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.

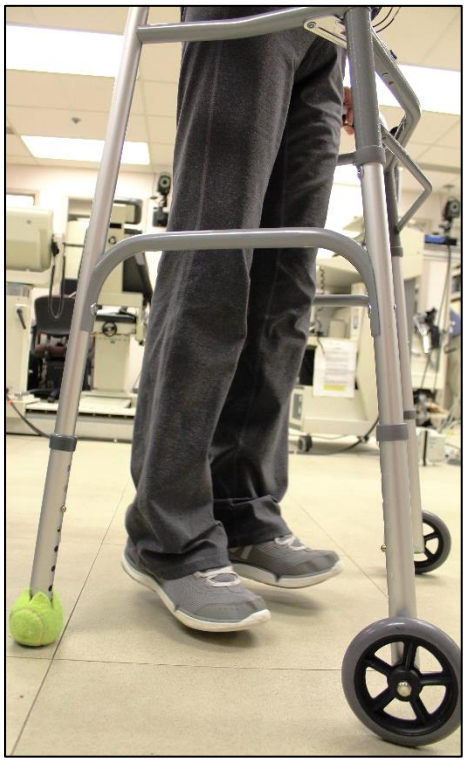
VIPs Visit the APT Center

In the past few months, APT Center Investigators, staff, and research subjects have spoken with numerous individuals touring the Louis Stokes Cleveland VA Medical Center about the amazing technological advancements and progress of our projects. The stimulating dialogue we have with our visitors is a great reminder of the importance of our research not only for Veterans, but for the community at large. We truly are doing some great things in Cleveland.

Secretary of the VA, Mr. Robert Wilkie, met with Dr. Ronald Triolo and his subject who has a lower limb amputation and uses an implanted neural stimulation system and a special orthotic designed to restore the sense of touch and pressure in his missing limb.

Navy Surgeon General and Chief of the Bureau of Medicine and Surgery, Vice Admiral C. Forrest Faison, III, met with Dr. Ronald Triolo and our subject who is a paraplegic and uses electrical stimulation on the surface of his legs to ride a trike.

Senator Sherrod Brown's Legislative Assistant for the VA and Military affairs, Anna Gokaldas, met with research participant Jen French as she showed off the latest advancement from her neurostimulation system – controlling the ankle/foot drop that allows her to pick up her feet as she walks rather than shuffling or dragging her feet.



Hershel “Woody” Williams, the last living Marine Medal of Honor Recipient from WWII, also met our biking subject and had us all in stitches. He is at our medical center today (August 31) to help dedicate Cleveland’s Gold Star Families Memorial Monument.

Wen H. Ko Summer Internship Program

As the summer ends, so has the 2018 Wen H. Ko Summer Internship Program cohort. Meet our interns below and learn a bit about their experiences this summer.

Stephanie Chin

Mentor: Steve Majerus, PhD

I am a rising senior studying Biomedical Engineering at CWRU. I applied to the APT Center internship program because I wanted to get more involved in research. I spent this summer researching stenosis characterization in dialysis patients. I worked on identifying spectral features from the digital analysis of blood flow sounds that could predict the location and degree of stenosis. I presented my work at the Cleveland Clinic Research Student Poster Session and SOURCE Intersections. I wrapped up my summer work by submitting a paper to the 2018 IEEE Signal Processing in Medicine and Biology Symposium. I learned so much about signal processing and how to handle my own project, and look forward to continuing my research with Dr. Majerus this school year.

Hayden Koerwer

Mentor: Allison Hess-Dunning, PhD

This summer I fabricated and tested microelectrodes, the goal being to develop neural electrodes with better spatial and temporal resolution for electrochemical measurement. Specifically, I developed a method for coating platinum electrode contact pads with reduced graphene oxide to increase the sensitivity of the electrodes to hydrogen peroxide. The resulting electrode is 63 times as sensitive compared to bare platinum electrode. The goal being to perfect a coating method before ultimately using glutamate oxidase to measure glutamate levels in vivo. I presented a poster at the SOURCE symposium and gave an oral presentation at the NEC meeting. I definitely learned a lot this summer. This was my first time working in a non-biology lab, so I got a lot of hands on experience with the devices and instruments. I really enjoyed working with Allison who was an awesome mentor. She taught me a lot about the research process and how to present scientific findings.

Noel Jeansonne

Mentor: Dustin Tyler, PhD

I began in the Capadona Research Lab in the APT Center and was encouraged to apply for the internship program based on my interest in neuroscience and medicine. While approaching my senior year of Biomedical Engineering and looking to apply to Medical School, I wanted more hands-on experience in the lab and the responsibility of leading an independent project. I choose Dr. Dustin Tyler as my mentor based on his ground-breaking work in Sensory Restoration and history of letting students work and design independently within the constraints of a project. I was given the opportunity to construct a new Magnetic Breakaway Connector (MBC) for the at-home sensory restoration device. I have completed my initial prototype and will be staying in Dr. Tyler's lab to test and tweak the design over the next year. In addition, I will be presenting my design during the spring semester and hope to engage in other research projects within the lab before I graduate in May.

Josh Rosenberg (also in the 2017 cohort)

Mentor: Matthew Schiefer, PhD

My experience this summer in the program vastly improved my skills as a researcher. My project did not always go smoothly, and I gained valuable insight into how to view data and when to try a different angle when making sense of the data. I also had the opportunity to present my project to other researchers with experience in the field I am working in through SOURCES Intersections. This October, I will also be presenting my research at the BMES annual meeting in Atlanta.

Marina Yu

Mentor: Andrew Shoffstall, PhD

I am a 4th year BME student at CWRU. I applied to this program because of the emphasis on the mentor-mentee relationship. I was also very excited about planning a mini project, because taking ownership of a project is a great way to practice designing an experiment from start to finish and thinking on your feet when things go wrong. This summer I learned a lot of new lab skills and worked on numerous projects, including a mosquito-inspired one. We are working to mimic the mosquito’s proboscis (a needle-like mouth) insertion tool and apply it to insertion of microelectrodes into the brain. This summer, we began looking at the mosquito’s use of oscillation during insertion and found that there are several parameters (frequency, displacement, etc.) that may play an additional role in insertion. I will be continuing this project during the upcoming school year.

FDA & Quality Fast Facts

International Standard IEC 62304 - Medical Device Software

The international standard IEC 62304:2006, Medical device software – Software life-cycle processes, provides requirements for the development and maintenance of medical device software. Published in 2006, it covers software, both embedded in medical devices and as a medical device.

The APT Center has fielded several questions recently about IEC 62304 and how it affects our research. Summarized from the FDA:

If your medical device has software that regulates its functionality in a way that contributes to Basic Safety or Essential Performance, you will need to comply with IEC 62304.

Below is a list of deliverables needed to cover both FDA and IEC 62304 requirements:

- Software Development Plan - Define processes, deliverables, and development activities, including the Life Cycle Activities, Risk Management Plan (including OTS software and cyber-security risks), Documentation Plan, and Configuration Management Plan.
- Software V&V Plan - Describe the plan to test the software. Include the unit test, integration test plans, and the final system software verification tests.
- Software Description - Describe what the software will do at a high level. Include programming language, hardware platform, OS, etc.
- Software Requirement Specification - Specify the functional, performance, interface, and safety requirements, hazard mitigations, etc.
- Software Architecture Chart - Include diagrams of subsystems and major components, and the interfaces between them. This can provide segregation of software entities for risk control.
- Software Hazard Analysis - Create an IEC 62304 hazard analysis, identifying potential hazards and the software items that could cause them. Mitigations should feed back into the requirements.
- Off-the-shelf (OTS) Software List – List of OTS software used, including the source, version, license, and function for the system.
- System Software Verification Protocols - Detailed test protocols for the final device software. These must trace to and provide coverage of the requirements. Each should have pass/fail criteria.
- Summary Test Report - Create a summary of all software tests per the V&V plan.
- Trace Matrix - Create a spreadsheet, tracing system requirements to software requirements to associated design specifications and Test Protocols. Include software hazards that have software mitigations.
- Unresolved Anomalies - List the anomalies still present and associated risks, providing justification for use.

This is a helpful link to summarize the requirement of IEC 62304.
http://www.spiq.com/abs/JF200809IEC62304%20SPIQ%20Rev004.pdf

WHERE DO I TURN FOR HELP?

Please contact Brad Boggs at bboggs@aptcenter.org with questions or for assistance. The APT Center maintains relevant standards in its library, including IEC 62304.

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

Congratulations to Glenn Wera, MD, who has been promoted to the rank of Associate Professor of Orthopaedics in the School of Medicine at Case Western Reserve University.

New Patents Awarded

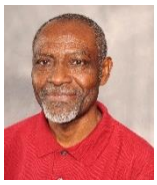
Wearable Socio-Biosensor Device
APTC Inventors: K. Lee
Date of Patent: May 15, 2018
Patent No: US 9,968,296 B2

Abstract: A wearable socio-biosensor device can include a plurality of sensors to detect bio-behavioral data of a subject, social data related to a proximity of the subject to other persons wearing socio-biosensor devices and bio-behavioral data measured during the time the subject is in close proximity to other persons, and environmental data related to the subject's environment.

Capacitive Sensing Apparatuses, Systems and Methods of Making Same
APTC Inventors: P. Mohseni, MA. Suster, M. Bakshiani, U. Gurkan
Date of Patent: June 12, 2018
Patent No: US 9,995,701 B2

Abstract: A sensor system can be configured to perform dielectric spectroscopy (DS). For example, the system can include a sensor configured to measure dielectric permittivity of a fluid in response to an RF input signal. Associated interface electronics can include a transmitter to drive the sensor with the RF input signal and a receiver to receive and process an RF output signal from the sensor in response to the RF input signal.

New Appointments and Service Commitments



Dr. Musa Audu

- Invited member of the NIH Biomedical Computing and Health Informatics Study Section, Center for Scientific Review, 2018-2022.

Dr. Kath Bogie

- Invited member (representing the VA) to the RESNA Standards Committee on Wheelchair and Related Seating working group on Heat and Water Vapor Transfer (ISO/TC 173/SC 1/WG 11 Wheelchair seating standards development).
- Elected to Board of Directors, Wound Healing Society, 2018-2021

Dr. Margot Damaser

- Appointment (representing VA IACUC chairs) to the Field Advisory Committee (FAC) of the Office of Research Oversight (ORO)

AWARDS & RECOGNITIONS

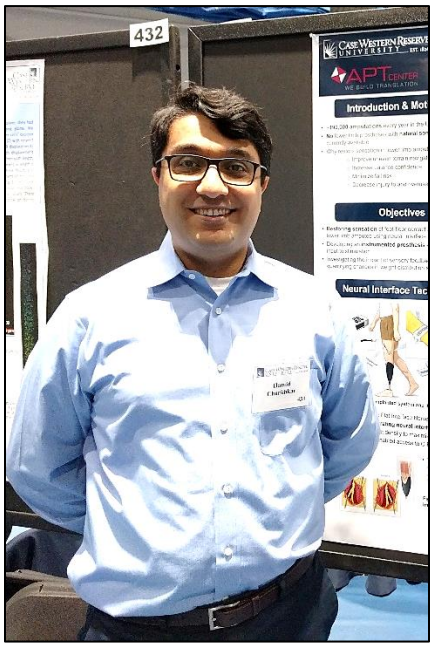
2018 Research ShowCASE

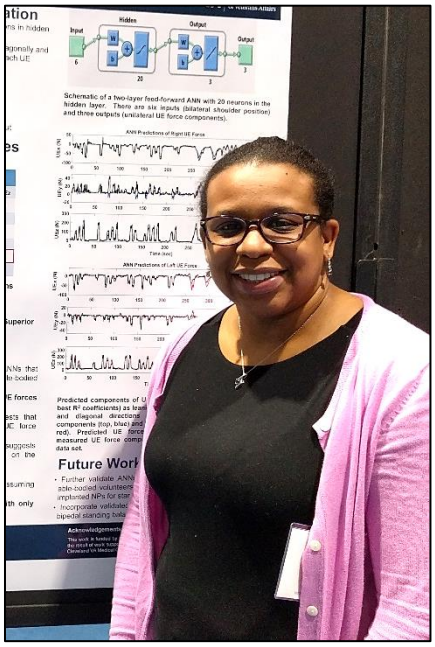
Postdoctoral Research Awards (*Winners received a $100 prize and framed certificate*)

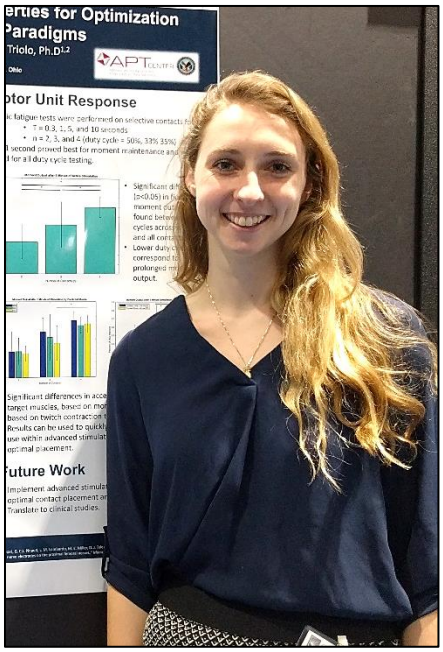
- Hamid Charkhkar, PhD, Postdoctoral Scholar in Biomedical Engineering, Case School of Engineering
- Brooke Odle, PhD, Postdoctoral Scholar in Biomedical Engineering, Case School of Engineering

Graduate Student Honorable Mention

- Kristen Gelenitits







AIP Biomicrofluidics
Fundamentals, Perspectives & Applications

2017 Best Paper Award Finalist

- Joseph Potkay, PhD, and team for *A small-scale, rolled-membrane microfluidic artificial lung designed towards future large area manufacturing*. Link to article

AMERICAN ACADEMY OF NEUROLOGY®

70th Annual Meeting, 2018 Abstract of Distinction

- Freeberg M, Pinault G, Tyler D, Triolo R, Ansari R. *Chronic Nerve Health Following Implantation of Nerve Cuff Electrodes Designed for the Proximal Femoral Nerve*

RECENT PUBLICATIONS

Bedell HW, Hermann JK, Ravikumar M, Lin S, Rein A, Li X, Molinich E, Smith PD, **Selkirk SM,** Miller RH, Sidik S, Taylor DM, **Capadona JR**
Targeting CD14 on blood derived cells improves intracortical microelectrode performance
Biomaterials
Link to article

Damaser, MS
Margot S. Damaser, PhD – Innovator in Regenerative Medicine and Urinary Incontinence
AUA Investigator
Link to article

Charkhkar H, Shell CE, Marasco PD, Pinault GJ, Tyler DJ, Triolo RJ
High-density peripheral nerve cuffs restore natural sensation to individuals with lower-limb amputations
Journal of Neural Engineering
Link to article

French J, Bardot D, **Graczyk E, Hess-Dunning A**, Lujan JL, Moynahan M, Tan W, **Triolo R**, Zbrzeski A
The Need for Understanding and Engaging the Patient as Consumer of Products Developed by Neural Engineering
Journal of Neural Engineering
Link to article

Iyer RR, Gorelick N, Carroll K, Blitz AM, Beck S, Garrett CM, Monroe A, Tyler B, Zuckerman ST, **Capadona JR, von Recum HA**, Luciano MG
Evaluation of an in vivo model for ventricular shunt infection: a pilot study using a novel antimicrobial-loaded polymer
Journal of Neurosurgery
Link to article

Majerus SJ, Fletter PC, Ferry E, **Zhu H**, Gustafson KJ, **Damaser MS**
Suburothelial Bladder Contraction Detection with Implanted Pressure Sensor
PloS One
Link to article

Maji D, De La Fuente M, Kucukal E, Sekhon UDS, Schmaier AH, Sen Gupta A, **Gurkan UA**, Nieman MT, **Stavrou EX, Mohseni P, Suster MA**
Assessment of Whole Blood Coagulation with a Microfluidic Dielectric Sensor
Journal of Thrombosis and Hemostasis
Link to article

Triolo RJ, Bailey SN, Foglyano KM, Kobetic R, Lombardo LM, Miller ME, Pinault G
Long-Term Performance and User Satisfaction With Implanted Neuroprostheses for Upright Mobility After Paraplegia: 2- to 14-Year Follow-Up
Archives of Physical Medicine and Rehabilitation
Link to article

Wera GD
CORR Insights®: American Joint Replacement Registry Risk Calculator Does Not Predict 90-day Mortality in Veterans Undergoing Total Joint Replacement
Clinical Orthopaedics and Related Research
Link to article

UPCOMING EVENTS

Early bird registration ends TODAY (August 31st) for the 2018 IEEE BiOCAS Conference and NeuroCAS post-conference workshop!

These events are being Co-Chaired by Dr. Pedram Mohseni and Dr. Dustin Tyler.

Dr. Steve Majerus and Dr. Michael Suster will function as Co-Chairs for the Live Demonstrations.

For more information about these events, visit http://www.biocas2018.org/.

If you're attending the 95th Annual Conference of the **AMERICAN CONGRESS OF REHABILITATION MEDICINE** this September, be sure to stop by the symposia below to see our Investigators.

Dr. Kath Bogie
- Tissue Health Biomarkers to Predict Highest Risk Individuals for Pressure Injury Recurrence (453159)
- SCIPUD+, a Healthcare Tool to Enable Clinical Practice Guidelines Personalization for Pressure Injury Care (453175)

Dr. Ela Plow
- Can TMS Serve as a Useful Measurement Tool in Rehabilitation and Neurology? (422163)
  - Also presenting, **Dr. Kelsey Baker**
- Tailored Neurorehabilitation Therapies in Stroke (422092)

UPCOMING GRANT DEADLINES

- First of the month – CWRU CTSC Core Utilization Pilot Grants
- Sept 12 – VA RRD SPiRE Applications
- Sept 13 – VA BLRD/CSRD Merit, CDA, Pilot Applications
- Sept 17 – CDMRP Parkinson's Research Program (PRP) Pre-Application
- Sept 19 – CDMRP Defense Medical Research and Development Program (DMRDP) Pre-Application
- Sept 27 – CDMRP Peer Reviewed Medical Research Program (PRMRP) Application
- Oct 3 – CDMRP Parkinson's Research Program (PRP) Application
- Oct 5 – NIH R01, U01 New Applications
- Oct 12 – NIH K New Applications
- Oct 15 – CDMRP Spinal Cord Injury Research Program (SCIRP) Application
- Oct 16 – NIH R21 New Applications
- Oct 18 – CDMRP Multiple Sclerosis Research Program (MSRP) Application
- Oct 24 – CDMRP Peer Reviewed Orthopaedic Research Program (PRORP) Application
- Oct 25 – CDMRP Orthotics and Prosthetics Outcomes Research Program (OPORP) Application
- Nov 1 – VA BLRD/CSRD LOI for CDA
- Nov 1 – VA CSRD LOI for Clinical Trial Merit
- Nov 1 – VA RRD LOI for Merit, RCS, CDA
- Nov 5 – NIH R01, U01 Renewal, Resubmission, Revision Applications
- Nov 12 – NIH K Renewal, Resubmission, Revision Applications
- Nov 13 – DARPA Young Faculty Award
- Nov 16 – NIH R21 Renewal, Resubmission, Revision Applications

LINKS TO STANDARD ANNOUNCEMENTS

NIH - 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
- 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 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.