to convert the pressure sensor output into a digital signal. A transmitter is configured to transmit the digital signal to an external base unit. A power control unit is configured to dynamically allocate power throughout the implantable sensor assembly, such that during an active measurement interval of the implantable sensor assembly, each of the pressure sensor, the signal conditioning component, and the transmitter are powered only for a portion of the active measurement interval necessary to perform a related function.

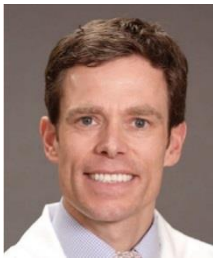




Congratulations to Jacinta “JC” Seton, MSN, RN, APRN, ACNS-BC who has recently earned a **Doctor of Nursing Practice (DNP) degree** from The Ohio University College of Health Sciences and Professions. The work completed for her dissertation, titled *The Impact of Pressure Injury Education on Hospice Nurse Knowledge & Practice*, was presented at LSCVAMC twice in 2018, and a poster based on this research was accepted to the National Pressure Ulcer Advisory Panel 2019 Annual Conference in March in St. Louis. Dr. Seton is a Senior Research Nurse and Study Coordinator in Dr. Kath Bogie’s tissue health lab.

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## Welcome new APTC Investigator and Operations staff!



Mark Weidenbecher, MD, FACS

Dr. Weidenbecher is currently an **Ear, Nose & Throat surgeon** at Louis Stokes Cleveland VA Medical Center and Metrohealth Medical Center, as well as an Assistant Professor in the Department of Otolaryngology at Case Western Reserve University. His specialty in the field of otolaryngology is **airway reconstruction** of patients who suffer from laryngeal or tracheal stenosis, but also voice restoration, treatment of head & neck cancer, and sleep apnea surgery with many years of clinical experience.



Jennifer Kerbo, BFA, *Medical Illustrator and Administrative Assistant*

Jennifer has a BFA from the Cleveland Institute of Art and extensive experience **creating graphics and 3D models** depicting anatomy and embryogenesis, physics, fluid dynamics, and biology that are both interactive and visually appealing. She is responsible for working with investigators to **illustrate research graphics** used for medical/scientific media, grant publications, and poster presentations, and providing administrative support and other APTC support functions. <http://www.kerbostudio.com/>



Frank Zitko, BS, *Technical Innovation Specialist* (for the VA and APTC)

Frank has a BS in Biomedical Engineering from Marquette University and a background in the medical device industry. He provides support navigating the **invention disclosure process** at VA and CWRU, and development of innovative ideas that improve the experience and medical outcomes of Veterans and their families by identifying needs for new technologies ranging from smart phone applications to more advanced medical devices, and guidance for the **SPARK, SEED, and SPREAD** funding mechanisms of the VA Innovation Center.



Congratulations to Kangli Deng, MD, PhD, a Postdoctoral Fellow in Dr. Margot Damaser’s lab, who won **Third Place** in the prestigious **Diokno-Lapides Essay Contest** for his essay titled *Daily Bilateral Pudendal Nerve Electrical Stimulation Improved Recovery from Stress Urinary Incontinence*. Originally established in 1985 to honor Jack Lapides, MD (renamed in 2013 to honor the contributions of Ananias C. Diokno, MD), this contest recognizes an individual or group doing outstanding work in the field of Urology. Essays are judged by an independent panel that is blinded as to the essayist and institution. Dr. Deng will receive a cash prize and present at the Diokno-Lapides dinner at the American Urological Association National Meeting in May.

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## Case Western Reserve University receives new School of Engineering Dean



Venkataramanan "Ragu" Balakrishnan, PhD spent the past 9 years as head of Purdue University's largest academic unit. Under his direction, it experienced dramatic growth in undergraduate enrollment, research funding, and faculty diversity. Dr. Balakrishnan earned his undergraduate degree in India, and two master's degrees and PhD from Stanford University. After postdoctoral positions at Stanford, California Institute of Technology, and University of Maryland, he joined the Purdue faculty in 1994. Within 9 years, he was a full professor and a leader of strategic initiatives and graduate admissions in Purdue's School of Electrical and Computer Engineering. He later led education within the school and then research across the entire college.

**Think Big**, Case Western's [new strategic planning effort](#) is in full swing. The purpose is to implement change, in the form of BIG IDEAS and DIRECTIONS, faster than traditional strategic planning by engaging the entire campus to help the university thrive. Activities planned range from outside speakers and discussion groups to pilot projects and strategic advisors, called Thinkers. Of the 150 submissions for the Thinkers group, 14 were chosen including **Dr. Umut Gurkan** and **Dr. Dustin Tyler**.



## TRAINING

### DO YOU USE ALTMETRIC?



A single research output can live online in multiple websites and can be talked about across dozens of different platforms. [Altmetric](#) tracks a range of sources to capture and collate this activity, to provide you with a single visually engaging and informative view of the online activity surrounding your scholarly content.

You can easily find out the Altmetric details for most articles by installing their [free bookmarklet](#) for Chrome, Firefox, and Safari (psst – this even works at the VA!).

Check out an example – [The neural basis of perceived intensity in natural and artificial touch](#).

## DEPARTMENT OF VETERANS AFFAIRS TECHNOLOGY TRANSFER PROGRAM

Ryan Davis, JD, a Technology Transfer Specialist in the VA Technology Transfer Program, recently visited LSCVAMC and presented an overview of the VA Technology Transfer program. Click [here](#) to see slides from the [presentation](#) or visit their [website](#).

For those researchers or engineers looking to obtain a patent or commercialize an invention, but have little familiarity of the process, check out these short yet informative articles:

[How to Write a Provisional Patent Application That Has Value](#)

[Why You Should Search for Prior Art Yourself](#)

VA Technology Transfer Program's Intellectual property management services include:

- ▶ Invention evaluation
- ▶ Obtaining intellectual property protection
- ▶ Marketing inventions
- ▶ Negotiating license agreements
- ▶ Advising on IP-related agreements and CRADAs



# TECHNOLOGY TRANSFER PROGRAM

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## GET INVOLVED

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### CALL FOR PROJECT LEADERS AND MAKERS

Challenge America and the VA Northeast Ohio Healthcare System will partner to launch the first CAMVETS program in Cleveland this April! This program enlists the talents of **ENGINEERS, DESIGNERS, and OTHER PROFESSIONALS** who come together to design innovative solutions to the unmet needs of injured Veterans.

Click [here](#) to fill out the Participant Interest form, or contact Maggie Tolan, Director of Research & Development. [maggie@challengeamerica.com](mailto:maggie@challengeamerica.com) | (970) 279-1661

Lead a team of innovators dedicated to one injured Veteran's daily challenge and make a direct and lasting impact on his/her life.

Challenge  America  
MAKERS ★ FOR ★ VETERANS



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# UPCOMING GRANT DEADLINES

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- ❖ First of the month – CWRU CTSC [Core Utilization Pilot Grants](#)
- ❖ Rolling basis – Case-Coulter Translational Research Partnership (CCTRP) [Pilot Projects](#)
- ❖ Feb 1 – VA RRD LOI for SPiRE Applications
- ❖ Feb 5 – NIH R01, U01 New Applications
- ❖ Feb 12 – NIH K New Applications
- ❖ Feb 15 – Klingenstein [Fellowship Awards in the Neurosciences Application](#)
- ❖ Feb 16 – NIH R21 New Applications
- ❖ Feb 28 – Case-Coulter Translational Research Partnership (CCTRP) [Full Projects](#)
- ❖ Mar 1 – VA BLRD/CSR, HSRD RCS Applications
- ❖ Mar 5 – NIH R01, U01 Renewal, Resubmission, Revision Applications
- ❖ Mar 10 – VA BLRD/CSR, HSRD Merit, CDA, Pilot Applications
- ❖ Mar 12 – NIH K Renewal, Resubmission, Revision Applications
- ❖ Mar 12 – VA RRD SPiRE Applications
- ❖ Mar 16 – NIH R21 Renewal, Resubmission, Revision Applications
- ❖ April 15 – VA HSRD LOI for CDA

## LINKS TO STANDARD ANNOUNCEMENTS

NIH - [https://grants.nih.gov/grants/guide/parent\\_announcements.htm](https://grants.nih.gov/grants/guide/parent_announcements.htm)

VA (intranet) - <http://vaww.research.va.gov/funding/rfa.cfm>

VA (external) - <https://www.research.va.gov/services/default.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](https://www.research.va.gov/services/blrd/clinician_bridge.cfm)
- ❖ National MS Society – [General deadlines for grant applications](#)
- ❖ Funding opportunities aggregated by CWRU: <https://case.edu/research/faculty-staff/funding-ops/>

APTC offers Business Plan templates to help with Transition Plans required in grant applications, such as the NIH. Contact Vi Huynh at [vi.huynh@va.gov](mailto:vi.huynh@va.gov) for more details.

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