



Hackensack
Meridian Health
Office of Research
Administration

RESEARCH ROUNDUP

OCTOBER 2021



MESSAGE FROM THE CHIEF RESEARCH OFFICER

Research at Hackensack Meridian Health continues to advance science in the interest of patients - not only ours, but also those across the globe.

Looking at the last quarter's updates, it's easy to see how scientists are pushing the envelope in everything from COVID-19 to pediatrics, from tuberculosis to cancer immunotherapies.

We are proud to be so versatile, and cutting-edge, at times when it's most needed.



NOTE FROM THE VP

It's our researchers who are continuing to make inroads in infectious disease as well as genomics studies.

Even as COVID-19 has resulted in some changing strategies, the science has "upped the ante" to continue making a difference where it is most needed.



HMH RESEARCH NEWS

Hackensack Meridian CDI Scientists Awarded NIH Grant for \$6.4 Million to Pursue TB Vaccine



Scientists from the Hackensack Meridian Center for Discovery and Innovation (CDI) were awarded \$6.4 million from the National Institutes of Health (NIH) to pursue an innovative new tuberculosis (TB) vaccine concept.

The team proposes to improve BCG by engineering it to stimulate the development and communication of B cells, an important part of the immune system. With this strategy, the researchers hope to develop a second-generation TB vaccine which provides reliable protection from new infections and can even help to cure existing TB infections by complementing antibiotic therapy. The novel approach could prove to be a critical breakthrough in the infection, which kills 1.4 million annually, and mostly in the developing world. [READ MORE](#)

KEEP GETTING BETTER

HMH Doctors Develop New Model to Help Clinicians Predict Risk of Death in Patients Hospitalized with COVID-19



Researchers from Hackensack Meridian University Medical Center and Berry Consultants, LLC, Austin, Texas have developed a new model to help clinicians predict the risk of death within 40 days in patients who are hospitalized with COVID-19 infection.

A new paper describing this retrospective, observational, multicenter cohort analysis, "[Development and validation of a prognostic 40-day mortality risk model among hospitalized patients with COVID-19](#)," was recently published in [PLOS ONE](#), a peer-reviewed, open-access scientific journal. The model considers six risk factors: age, respiratory and oxygenation rates, and preexisting conditions such as high blood pressure, coronary artery disease, or chronic kidney disease that play a role in COVID-19 deaths. [READ MORE](#)

HUMC Neurologists Publish Research Identifying New Form of ALS

Four clinicians from the Department of Neurology at Hackensack University Medical Center, and from the Division of Genetics, Department of Pediatrics at the Joseph M. Sanzari Children's Hospital at Hackensack University Medical Center, participated in research that led to the discovery of a new and unique form of juvenile amyotrophic lateral sclerosis (ALS).

This newly discovered form of ALS begins in childhood, worsens more slowly than usual, and is linked to the SPTLC1 that manufactures a type of lipid called sphingolipids.

News of this research comes a year after the establishment of a multidisciplinary [Amyotrophic Lateral Sclerosis \(ALS\) Affiliated Clinic Program](#) which brings together all of the specialists a patient and family may need in one clinic during one visit at Hackensack Meridian Hackensack University Medical Center. The new ALS Affiliated Clinic is the second such program established in the Hackensack Meridian Health network; the other is located at Hackensack Meridian Jersey Shore University Medical Center.

[READ MORE](#)

Joseph M. Sanzari Children's Hospital Becomes First in New Jersey to Implant Responsive Neurostimulation Device in a Pediatric Patient with Epilepsy

Pediatric neurosurgeon Arno Fried, M.D. has implanted the first responsive neurostimulation (RNS) device in a patient to treat drug-resistant focal epilepsy. The procedure was performed at Hackensack Meridian Joseph M. Sanzari Children's Hospital at Hackensack University Medical Center.

Epilepsy is a neurological disorder caused by abnormal electrical activity in the brain. This abnormal electrical activity results in recurrent seizures that can range in severity and frequency. The patient, who is 16 years old, and had been treated for epilepsy for two years by Eric Segal, M.D., co-chief of Epileptology, did not see significant improvement in seizures after trying multiple anti-seizure medications. [READ MORE](#)

Research: Nasal Spray Seizure Rescue Medication Safe and Effective When Used with Oral Medication

[Eric Segal, M.D.](#), co-director of Epilepsy at Joseph M. Sanzari Children's Hospital at Hackensack Meridian Children's Health has published new research showing that diazepam nasal spray*, which uses a type of medication called a benzodiazepine, is safe and effective for emergency seizure cluster treatment in patients who are already taking oral benzodiazepines.

The research was published in *Epilepsia*, the official journal of the International League Against Epilepsy.

[READ MORE](#)

CDI Director Perlin Named to Modern Healthcare's Class of Top 25 Innovators



Hackensack Meridian *Health* is proud to announce that David S. Perlin, Ph.D., chief scientific officer and senior vice president of the Hackensack Meridian Center for Discovery and Innovation (CDI), has been recognized by *Modern Healthcare* as one of this year's Top 25 Innovators. The complete ranking is featured in the August 16 issue of MH magazine, and profiles of the honorees are available at [ModernHealthcare.com/awards/top-25-innovators-2021](https://www.modernhealthcare.com/awards/top-25-innovators-2021). The nomination of Perlin focused on the CDI's achievements during the COVID-19 era, which included testing, tracking, and therapeutic breakthroughs to benefit patients across Hackensack Meridian *Health*, New Jersey's largest and most comprehensive health network.

[READ MORE](#)

New Review of Metaphyseal Cones and Sleeves in Revision Total Knee Replacement Published in JAAOS

A new comprehensive review article by orthopedic surgeons from Hackensack Meridian Jersey Shore University Medical Center, Hackensack University Medical Center, Hackensack Meridian School of Medicine, Brigham and Women's Hospital, and the Cleveland Clinic, "[The Use of Metaphyseal Cones and Sleeves in Revision Total Knee Arthroplasty](#),"¹ was published in the September 2021 edition of JAAOS®, the Journal of the American Academy of Orthopedic Surgeons.

The article presents different design philosophies, types of manufacturing, clinical outcomes, and the versatility and interchangeability of varying cones and sleeves with different total knee arthroplasty systems.

[READ MORE](#)

Tracking COVID-19's Next Chapter

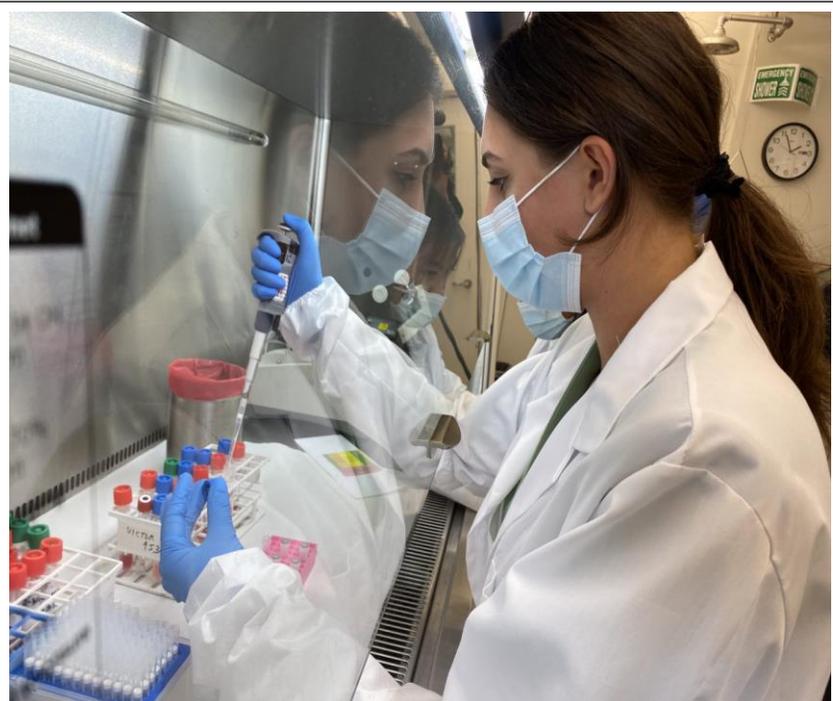
The team of experts at the Center for Discovery and Innovation continue to use their skill set to better understand SARS-CoV-2 - and help everyone in the fight against an ongoing global pandemic.

This science includes tracking variants like those with the highly contagious "Delta" mutation, as the COVID-19 pandemic continues.

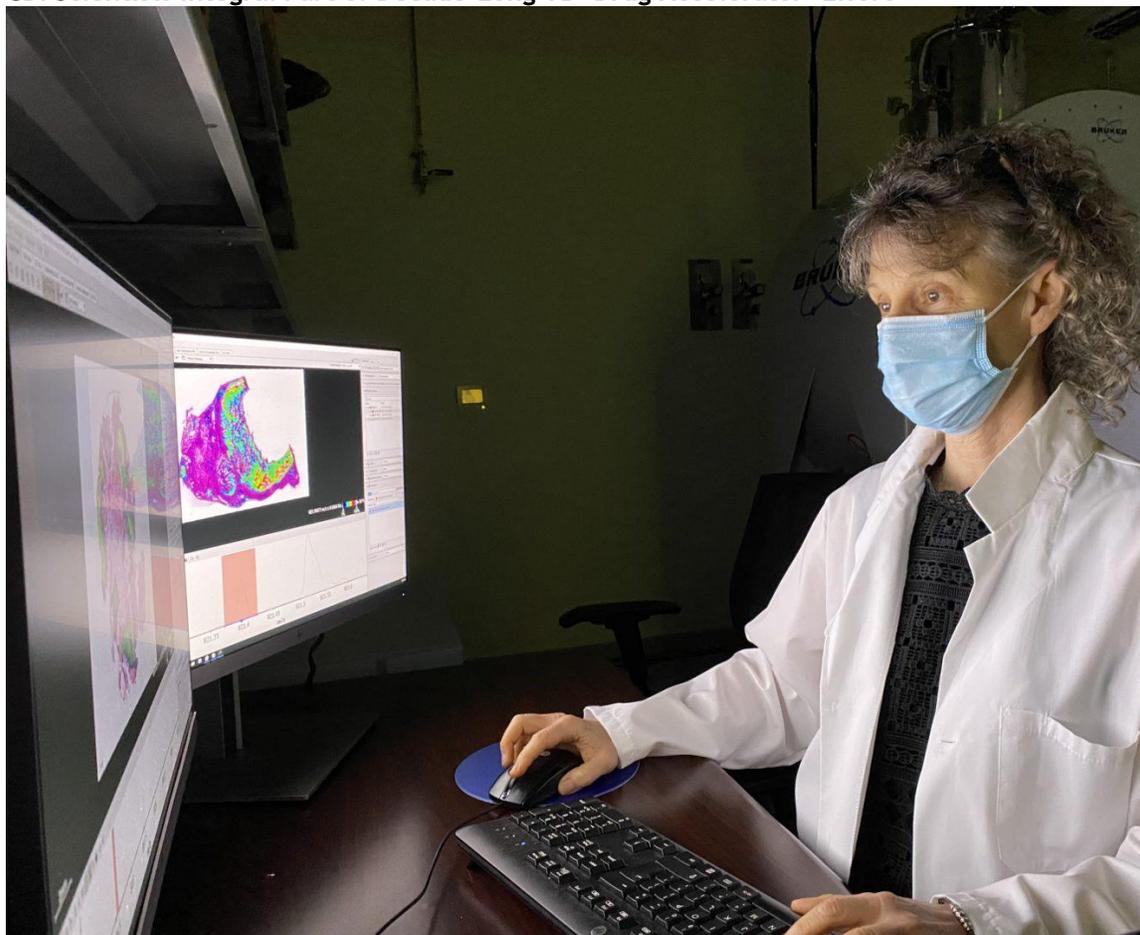
It also included some real-time tracking of "breakthrough" cases - the statistics of which were cited by the State of New Jersey at one of its regular COVID-19 update conferences. New York regional media outlets profiled some of the CDI's discoveries well into the summer of 2021, as COVID-19 continues to hang around past the 18-month mark.

Find some of the highlights of this coverage linked here:

[READ MORE](#)



CDI Scientists Integral Part of Decade-Long TB ‘Drug Accelerator’ Effort



Tuberculosis may not grab headlines in the developed world, but in the developing world it continues to kill an estimated 1.4 million people each and every year. The scourge has proven exceptionally stubborn to treatments which have successfully pushed back what used to be a rampant killer in Europe and North America.

But a core group of experts including scientists and pharmaceutical leaders have come together to try to “move the needle” when it comes to this dreaded disease over the last decade.

Known as the TB Drug Accelerator, it was started in 2012, and is supported by the philanthropy of the Bill and Melinda Gates Foundation.

The Hackensack Meridian Center for Discovery and Innovation (CDI) is part of this ongoing effort. In particular, the work of Véronique Dartois, Ph.D., a member of the CDI, plays a key role in the TBDA’s strategy: discovering how prospective drugs reach the location of infection in the body, and help wipe out the disease.

Dartois is one of the authors of [a new paper in *Nature Medicine* entitled “The Tuberculosis Drug Accelerator at Year 10: what have we learned?”](#)

The paper is a retrospective about drug combinations, therapeutic strategies, and the interagency cooperation between the worldwide partners.

[READ MORE](#)

New Case Study Finds Need to Incorporate Speech-in-Noise Testing in Pediatric Hearing Test Battery

Authors from the Center for Audiology at Hackensack Meridian JFK Johnson Rehabilitation Institute present case of young boy with normal hearing who had difficulties in real-world listening conditions

“Incorporating Speech-in-Noise Testing in the Pediatric Test Battery,” supports the need to include a signal-to-noise ratio loss screening tool as part of standard pediatric hearing testing. In the article, audiologists from Hackensack Meridian JFK Johnson Rehabilitation Institute’s Center for Audiology present the case of a boy with normal hearing who had difficulties in how he performed in complex, realistic listening conditions over the course of several years while his hearing and other abilities were being evaluated.

Signal-to-noise ratio (SNR) is the measurement used to describe how much desired sound is present, as opposed to unwanted sound, in the environment.

The “routine” audiological battery administered by audiologists does not typically include a screening tool to identify SNR loss, which can lead to further evaluation. The child in this case did not initially get screened for SNR ratio.

[READ MORE](#)



REGULATORY & PROCESS CHANGES & REMINDERS

OCTOBER 2021

Reminder about Research Reviewed by an External IRB:

Researchers must provide all initial and continuing review approval letters to Elaine Mordecai and Dawn DeCicco for research reviewed by an external IRB (i.e. WIRB, NCI CIRB, Advarra, Georgetown IRB, etc.). Sharing these documents with them as soon as possible will enable eResearch to be updated in a timely manner and ensure that we are maintaining accurate records. This is a necessary step for compliance purposes. Questions? Please email hmhird@hmhn.org.

Research Administration Role/Position Updates:

Yael Kramer, M.S. was promoted to Director of Network Biorepository Operations. The Office of Research Administration congratulates her on her new role.

Simon Gelman, M.S., Ph.D. joined the HMH biostatistics team. Originally from the Ukraine, Dr. Gelman immigrated to the U.S. at 16 years old. He earned both a B.S. and a Ph.D. in Biology from Yeshiva University and University of Maryland - College Park, respectively. He completed his post-doctoral fellowship at Albert Einstein College of Medicine and then joined Psychogenics, a CRO that specializes in pre-clinical drug development. He spent almost 10 years at the company, ultimately being promoted to Associate Director. However, it became clear to Dr. Gelman that his passion really lies in statistics. He earned an M.S. in Statistics from Montclair University and was hired by HMH shortly thereafter. We welcome Dr. Gelman and are excited to have him on board!

Pre-Registration Form Reminder - How to Avoid Duplicating Forms for the Same Project

This past July, the Office of Research Administration and Research Compliance began implementing the pre-registration form as part of the research application process. The purpose of the form is to expedite the review turnaround time and to boost compliance. For more information about the form, please see the [earlier communication](#).

In recent months, reviewers have noticed that some groups have been submitting duplicate forms for the same project. Please note that only one pre-registration form should be

submitted per project. Below are instructions for returning to a form (so that duplicate forms aren't generated for the same project):

- Click on the link to get to the pre-registration forms: <https://redcap.link/HMHPreRegistrationForm>
- If you are unable to complete the whole form, click the "Save and Return Later" button at the bottom of the page. At that point, a "return code" should pop up on your screen.
- Document the code for your records.
- When you (or a colleague) are ready to continue to work on the form, click on the original link to the pre-registration forms (<https://redcap.link/HMHPreRegistrationForm>). The link will bring you to a clean form.
- At the top right-hand corner of the form, there is a "Returning?" icon.
- Once you click on the icon, you will be asked to provide the code that you received when you saved your earlier form. When you provide the code, it will bring you back to the form for your project. You can add information as needed and either submit it or save it for later.
- If you don't know the return code, the REDCap administrator can find it for you. Please reach out to hmhredcap@hmhn.org with your name, the PI's name, and an approximate date of the original form completion to facilitate the process.
- Once the form is complete, please click "Submit" and the form will be sent automatically to the relevant department reviewers. You should receive a copy of the form to the email provided; if you did not receive a copy of the form, it has not been submitted. The copy will be needed for your eResearch application, if applicable.

Case Report Guidance: IRB Review and HIPAA Compliance

Many journals now require a letter, or other acknowledgement, from an Institutional Review Board (IRB) prior to publication of a case report or case report series. Specifically, they wish to know whether IRB review/approval was obtained or was not required for the described case.

[Here](#) are some FAQs that might shed a little light on what constitutes a case report and what HMH's policy is with respect to IRB review and HIPAA requirements. Please also refer to the [Human Research Protections Program \(HRPP\) SOPs](#), section 25.9 *Case Report Requiring IRB Review*. Please contact hmhirb@hmhn.org with any questions.

Upcoming Education - What's on the Agenda?

Friday, October 22, 11a-12p

Science Friction: What's Slowing Progress in Biomedical Research

Presenter: Richard Harris, Science Journalist and Author

Tuesday, October 12, 1-2p

State of the Science: Generation Z and the Transition to Nursing Practice

Presenter: Kristi Stinson, Ph.D., R.N., Associate Professor and Chair, Undergraduate Nursing, Seton Hall University

[More from the IHS IPE Research Seminar Series](#)

Tuesday, October 22, 12-1p

Feedback from a Chief Editor: Best Practices for Avoiding that Rejection Letter

Presenter: Florian Thomas, M.D., Interim Associate Dean of Faculty & Founding Chair & Professor, Department of Neurology, HMH School of Medicine;

Chair, HUMC Neuroscience Institute & Department of Neurology

[More from the Investigator Training Lecture Series](#)

Thursday, October 28, 10-11a

Preparing for Your Investigator Initiated Research Project: The Protocol, the Consent Form and the Data Collection

Presenters: Elli Gourna Paleoudis, Ph.D., MSc; Anne DeToro, RN, BS, CCRC; Colleen Monaco, MS, MBA; Jasmyne-Rian Charles, MS

*Login information and more details will be distributed through eResearch emails. If you do not receive the emails and would like to attend, please contact Tamara Friedman at tamara.friedman@hmhn.org for the link.



FEATURED RESEARCHERS

OCTOBER 2021



Deborah A. Goss, M.D.
Senior Attending, Pulmonary, Critical Care & Sleep Medicine, Hackensack University Medical Center
Medical Director, Respiratory Care Program, Bergen Community College
Core Assistant Professor, Hackensack Meridian School of Medicine

Dr. Goss is an accomplished physician-scientist; she has a busy pulmonology practice and has served as an investigator on countless studies. But what might be most striking about Dr. Goss: her tireless advocacy on behalf of patients and research subjects. She began her research career by conducting a study in which she intentionally included patients who were normally underrepresented in research. And as a long-time IRB member, she continues to ensure that underrepresented or vulnerable populations receive their fair share when it comes to research. Dr. Goss met with us to share a little bit about her first experiences with research

and why she believes that her involvement in research enhances her clinical work:

As an investigator, you have been the recipient of grants from major pharmaceutical companies, have worked with large medical device companies, and have been involved in innovations in artificial intelligence. Did you always know that you wanted to be a researcher?

I never had this sudden realization that research was what I wanted to do. It was more like it slowly gnawed at me. I was a curious child of a mechanical engineer - interested in cause and effect - but my first encounter with the concept of research was in college. My physiology professor at the small Catholic college that I attended assigned us the task of coming up with our own experiments and then he guided us through the approval and execution process. I had the opportunity to work with equipment that was new to me and conduct an experiment that I had come up with myself. That was the first hint that research might be interesting. But when I enrolled in medical school, it seemed like there were two tracks: the clinical track (M.D.) or the research track (M.D./Ph.D.). I didn't realize that you could be a clinician that also conducts research, that you could use research to inform your clinical work. As a resident, I attended a research lecture series, but I was profoundly sleep-deprived and could barely keep my eyes open for most of the talks. They also didn't seem that relevant to me; after all, I had chosen the path of the clinician, not the researcher. It was not until a presentation by Dr. Sperber about the number needed to treat (NNT) that I perked up. He had let us know that this was an important concept for clinicians, that it would determine whether an intervention would likely benefit a patient or not. That spurred a real interest for me. I discovered that I could read about new practices and techniques and use that knowledge to take care of patients, to be a better doctor. I was able to use research as a reference point against which to measure my work. I could compare my patients' outcomes to those in the research literature and strategize on how to do better. Ms. Barbara Reich and her team have been invaluable in this respect. I still start every project and every paper with a visit to the medical library. In an age of information overload, I am still amazed at how fast and efficient she and her team are.

What were some of your first research projects?

As a resident, I assisted with some retrospective chart reviews early on, but I really gained steam during my fellowship with my early prospective studies. I knew that I wanted to do something in pulmonology and sleep. My first mentors were pulmonologists, Drs. Hormoz and Ashtyani, and my work with them on a paper focused on a new technology now known as CPAP (continuous positive airway pressure) and esophageal pressure monitoring (the precursor to pressure transducers and adaptive ventilation) led to the receipt of the Young Investigator Award and the opportunity to present a paper to the American College of Chest Physicians. It was important to me that my research capture patients that often get excluded from studies, so along with Dr. Abdulla Al-Khan, I looked at the effect of untreated obstructive sleep apnea on the health of the pregnancy. This paper led to an invitation to present my work overseas at an International Sleep Conference and an award from Dr. Guilleminault, a preeminent sleep researcher and pioneer in the field. He subsequently published quite a few papers on the topic of pregnancy and sleep.

I have since continued my work in sleep research, and it has only become more exciting. Because of developments in technology, there are collaborations with many different fields. There are expanding options for patients. My job is to sift through the old and new research, critically evaluate it all, and recommend what looks good for my patients.

You are a long-time member of the Institutional Review Board. At what point did you join the IRB - and why?

As a young researcher, I had a sometimes rocky relationship with the IRB. I would submit a project and then get frustrated when it wasn't approved. I was often unsure of what I needed to do. However, Ms. Cheryl Fittizzi really took me under wing. She provided me with incredibly helpful guidance that made things so much smoother for me. Linda Regensburg also helped me so much. At one point, the Office of Research Integrity was looking for people for the IRB. They tapped me for the role, and I couldn't refuse; they had helped me so much, and I felt that I owed it to them and others to pass along what I knew. At this point, I've been on the IRB for over 10 years, and I try to make a point to provide as much guidance to investigators as possible. I also see that the administration is continually working to make the IRB and the whole Human Research Protection Program better - via accreditation, education (including a lecture series), and more.

Do you have any hobbies or interests outside of medicine?

My 8-year-old daughter and I are involved in the Girl Scouts. I am a Girl Scout co-leader, and as such, I help plan and run the events. Our last event was JEDI training, and our next event is a church tour and pumpkin picking. We also do cookie sales and volunteering. I have also been volunteering for the American Lung Association for many years; we run an annual stair climb to fundraise for research. I am also involved in a consortium that aims to prevent fetal and maternal deaths. Finally, I love teaching - both as part of my job and extra-curricularly - so I regularly go to universities and give lectures to pre-med students on strategies for standardized testing.



FEATURED RESEARCHERS

OCTOBER 2021

The CDI Experts: Butler and His Lab Investigate Blood Aging, Cancer



Blood is made of cells that sustain life, and virtually all biological processes. But as the blood cells start to develop problems over time, the body follows suit. That is aging.

Jason Butler, Ph.D., and his laboratory are looking into the fundamentals of aging at the very foundations of the cardiovascular system - and they are finding new ways to keep that system healthy, with implications for cancer treatments, organ transplants, and many other diseases and their treatments.

“The common denominator for all age-related disease is cardiovascular dysfunction,” said Butler, director of Stem cell Therapeutics at the Hackensack Meridian Center for Discovery and Innovation (CDI), and also an associate professor at the Hackensack Meridian School of Medicine. “The thrust of our work is to make the blood system age healthy... The adage holds true: you’re as old as your arteries.”

The Butler Laboratory was the first to set up their science at the CDI, moving into the Nutley campus in 2018.

But by then they had already made a significant splash into this new understanding of the foundations of the blood system.

“Jason Butler and his team are doing work that has real-world applications in the very near future,” said David Perlin, Ph.D., chief scientific officer and senior vice president of the CDI. “This is exciting work, and he is continuing to push the envelope in a critical discipline.”

Blood’s Beginnings

Butler and colleagues Mike Poulos, Ph.D., and the rest of the laboratory (then at Weill Cornell Medical) published a paper in the *Journal of Clinical Investigation* in 2017 which upended some of the widely-accepted knowledge of hematopoiesis (the creation and maturation of blood cells). The paper showed that aged endothelial cells, those that line the blood vessels and serve as intermediaries between tissues and blood, have a significant influence on stem cells.

For the first time, Butler and colleagues showed that the aging process led to endothelial cell dysfunction that interfered with their instructive capacity to support blood stem cells. Utilizing these findings, they were able to harness the therapeutic application of young endothelial cells to rejuvenate older stem cells. This finding is the foundation of the ongoing work, investigating variations upon the mechanisms within the bone marrow, and the foundational creation of blood cells there. Butler, Poulos, colleague Pradeep Ramalingam, M.D., Ph.D., and the other scientists in the laboratory have developed two models mimicking the aged bone marrow microenvironment, allowing them to use it as a screening system. They can observe and manipulate dynamics and interventions in the aging process in these models.

“The overall goal is to define what goes wrong with the aging vascular system - and correct it,” said Butler. [READ MORE](#)



FEATURED RESEARCH ADMINISTRATOR

OCTOBER 2021



Tracy Micalizzi

Manager, Clinical Research Operations

Tracy Micalizzi is consistent: she finds what she likes, and she sticks with it. She has been involved in clinical research for over 25 years and has been at JSUMC (later HMH) for over 15. If, as some claim, the key to success is grit and persistence, that explains why Tracy now oversees a large team of over 50 HMH employees and contract staff and is held in high esteem by her colleagues. Tracy took some time out of her packed schedule to share a little bit about what she does in her role as Manager of Clinical Research Operations for the network.

You have been involved in research operations for many years now. It looks like you started on this route very early on in your career. How did you get into this field, and what about it kept you there?

One of my first jobs was working for a group of emergency physicians in an urgent care setting. They had opened clinical trials testing various anti-infectives and antibiotics. I served as the study coordinator - I screened the patients, worked with the physicians to obtain consent, enrolled the patients, worked with them through the lifecycle of the study, submitted the data, and met with the sponsor regularly. During my time there, I was able to work on drugs as they went through the pipeline and ultimately got approved. Being able to see the drug go through the process from start to finish so early on in my career held my attention; I wanted to continue to be involved.

Not only have you been in this field for a while, but you have also been at HMH for nearly 15 years now. What kind of changes have you seen over the years in terms of research here at HMH?

The biggest shift in research came as a result of the Hackensack and Meridian merger. Coming together allowed for harmonization of the research process. From a strategic standpoint, we were able to pool our relationships with sponsors, which opened new doors across campuses and enabled us to study new areas of research. But beyond that, we were able to tap into the contracts, budgets, and other ancillary specialists at the Office of Research Administration. Having people who were experts in those areas enabled the clinical team to focus on study start-up and get through the documentation needed to get the project off the ground more quickly. I think that this was really showcased during COVID - our teams were able to change gears at the drop of the hat. Because the research process was more efficient, our team members were able to pivot when needed and get some really meaningful and crucial work done.

Can you share a little bit about what you do in your current role?

On the team member level, I ensure that everyone has what they need to conduct their duties as well as possible. This includes providing everyone with up-to-date training, the right study-specific materials, a workspace, and anything else needed to keep things running. I also make sure that everyone is following SOPs and that new information is shared readily and quickly. At the study level, I work across various therapeutic fields to make sure that we have the resources, locations, and recruitment strategies to execute the studies. I also make sure that the physicians are informed about the research - that they know study enrollment status and where the research gaps are (and what are potential available studies to fill those gaps). I work directly with the sponsors to make sure we're meeting everyone's needs for successful studies.

What are some of the biggest challenges that you see researchers encounter when trying to initiate and run research projects? What are some strategies and resources that they can employ or utilize to overcome these hurdles?

I think that one of the biggest challenges that researchers encounter may be what they don't yet know. While some departments have a strong research program embedded in their cultures, there are other groups for which research is still a bit of an enigma. I would strongly encourage practitioners to wet their feet a little, maybe attend a presentation from the Investigator Training Lecture Series or listen to a beginner presentation available on the website library. They could even invite a member of the Office of Research Administration to speak to their groups about what research is and what it entails. We have a lot of [educational resources here at HMM](#) that could be helpful.

Do you have any hobbies or activities that you enjoy outside of work?

Yes, I enjoy spending time with my two grown children and my husband. Depending on the weather, we like catching ice hockey games or walking on the beach.



QUARTERLY QUESTION

OCTOBER 2021

How often does CITI human subjects training need to be completed?

To answer the question, please click [here](#).

The first person to submit the correct answer will receive a shiny new Hackensack Meridian *Health* mug that can be picked up at the Jurist building at HUMC or mailed to his/her home/site.