In this Issue

Silence is Not an Option .................................................................................................................................................. 1
iTHRIV distributes $200k to Fund Innovative Research Projects .................................................................................. 2
VT’s Kory Trott comments on the Importance of Diversity in Research ......................................................................... 4
iTHRIV’s Recruitment Enhancing Resources Program ......................................................................................................... 5
Inova launches Clinical Trials Diversity and Inclusion Working Group ........................................................................... 7
iTHRIV Under the Microscope: Taryn Pelletier .................................................................................................................. 8
Resources concerning Integrity and Scientific Misconduct .................................................................................................. 9
Silence is not an option...

As we move forward through the new year, now is a good time to look back and reaffirm our commitment to equity.

*iTHRIV Equity Statement, issued June 2020*

Say their names.


Now reflect on how these names represent only a tiny portion of the violence that black and brown communities have been subjected to in the United States. We must come together to dismantle white supremacy. Silence is not an option.

American society is built on systematic racism. This oppression is not a mistake, it is explicit and purposeful. Though some progress has been made, racism continues.

Western medicine is founded on the principle of “first, do no harm” and attracts those called to heal, but it is not immune to racism. Progress in medical care and research has long been at the expense of marginalized people. The brutal practices of J. Marion Sims, the shockingly unethical Tuskegee Experiment, and the disregard for individual consent surrounding the case of Henrietta Lacks are examples. While some reforms have been established to address these events, dramatic and very real healthcare disparities still exist. According to an analysis from the Center for American Progress: In 2017, 12.6 percent of American African children had current asthma compared with 7.7 percent of non-Hispanic white children. 42 percent of African American adults over age twenty suffer from hypertension compared with 28.7 percent of non-Hispanic white adults. 13.8 percent of African Americans reported having fair or poor health compared with 8.3 percent of non-Hispanic whites. The list goes on…

What can we do to be a force for good? How can we join the effort to dismantle a system supported by over 400 years of white supremacy? We must first look to challenge our own perspectives, examine white privilege, listen to previously ignored voices, and change what we can. iTHRIV will begin our evolution from silence, to a strong and clear anti-racist voice.

In an attempt to affect positive change where we can, iTHRIV proudly stands in solidarity with Black Lives Matter and will commit to the following:

- Mentor early career medical professionals to recognize and confront implicit bias in their everyday interactions.
- Support minority led medical research teams and continue to fund community health focused seed grants.
- Continue to engage with community voices, understand what is important to them regarding their health and their needs.
- Bridge the communication gap between community and health researchers through facilitated collaborations and online resources; helping to empower marginalized communities to become health advocates.
- Examine all iTHRIV programs through an anti-racist lens.

The above actions represent the first steps in a new life journey dedicated to anti-racist action. We at iTHRIV are committed to listen, to learn, and to evolve towards a future of equity.
iTHRIV distributes $200k to Fund Innovative Research Projects

by Keith Jones, iTHRIV Communications Coordinator

The integrated Translational Health Research Institute of Virginia (iTHRIV), a National Institutes of Health (NIH)-funded Clinical and Translational Research Award hub, has awarded $200,000 in pilot funding to five multi-institutional research projects. Teams of physicians, researchers and engineers at the University of Virginia, Virginia Tech, Inova Health System, and Carilion Clinic were awarded the funds as part of the iTHRIV NIH-NCATS award UL1TR003015. Support of these early-phase research projects will help accelerate the discovery of potential treatment options for Parkinson’s disease, celiac disease, epilepsy, as well innovation in the fields of telemedicine and pediatric heart transplant. The awarded pilot projects include:

Searching for genetic markers for celiac disease with machine learning

Sana Syed, an assistant professor in the UVA School of Medicine’s department of pediatrics, and Suchitra Hourigan, Inova Children’s Hospital’s vice chair of research and innovation seek to determine if machine learning is useful in diagnosing celiac disease sub-types. Currently, treatment and management of celiac disease involves gluten-free diet and is not intended to help assess the specific for the risk of patients developing other diseases. Syed and Hourigan will investigate gut tissue biopsies as well as genetic markers of patients with celiac disease and type 1 diabetes and/or hypothyroidism. Their aim is to determine whether biopsy or gene markers at the time of disease diagnosis can predict the risk of developing these diseases in the future. The team will utilize machine learning algorithms to analyze multiple datasets. If successful, the team is hopeful that any patterns found will enable them to create linkages between biopsies and unique genes; thus paving the way for improved care of patients with celiac disease.

Measuring medication in patients with epilepsy

In most instances how medications act on the brain to produce their therapeutic effect (e.g., pain relief) are not well understood. Aashit Shah, and a professor of internal medicine at the Virginia Tech Carilion School of Medicine, and Virginia Tech’s Sujith Vijayan, an assistant professor in the Virginia Tech College of Science’s School of Neuroscience will study patients with intractable epilepsy who have been implanted with electrodes to determine the region responsible for their seizures. The team will study signals measured in epileptic patients undergoing intracranial electroencephalography. They will review intracranial electrical signals from various brain regions following administration of medications that work on the brain. Shah and Vijayan hope to improve the understanding of how and where these medications work. They anticipate this can help in the development of new biomarkers for neuroactive drugs, which may improve development of medications in the future.
Studying auditory therapy for Parkinson’s disease

Della Williams, a neurologist at Carilion Clinic and an assistant professor of internal medicine at the Virginia Tech Carilion School of Medicine, has also partnered with Sujith Vijayan, to study auditory therapy for patients living with Parkinson’s disease. Their project seeks to better understand the disease progression and if it can be slowed by providing some background noise to patients as they sleep. Additionally, simple auditory stimulation during sleep may help to improve learning and memory processes.

Designing an interactive training system for pediatric telemedicine cart operations incorporating augmented reality

Elham Morshedzadeh, an assistant professor of industrial design in Virginia Tech's College of Architecture and Urban Studies; Andre Muelenaer, a professor of practice in Virginia Tech’s College of Engineering, a professor of pediatrics for the Virginia Tech Carilion School of Medicine, and a pediatric pulmonologist at Carilion; Wallace Lages, an assistant professor in the School of Visual Arts; and Melinda Schriver, Carilion’s director of digital health, are designing a robust and affordable training program to help improve telemedicine encounters for infants and pre-school children. They’ll seek to provide a robust, feasible, and affordable training program integrating augmented reality, online and hands-on learning experience. The study will hopefully make telemedical encounters vastly more inclusive and efficient.

Defining donor characteristics for pediatric heart transplants

Heart transplantation is the standard of care for pediatric patients with end-stage heart failure or inoperable congenital defects, yet nearly 20 percent of patients with these conditions die while on the waitlist. To help increase the odds of successful pediatric heart transplants, Michael McCulloch, an associate professor and a pediatric cardiologist at UVA Children’s Hospital Heart Center, and Michael Porter, an associate professor of systems engineering in UVA’s School of Engineering and Applied Science, will analyze donor echocardiographic data to identify which donor characteristics contribute to positive heart transplant recipient outcomes.

About iTHRIV

iTHRIV is a cross-state translational research institute which combines the expertise of clinical translational biomedical researchers and data scientists to create infrastructure and investigator resources for using data to improve health across the Commonwealth of Virginia. Partner sites include University of Virginia, Virginia Tech, Carilion Clinic and Inova Health System. iTHRIV is funded by the National Center for Advancing Translational Sciences, part of the National Institutes of Health, through award number UL1TR003015.

For more information about the NIH CTSA program, see: https://ncats.nih.gov/ctsa

For more information about iTHRIV, see: www.ithriv.org

For media inquiries regarding pilot grants please contact Joshua Barney, Deputy Public Information Officer Email | jdb9a@virginia.edu
VT's Kory Trott Comments on the Importance of Diversity in Research

Kory Trott J.D. examines the need for and benefits of diversity in scientific research. Trott is director of the research integrity and consultation program for Virginia Tech’s Office for Research and Innovation. He also educates the iTHRIV Scholars on need for diversity and inclusion within the scientific community.

“Diversity brings new perspectives, ideas, and experiences. But a commitment to diversity extends beyond simply creating a cohort of diverse people. Work is required to foster an environment that provides a forum to openly discuss different ideas, opinions, and beliefs. Without the free exchange of ideas, we limit ourselves to well-worn and familiar paths that are shaped by our own experiences. Debates about how to create spaces that are both emotionally safe and intellectually challenging have been happening on college campuses for decades, but that conversation rarely extends to the research environment.

All too often the voices of people who hail from underrepresented groups are marginalized in the scientific discourse. This perpetuates perceptions that the contributions of women, minorities, and LGBTQ people are somehow less significant than the contributions of other researchers. A limited exchange of ideas also hinders our ability as a university to address fundamental scientific questions and pressing societal challenges. Debate inspired by diverse perspectives can be a catalyst for innovation.

Virginia Tech values collaboration and partnerships, guided by open expression, self-awareness, and mutual respect. We can all help to realize that aspiration by being more open to ideas that challenge us to walk new paths. Not only will that help create a more welcoming environment, but it will also help make Virginia Tech an even more successful research institution.”
iTHRIV’s Recruitment Enhancing Resources Program

by Kris Miller, iTHRIV Partnership Manager

The integrated Translational Health Research Institute of Virginia (iTHRIV) team is committed to increasing the integration of underrepresented populations in research. To that end, iTHRIV has launched the Recruitment Enhancing Resources Program (RERP). The iTHRIV Hub Capacity Core, under the leadership of Christopher Kramer, MD and James Nataro, MD will lead this effort in collaboration with the Clinical Research Access Committee (C-RAC). Together, these groups will work closely with the Community and Collaboration Core to ensure that information on clinical research and clinical trial opportunities are disseminated throughout the local community, especially throughout minority groups and rural populations. iTHRIV seeks to facilitate inclusive, collaborative research in partnership with our diverse, often underrepresented, communities in Virginia.

The overall purpose of the RERP effort is to improve diversity in clinical research. According to Kramer “to provide resources for researchers at any of the iTHRIV institutions to enhance recruitment in clinical trials with a primary goal of improving the representation of underrepresented minorities, the elderly, rural populations, and pediatric populations in clinical trials across all participating institutions”. To accomplish this, researchers will be directed to teams who can answer general recruiting questions, along with several services specifically aimed to support integrating diverse populations into translational health research.

The assistance is designed to be comprehensive in scope; the RERP will provide educational, consultative, and financial resources. RERP will: 1) facilitate educational opportunities to help researchers learn skills and techniques to recruit and work with diverse populations, 2) conduct consultation services to discuss ideas relevant to individual studies, and 3) provide an application process for researchers to request financial resources. “The funds will help cover costs of transportation, housing, etc. for research participants that otherwise would not be able to engage with clinical trials” states Kramer. Funded projects will receive up to $5,000 worth of resources. The application process is now open and iTHRIV will continue to accept applications throughout the year. Resources can be dedicated to: language and translation service, transportation assistance, and community engaged studios.

The RERP application will enable researchers to request resources which will be provided by the iTHRIV CTSA.

List of possible resources:

- Language services and translation of materials
- Transportation assistance
- Lodging
- Community Engaged Studios (study ideas, recruitment innovation and protocol assistance, dissemination planning)
Other iTHRIV resources you may find useful:

- Study Design - [Biostatistics, Epidemiology, Research and Design](#) (BERD)
- Proposal Development
- Trial Innovation Network (TIN)
- Protocol support for inclusivity of underrepresented populations
- Educational Articles, Webinars and Podcasts
- Events and Workshops

If you are a researcher at an iTHRIV institution and would like to learn more about resources for facilitating inclusive research, please contact [Kris Miller](#).
Inova launches Clinical Trials Diversity and Inclusion Working Group

by Stephanie Van Bebber, Sr. Director, Inova Schar Clinical Trials Office Inova Fairfax Hospital - Inova Schar Cancer Institute

Events over the summer of 2020 shook our country and led to an outpouring of commitment across organizations to intentionally address systemic issues around race and diversity. At the Inova Health System, a multi-disciplinary group of clinical research team members came together to ask what role we might have in our field of work to engage in thoughtful actions towards inclusivity.

This group quickly assembled research staff and other related team members to discuss next steps and identify actionable items focused on our own day-to-day operations and within the framework of clinical trials. As therapeutic responses can differ across age, ethnicity and gender, including diverse patient populations in clinical trials is critical to understanding potential “real world” settings where therapies will be used. This group is developing actions to address the overarching question: How do we, at Inova, increase the diversity of participants in clinical research studies we manage?

One of our first actions has been to gather baseline data on our current enrollments to clinical research in order to benchmark our “diversity starting point.” As a group we have discussed and continue to analyze how this compares to the overall general patient population served by our institution. We are also seeking to identify barriers and facilitators to diversifying participation in clinical trials with a focus on our own day-to-day operations and institutional barriers. In contrast to more wide ranging and well-known barriers such as the increasing number of eligibility criteria that often limit diversity we believed that our own impacts could be greater if we focused on things that are to some extent within our control. As a result of these initial discussions we are entering 2021 with a focus on educating our research staff to be better able to identify, inform and enroll diverse populations.

Already these discussions have alerted our clinical research teams of things we can immediately improve. We have created a list of research staff who are Inova-trained interpreters, had research staff seek training to be an interpreter and have department requests for the technology to support enrolling our non-English speaking participants to clinical trials. Probably the most important signal however is that more than 50 individuals have attended the meetings to date and we have had individuals asking, “Is the diversity/inclusion committee something I can join?” The answer is YES!
Under the Microscope

iTHRIV is relies on its dedicated workforce to ensure operations run smoothly. With cross Commonwealth institutions, it’s important to recognize the individuals contributing behind the scenes to iTHRIV’s success. In this issue we meet Virginia Tech’s Taryn Pettetier:

Taryn Pelletier, MHA, is the Health Sciences Program Coordinator for Virginia Tech’s Health Sciences and Technology campus located in Roanoke. Taryn joined Virginia Tech in 2017 and brings years of experience in administration. As part of iTHRIV, she serves on the Workforce Development Core, coordinates the Scholar Career Development Program for Virginia Tech, and manages the iTHRIV Portal – a translational research resource hub that is shared between iTHRIV partners to increase efficiency and ease of collaborative, multi-institutional research projects. Taryn is passionate about the future of the greater Roanoke Valley and serves on the Experience Advisory Committee for young professionals. In her free time, she enjoys trying new local restaurants, indoor rock climbing, and long walks with her husband and crazy dog, Piper.
Resources concerning Integrity and Scientific Misconduct

by Medard Ng, iTHRIV Research Quality Manager

iTHRIV’s Director of Research Quality, Medard Ng has collated helpful Scientific Integrity resources to assist researchers.

Per the NIH, research integrity includes: (1) the use of honest and verifiable methods in proposing, performing, and evaluating research; (2) reporting research results with particular attention to adherence to rules, regulations, guidelines; and (3) following commonly accepted professional codes or norms. Research misconduct (42CFR93) is defined as fabrication, falsification and plagiarism (FFP).

To help investigators understand these important topics, the following resources are available in the iTHRIV Research Concierge Portal.

To learn more on this topic, it is suggested that investigator starts with a lively presentation by the late Dr. Schachman on a historical perspective of the government’s involvement in issues of misconduct in science, starting with congressional hearings on fraudulent research. Dr. Michael Lauer (NIH's Deputy Director for Extramural Research) discussed how institutions can promote a culture of research integrity. In the 'All About Grants' Podcast on Research Misconduct, Dr. Christine Ring (NIH Research Integrity Officer) discussed what is meant by fabrication, falsification, and plagiarism, how it affects the integrity of NIH supported research, what to do if you suspect research misconduct, and much more.

Last, but not the least, be sure to check out the resources (education resources, compliance program) from your own institution: the University of Virginia, Virginia Tech, Carilion Clinic, and Inova Health System.

For additional queries please feel free to reach out to iTHRIV.