

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.

Investigator's Corner



This issue, we will highlight a remarkable training program completed by Dr. Jeffrey Capadona and team

This summer, [Dr. Jeff Capadona](#) and his team, including [Dr. Andrew Shoffstall](#) and graduate student Griffin Rial, completed a competitive training program for [I-Corps@Ohio](#), a statewide program to assist faculty and graduate students from Ohio universities and colleges to validate the market potential of their technologies and assist with launching startup companies. The goal of I-Corps@Ohio is to bridge the gap between academia and industry, while training faculty and students in entrepreneurship and innovation.

Dr. Capadona and team discovered that I-Corps teaches you how to think differently. The training is not focused on your technology, but instead on future development and commercialization. Through their Customer Discovery Process, they teach a data driven method to help the team understand their potential customer's needs and how their technology solution fits those needs, as well as provide a blueprint on how to determine market size and competitors.

HOW TO APPLY

An I-Corps@Ohio team consists of at least 3 participants fulfilling the following 3 roles:

- Principal Investigator(s)
- Entrepreneurial Lead(s) – Two EL's are recommended
- Executive/Entrepreneurial Mentor(s)

The [proposal submission process](#) consists of 4 steps:

1. Mandatory discussion with the appropriate TTO representative at the PI's institution
2. Team registration and completion of an online executive summary questionnaire (Jan)
3. Full Proposal submission (Feb - by invitation only)
4. Team interview by program administrators (Mar)

TIMELINE

April	Orientation (1 day)
May	Launch Week in Columbus
May-July	Weekly webinars to present progress and receive training, such as communication strategies
July	Final presentation and a 2 minute "commercial"

THE TEAM



Jeffrey Capadona, Ph.D.

Principal Investigator

- Research focuses on identifying therapeutics and materials to improve integration of neural implants into the brain.
- Pioneered research leading to development of the technology

Andrew Shoffstall, Ph.D.

Entrepreneurial Lead

- Studying biomaterial modifications to reduce inflammation associated with neural implants.
- Strongly assisted in customer discovery process



Griffin Rial, MS

Entrepreneurial Lead

- Doctoral Candidate
- Studying anti-inflammatory therapies for neural devices
- Led the customer discovery process

Steve Fening, Ph.D.

Executive Mentor

- Head of Coulter Program at CWRU
- Personal experience in startup company
- Mentored Entrepreneurial Leads throughout the customer discovery process



Andy Jarrell, MBA

Executive Mentor

- Licensing Associate at CWRU
- Mentored team in customer discovery with a focus on understanding and developing solid IP

THE TECHNOLOGY AND MARKET POTENTIAL

The technology: OccuBLOCK – A medical device coating designed to reduce inflammation.

Initial hypothesis: Our intracortical microelectrode coating will help patients and researchers who want to use and develop brain computer interface technologies by reducing inflammation around the device and extending device longevity and preventing failure.

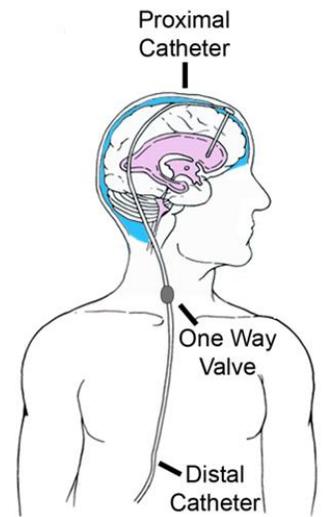
Potential applications: Coating microelectrodes used in brain-computer interface (BCI) or deep brain stimulation (DBS).

Limitations: Patient population for BCI is small. Inflammation is not a major clinical issue with DBS.

Solution: The team quickly learned a keyword used in I-Corps training – PIVOT – meaning to stop at some point in the development of your technology and choose a different route. I-Corps mentors suggested a pivot to focus on hydrocephalus shunts. There are approximately 40,000 ventriculostomy surgeries per year, many on newborns, to release the build-up of fluid in the brain using a tube (shunt) inserted through a small hole in the skull, which have a 50% failure rate within 2 years of surgery. OccuBLOCK has the potential to reduce occlusion rates and re-hospitalizations.

Approximately 40 full proposals were submitted, 20 of which were accepted. The \$15,000 grant for each team paid for travel and a laptop for the interviews conducted over eight weeks. In total, 100 interviews were conducted by Griffin with patients, researchers, neurosurgeons, intellectual property lawyers, the Hydrocephalus Association, medical device manufacturers, and many more, both in-person and remotely.

I-Corps participants gained leadership experience and networking skills. While going through the process of setting up interviews, Griffin learned that an email subject header with "Student project" garnered more responses. In the end, many teams pivoted and needed more bench testing and, therefore, were not ready for commercialization. Dr. Capadona and team learned they needed to modify the application of OccuBLOCK to increase their market size and plan to continue testing their technology. All projects that continued after training will be submitting a semi-annual report.



FUTURE FUNDING OPPORTUNITIES

The I-Corps@Ohio program is conducted annually and could be a step to applying for a [Case-Coulter](#) grant. Also, CWRU offers a cost match of grant funds through the [CWRU Technology Validation & Start-up Fund Program \(CTP\)](#).

FDA & Quality Fast Facts

LABELS AND LABELING: MEDICAL DEVICES AND DRUGS



Federal regulations require that manufacturers/marketers of commercially approved medical devices and drugs label each unit sold; the **regulations also apply selectively to non-commercial or investigational devices and drugs**. It is important for you to know which of these regulations apply to your technology prior to obtaining IRB approval and applying to the Food and Drug Administration (FDA) for an Investigational Device Exemption (IDE) or Investigational New Drug (IND).

Title 21, Chapter 9, Subchapter II: Definitions, (§ 321) Section 201 of the Federal Food, Drug and Cosmetic (FD&C) Act distinguishes between 'labels' and 'labeling.' These terms are related but are not interchangeable.

- **Section (k) defines LABEL** as a clearly legible display of written, printed, or graphic matter upon the immediate wrapper or container of any article. Package liners are excluded.
- **Section (m) defines LABELING** as that which deals with the label on the device, as well as any descriptive and informational literature that accompanies the device. This would include the 'label' that would be affixed to any article (or its container or wrapper), and the information accompanying the article. The term "accompanying" is interpreted liberally to mean more than physical association with the product: it extends to posters, tags, pamphlets, circulars, booklets, brochures, user manuals, instruction books, direction sheets, fillers, etc.

LABELING AND ADVERTISING

The distinction between labeling and advertising can be confusing. Both are used for a similar purpose, which is to provide information about the product. Thus, according to an appellate court decision, most, if not all advertising, is labeling. The term 'labeling' is defined in the FD&C Act as all printed matter accompanying any article and does not exclude printed matter that constitutes advertising.



WHERE DO I TURN FOR HELP?

Click [here](#) to read the pertinent sections of the referenced FD&C Act.

Other Federal oversight bodies, the local IRB, and LSCVAMC also have guidelines and procedures that direct labeling in human subjects research. The APT Center can help you meet these requirements. Contact Jen Wall, PAHM, CCRP, at (216) 791-3800 ext. 3578 or Jennifer.wall@va.gov with questions.

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 [Kath Bogie, DPhil](#), who had been promoted to the rank of **Associate Professor** in the Departments of Orthopaedics and Biomedical Engineering at Case Western Reserve University (CWRU). Dr. Bogie is the APTC's Wireless Health Maintenance and Monitoring Research Area Lead, as well as the Director of the Additive Manufacturing for Biotechnology Core at CWRU that houses the 3D-Bioplotter.

Due in part to the clinical research conducted by [Drs. Aasef Shaikh](#) and [Mark Walker](#) related to Parkinson's Disease and movement disorders (along with the many Neurologists that offer specialized treatment), the Louis Stokes Cleveland VAMC has been designated a [National VA Parkinson's Disease Consortium](#) center. The 51 established Consortium Centers ensure accessibility and continuity of specialized care for veterans afflicted by parkinsonism, regardless of locality.



National VA Parkinson's Disease

C O N S O R T I U M

Education • Collaboration • Advocacy



Congratulations to [Kelsey Potter-Baker, PhD](#), who was chosen for the Jayanthi Lectureship at the Academy of Spinal Cord Injury Professionals conference in September for her presentation ***It's All in Your Head: Driving Cortical Plasticity to Improve Muscle Contraction Below the Level of Injury***. The Jayanthi Charitable Foundation supports this distinguished lectureship at each annual conference. One of the objectives of the foundation is to encourage and support the dedication of professionals to the care of individuals with disabilities.



Congratulations to all APTC investigators and staff that participated in the **VA Innovation Demo Day**. Out of the 14 projects presented from our Medical Center, 5 were from the APTC! Dr. Ronald Triolo and team's **Self-Leveling Walker for Safe Stairclimbing (below, right) was voted the AUDIENCE FAVORITE** out of more than 90 innovations, with 23% of the overall audience vote. The walker is aimed at helping Veterans with orthopedic injuries or movement difficulties to independently and safely climb stairs, while minimizing home adaptation costs and possibly reducing rehabilitation training time.



APTC projects presented:

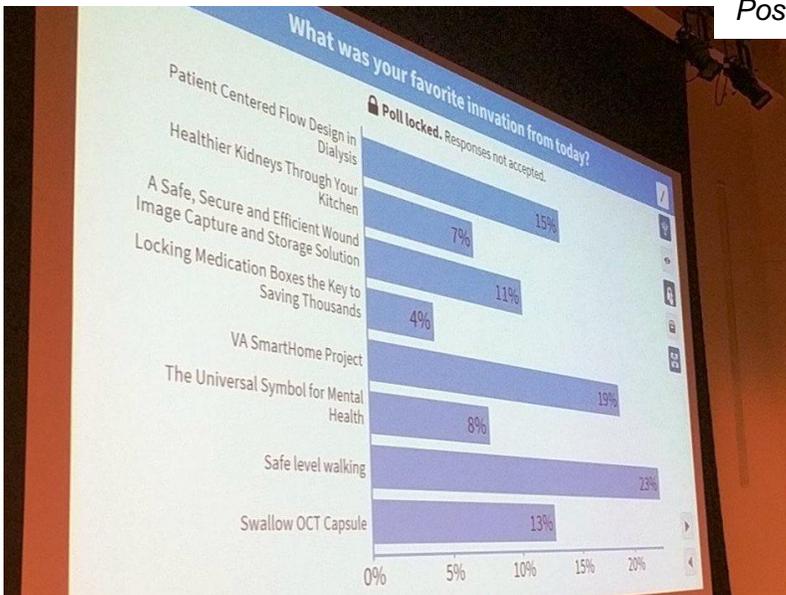
Frank Jacono, MD
Measuring Blood Pressure in the Home Environment

Frank Jacono, MD and Musa Audu, PhD
(presented by Dr. Frank Jacono)
Fall Sensor

M. Kristi Henzel, MD, PhD
Intervention to Prevent Power Wheelchair User Foot and Leg Injuries
(Watch the above 3 presentations [on YouTube](#) at 2:42, 2:47:50, and 2:53, respectively.)

Ronald Triolo, PhD
(presented by Stephanie Bailey)
A Self-Leveling Walker for Safe Stairclimbing
(Watch this presentation [on YouTube](#) at 2:33.)

Kevin Foglyano, MS
Development of Cycling Program for Patients with SCI
Poster presentation



**Innovators
Network**

To learn more about Demo Day 2017, check out the [VA Research Currents story](#).

INSIGHTS FROM THE APT-SIP RECIPIENTS

The inaugural APT-Summer Internship Program (APT-SIP) ended in August. Read what our 4 interns had to say about their 10-week experience in the APTC.

Keying Chen (Mentor: Dr. Evon Ereifej)

I realize that I learned a lot in 2 months - not only the science, but also the way to present the work. Based on the data we collected, I gave a poster presentation at a SOURCE session. My work interested a researcher in the brain-computer interface field who would like to **build future collaborations with our lab**. In addition, I presented at the Neural Engineering Center meeting, and my **abstract was accepted** to the [Biomedical Engineering Society 2017](#) conference. This APT-SIP experience was amazing and wonderful, and will allow me to step further into my academic field.

Keith Dona (Mentor: Dr. Jeffrey Capadona)

I believe my experience this summer has been invaluable to my development as an engineer and a professional. I enjoyed learning more about the operation of the APT Center and also the VA Hospital on the whole. I faced some setbacks in my own project, but was able to reach a strong completion point by the end of the summer. I am **happy with my ability to complete my work while given some autonomy** and look forward to continuing this work throughout the school year. I plan to use my experiences in the APT-SIP to **expand my resume and gain employment** in the coming year.

Fangze "Helen" Liu (Mentor: Dr. Ronald Triolo)

I think I achieved exactly what I had wanted to achieve at the beginning of the summer. I took the lead on part of a project and worked on it independently, with the help of Dr. Triolo, Mike Miller, and others at the APT Center. I did not even know I could do that before I started this summer, but now **I have the confidence to continue this project and take on other challenges** in the future. More importantly, this internship showed me why my education is important. It was a **truly inspiring moment** when I watched a paralyzed man stand up from his wheelchair and walk around with the stimulation of implanted electrodes. It was almost magical and I realized that should be my motivation - for magical moments like that to happen and **to really make a difference in someone's life**. I think that is the most valuable thing I learned all summer.

Joshua Rosenberg (Mentor: Dr. Matthew Schiefer)

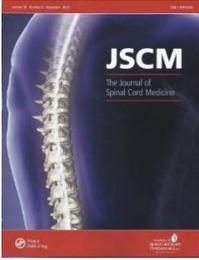
During my time at the APT Center, I worked with Dr. Matthew Schiefer to make a model of sensory axons that could be used to refine and optimize electrical stimulation parameters in his obesity study. Throughout the course of this project, I had the opportunity to **learn to use software such as Maxwell Electronic Workbench** and how to **utilize a supercomputing cluster for computational problems**. I enjoyed my time in the APT-SIP and I hope to continue this project in the fall semester.



(L-R) Dr. Evon Ereifej, Dr. Brooke Odle, Helen Liu, Joshua Rosenberg, Vi Huynh, Dr. Matt Schiefer, Alex Wolkoff, Keying Chen, Keith Dona, Dr. Hamid Charkhkar, Dr. Naji Alibeji

RECENT PUBLICATIONS

Transcranial direct current stimulation (tDCS) paired with massed practice training to promote adaptive plasticity and motor recovery in chronic incomplete tetraplegia: a pilot study



Journal of Spinal Cord Medicine, 2017

Authors: Potter-Baker KA, Janini DP, Lin YL, Sankarasubramanian V, Cunningham DA, Varnerin, NM, Chabra P, Kilgore KL, Richmond MA, Frost FS, Plow EB

This [article](#) presents results of the potential benefit of pairing transcranial direct current stimulation with two weeks of training to improve the effectiveness of rehabilitation interventions on motor function for individuals with SCI.

Using theoretical models from adult stroke recovery to improve use of noninvasive brain stimulation for children with congenital hemiparesis

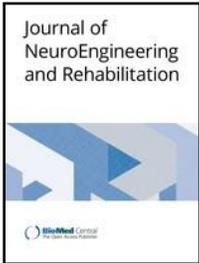
Journal of Neurophysiology, 2017

Authors: Lin YL, Potter-Baker, KA



This [article](#) explores theories about cortical reorganization in both adult and children with hemiparesis and discusses how to improve the approaches of noninvasive brain stimulation to generate optimal motor improvement and development for children with congenital hemiparesis.

Long-term stability of stimulating spiral nerve cuff electrodes on human peripheral nerves



Journal of Neuroengineering and Rehabilitation, 2017

Authors: BP Christie, M Freeberg, WD Memberg, GJC Pinault, HA Hoyen, DJ Tyler, RJ Triolo

This [article](#) presents a long-term examination of implanted spinal nerve cuff electrodes. The authors found the electrodes remained functional in motor and sensory neuroprostheses for 2–11 years after implantation. Non-penetrating spiral nerve cuff electrodes appear to be a suitable option for long-term clinical use on human peripheral nerves in implanted neuroprostheses.

Infection prevention using affinity polymer-coated, synthetic meshes in a pig hernia model

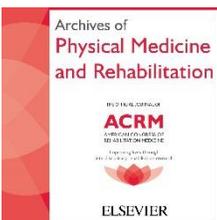
Journal of Surgical Research, 2017

Authors: Blatnik JA, Thatiparti TR, Krpata DM, Zuckerman ST, Rosen MJ, von Recum HA



This [article](#) presents results evaluating mesh coating that uses a cyclodextrin-based polymer to locally deliver a sustained release of the antibiotic vancomycin to a hernia repair site to prevent prosthetic mesh infection, and also allow a durable repair.

Long-term performance and user satisfaction with implanted neuroprostheses for upright mobility after paraplegia: Two to 14-year follow-up



Archives of Physical Medicine and Rehabilitation, 2017

Authors: Triolo RJ, Bailey SN, Foglyano KM, Kobetic R, Lombardo LM, Miller ME, Pinault G

This [article](#) quantifies objective and subjective measures of the technical and clinical performances of implanted lower extremity (LE) neuroprostheses (NPs) for standing, transfers, stepping, and seated stability after spinal cord injury. Results generally remained consistent for 22 participants after an average of 6 years of unsupervised use at home. These findings suggest that implanted LE NPs can provide lasting benefits that recipients value.

UPCOMING GRANT DEADLINES

OCTOBER

5 - NIH: R01, U01 New Applications

11 - CDMRP: Psychological Health/Traumatic Brain Injury Research Program (PH/TBIRP) Preproposal

12 - NIH: K New Applications

15 - VA HSRD: LOI for CDA Applications

16 - NIH: R21 New Applications

20 - CDMRP: Orthotics and Prosthetics Outcomes Research Program (OPORP) Preproposal

NOVEMBER

1 - VA BLRD/CSR, HSRD: LOI for Merit, CDA Applications

1 - VA RRD: LOI for Merit, CDA, RCS Applications

5 - NIH: R01, U01 Renewal, Resubmission, Revision Applications

12 - NIH: K Renewal, Resubmission, Revision Applications

16 - NIH: R21 Renewal, Resubmission, Revision Applications

29 - CDMRP: SCIRP Applications

DECEMBER

1 - VA BLRD/CSR, HSRD: Merit, CDA Applications

1 - VA RRD: Merit, CDA, RCS Applications

27 - CDMRP: Psychological Health/Traumatic Brain Injury Research Program (PH/TBIRP) Applications

JANUARY

8 - CDMRP: Orthotics and Prosthetics Outcomes Research Program (OPORP) Applications

15 - CWRU CTP: Pre-Proposal for CWRU Technology Validation & Start-up Fund Program

LINKS TO ANNOUNCEMENTS

<https://case.edu/research/faculty-staff/tto/technology-validation-and-start-up-fund/>

<http://cdmrp.army.mil/funding/prgdefault>

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.

