



Hackensack
Meridian *Health*

RESEARCH ROUNDUP

FALL 2022



MESSAGE FROM THE **PRESIDENT**

The Hackensack Meridian *Health* quarterly research newsletter has grown by leaps and bounds — and with so much good news to share, we have decided to expand it further. With the help of an editorial board of research leaders, our newsletter is an even more valuable resource.

Ihor Sawczuk, M.D., FACS, President of Academics, Research and Innovation



NOTE FROM THE **VP**

We are proud of the discovery and innovation in the field of research that is occurring in every department across the Hackensack Meridian *Health* system. Learn more in our quarterly newsletter.

Cheryl Fittizzi, RN, MBA, CIP, Vice President of Research and Regulatory Affairs



HMH RESEARCH NEWS



HMH Researchers Publish Important COVID-19 Findings Throughout Pandemic

Hackensack Meridian *Health* researchers have published more than 261 publications on COVID-19, a growing literature contributing to virtually every facet of our knowledge about the virus and how to diagnose, treat, and manage it.

The papers were authored by experts from the Hackensack Meridian *Health* Research Institute's (HMHRI's) diverse network of locations: the 17 hospitals across the network including the three academic centers at Hackensack University Medical Center, JFK University Medical Center, and Jersey Shore University Medical Center; the Center for Discovery and Innovation (CDI); the Hackensack Meridian School of Medicine; and numerous other locations.

The HMH findings appeared in prestigious journals including: *The New England Journal of Medicine*, *JAMA*, *BMJ*, *Lancet Microbe*, *The American Journal of Surgery*, *Pediatrics*, *Journal of Clinical Infectious Diseases*, *Proceedings of the National Academy of Sciences*, *Journal of Oncology*, *American Journal of Cardiology*, *Academic Medicine*, and many others. (continued)

KEEP GETTING BETTER

COVID-19 (continued)

“Our network’s researchers really rose to the occasion when the health challenge of our time appeared with little warning,” said Ihor Sawczuk, M.D., FACS, Hackensack Meridian *Health*’s president of Academics, Research and Innovation, and also associate dean of Clinical Integration and professor and chair emeritus of Urology at the Hackensack Meridian School of Medicine. “Our spirit of collaboration and innovation have provided incalculable benefit to patients in New Jersey - and beyond.”

The publications span the gamut of the COVID-19 experience, including: clinical research on the acute and post-acute treatment of the SARS-CoV-2 virus; clinical trials and novel interventions; infection control; investigating the ins and outs of the new virus; the long-term effects of infection; and the best practices in continuing other care in a changed health landscape.

Physicians, nurses, scientists, and other experts often collaborated across Hackensack Meridian *Health*, and partnered with other institutions, to get the best findings possible.

[READ MORE](#)

HMHRI Garner \$100 Million in Grants in First Year of Operation

The Hackensack Meridian *Health* Research Institute (HMHRI) has successfully secured more than \$100 million in grant funding this year, in the first year of the Institute officially coming together within the state’s largest and most integrated health network.

The \$100 million comes from federal and state funding sources including the National Institutes of Health, the National Cancer Institute, the Department of Justice, and other agencies.

“The Hackensack Meridian Research Institute has done a terrific job to push this health network forward,” said Robert C. Garrett, FACHE, chief executive officer of Hackensack Meridian *Health*. “The dollar amount merely shows how significant the work of experts at our hospitals and at the CDI continues to be, from COVID-19 and into the future.”

“The Institute is already exceeding our ambitious goals,” said Ihor Sawczuk, M.D., FACS, Hackensack Meridian *Health*’s president of Academics, Research and Innovation, founding chair of the HMHRI, and also associate dean of Clinical Integration and professor and chair emeritus of Urology at the Hackensack Meridian School of Medicine. “The importance of our work, and the expertise we’ve demonstrated over the years, has earned the support of public officials and philanthropic donors alike.”

The HMHRI is an academic health ecosystem connecting clinicians, scientists, and educators to respond to the health problems of our time, in real-time - seamlessly and rapidly translating discoveries into novel interventions and therapy

developments. The HMHRI is dedicated to accelerating discovery, innovation, and translation of scientific breakthroughs that address unmet clinical needs, and brings together Hackensack Meridian *Health* hospitals across New Jersey, including three academic medical centers and a teaching hospital; the Center for Discovery and Innovation (CDI); the Hackensack Meridian School of Medicine; and numerous other locations.



CDI Lab Develops Promising New Antibiotic for Resistant Gonorrhea

A new preclinical drug candidate developed by scientists at the Hackensack Meridian Center for Discovery and Innovation (CDI) shows great promise in eradicating the bacteria causing gonorrhea, according to a new publication.

JSF-2659, developed to be administered orally, could be a game changer in treating *Neisseria gonorrhoeae*, which is on the World Health Organization’s global list of “priority pathogens” for its resistance to existing drugs.

“This compound shows great promise, and is addressing an emerging health threat head-on,” said David Perlin, Ph.D., chief scientific officer and senior vice president of the CDI. “We need more drugs, and better drugs. This molecular strategy could also very well have promise for pathogens beyond this one species of bacteria, as well.”

The parent compound JSF-2414 works simultaneously on two molecular targets, making it extra effective at inhibiting the bacteria’s DNA replication, according to the paper in the journal *Antimicrobial Agents and Chemotherapy*, an American Society for Microbiology publication.

The dual-targeting strategy means that more bacteria are wiped out - and the lack of survivors and very low probability of modifying two cellular targets during therapy means less chance for the rise of drug resistance, according to the various CDI models of the drug in action against *N. gonorrhoeae*.

[READ MORE](#)

Study Supports Promise of Innovative Immunotherapy Vaccine for Aggressive Brain Cancer

Researchers from Hackensack Meridian Health's John Theurer Cancer Center participated in a multicenter study showing that a new cancer vaccine more than doubled the survival of patients with recurrent glioblastoma compared to historical controls. The findings suggest the vaccine has promising efficacy, and support its further evaluation in randomized clinical trials. The data was reported in June 2022 in the online journal *Frontiers in Oncology*.

Recurrent glioblastoma (rGBM) is a brain cancer that is notoriously difficult to treat successfully, with an average survival from recurrence of only eight months. Effective chemotherapy is limited by the blood-brain barrier (BBB), and immunotherapeutic approaches such as immune checkpoint inhibitors (ICI) have been largely ineffective in this disease.

This study treated 21 patients with recurrent glioblastoma with a vaccine called Sitoiganap, made from the patients' own tumor tissue, along with the standard anticancer drugs cyclophosphamide, bevacizumab, and checkpoint inhibitors (nivolumab or pembrolizumab), plus GM-CSF (a medication which boosts white blood cell counts). The median time it took for a patient's cancer to progress (progression-free survival) was nine months and the overall survival from study entry was 20 months from the date the patients entered the study. The treatment was very well tolerated, with few side effects.

"The outcomes we observed are excellent for this disease when compared with historical controls, who have an average overall survival of eight months, and progression free survival of only 2.4 months in prior reported clinical trials," said Samuel Singer, M.D., a neuro-oncologist who directed John Theurer Cancer Center's participation in the study. "The findings show there may be a synergistic effect between the vaccine and the other treatments, suggesting that combination therapy may be the best way forward for the use of immunotherapy in people with GBM," Dr. Singer added. [READ MORE](#)

HUMC Receives Funding to Provide AI-Assisted Colonoscopy Technology to Underserved Communities

Hackensack University Medical Center is the only hospital in New Jersey – and the first in the tri-state area – to receive Medtronic's GI Genius™ artificial intelligence, which is AI-assisted colonoscopy technology to low-income and underserved communities. The Health Equity Assistance Program will fund the installation of GI Genius™ modules in the Outpatient Endoscopy and Surgery Department, plus training and ongoing support.

"Hackensack Meridian Health is deeply committed to ensuring that all New Jersey residents have access to high quality, innovative care, regardless of who you are or where you live," said Robert C. Garrett, FACHE, CEO, Hackensack Meridian Health. "We will continue to innovate health care and work diligently to

eliminate unacceptable gaps in outcomes based on race, ethnicity and socioeconomic status."

The GI Genius™ intelligent endoscopy module, authorized by the FDA in April 2021, detects colorectal polyps of varying shapes and sizes automatically in real-time which helps in the early detection of polyps to impact patient care. [READ MORE](#)



NJ's First Dual-Chamber Leadless Pacemakers Implanted at Jersey Shore

"This is incredibly significant as nearly 80 percent of people who receive a pacemaker need a dual-chamber option to pace both chambers on the right side of the heart," said Dr. Mascarenhas.

The cardiovascular team at Hackensack Meridian Jersey Shore University Medical Center recently implanted New Jersey's first dual-chamber leadless pacemaker systems in patients, as part of Abbott's Aveir™ DR i2i clinical study.

People who experience a slower-than-normal heart rate may receive a pacemaker; a small battery-powered device implanted in the chest that delivers electrical impulses via thin insulated wires, called cardiac leads. The leads cause the heart muscle chambers to contract to help restore a normal heart rhythm. Unlike traditional pacemakers, leadless pacemakers are implanted directly into the heart through a minimally invasive catheter-based procedure and eliminate the need for cardiac leads. Nearly two million Americans have a pacemaker implantation.

Electrophysiologist Mark Mascarenhas, M.D., implanted the first dual-chamber leadless pacemakers at Jersey Shore University Medical Center. "Providing this new system is a landmark moment for people requiring assistance to maintain a healthy heart rhythm," said Dr. Mascarenhas. Leadless pacing options have been limited to single-chamber devices until now since synchronization of two leadless pacemakers has been highly difficult to achieve.

Medical device company Abbott designed their i2i technology to provide beat-by-beat communication between two leadless pacemakers, one positioned in the right ventricle and one positioned in the right atrium of the heart. This technology is designed to regulate the heart rate synchronously between chambers allowing for dual-chamber leadless pacing. [READ MORE](#)

JTCC Researchers Report Value of More Efficient Liquid Biopsy Genetic Sequencing Technique for Diagnosing and Monitoring People with Blood Cancers

A study by researchers from Hackensack Meridian John Theurer Cancer Center — part of the Georgetown Lombardi Comprehensive Cancer Center, an NCI-designated Comprehensive Cancer Center — has reported the effectiveness of a liquid biopsy genetic sequencing technique for detecting chromosome abnormalities in the blood of people with certain blood cancers. The technique, called targeted next-generation sequencing (NGS), was as effective as conventional methods, namely bone marrow biopsy and cytogenetic testing, for detecting chromosome abnormalities. Targeted NGS will become the new standard in managing these patients, through a single test adding convenience, while providing all information required to guide therapies. The study was published in the journal *Frontiers in Oncology*.

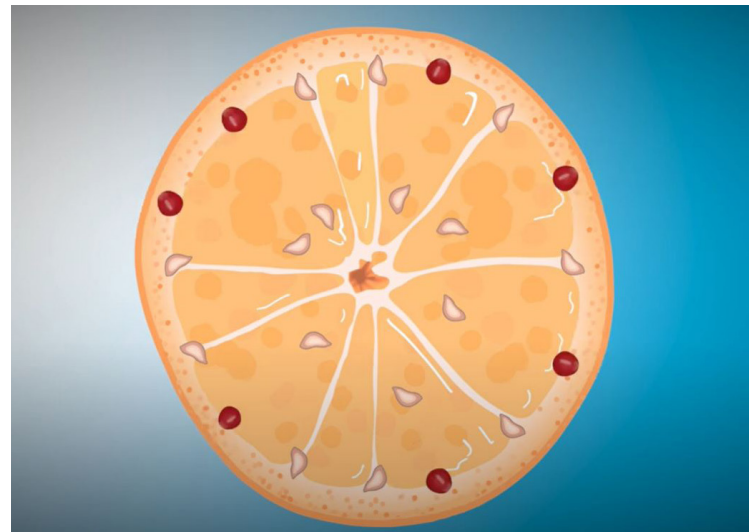
Liquid biopsy is a less invasive method to look for fragments of cancer DNA (cell-free DNA or cfDNA) in the blood, requiring only the drawing of a blood sample. People with blood cancers, such as acute myeloid leukemia (AML), myelodysplastic syndromes (MDS), myeloproliferative neoplasms (MPN), and but also some lymphoid malignancies like CLL, typically have bone marrow biopsies and/or cytogenetic testing of the blood to look for genetic changes that may confirm their diagnosis, predict the behavior of their cancer, help doctors match them with the best treatments, and monitor their progress. Bone marrow biopsy is effective but invasive for patients. Cytogenetic testing is labor-intensive and takes two weeks to obtain results. Whole genome sequencing is expensive and also takes a long time to receive results.

NGS is a newer technique implemented to evaluate structural chromosome changes in blood cancers and can take as few as 5-7 days to provide results. It is more focused and targeted, zeroing in on some 180 DNA mutations involved in cancer, and is more efficient to use. There is a continued need for data to support its accuracy in detecting chromosomal abnormalities in liquid biopsies of patients with blood cancers. [READ MORE](#)

CDI Laboratory Identifies Critical Regulators Controlling T-Cell Homeostasis Which Could Improve Cancer Therapies, Vaccines of the Future

A new publication in a major journal by scientists from the Hackensack Meridian Center for Discovery and Innovation (CDI) could hold the key to better modulating the human immune system to fight cancer and produce vaccines of the future.

The laboratory of Hai-Hui “Howard” Xue at the CDI published the findings of the complex and cascading molecular interactions modulating T-cell immunology in the August issue of the journal *Nature Immunology*.



“This is our second *Nature Immunology* paper from the CDI this year. The initial observation was made eight years ago, and Drs. Qiang Shan (the first author) and Weiqun Peng (our collaborators at the George Washington University) have continuously pursued mechanistic insights since then,” said Xue, Ph.D., a member of the CDI.

“It seeks to understand how T cell homeostasis is regulated beyond the known classical pathways,” added Xue. “The findings indicate that T cells can be induced to cycling while maintaining their naive status. This could change the way we harness the power of T cells heading forward.”

The Xue lab in the two successive *Nature Immunology* publications has focused on a key dynamic of T-cell immunology: the Tcf1 transcription factor and its far-reaching molecular complexity.

Tcf1 is crucial to the immune system’s “memory” in recognizing threats it has already faced before.

The Tcf1 transcription factor essentially “preprograms” a particular type of memory CD8+ T cells, called T central memory (Tcm) cells, prepping them to respond quickly and robustly to known threats, i.e., pathogens that the immune system has seen before, **according to the paper earlier this year in the same journal.**

That first paper pointed toward a way to improve the “memory” of these cells – meaning potentially improving vaccines and boosting immune responses in future encounters with the same pathogens.

The new paper brings the results a step further in complexity. The scientists found that Tcf1 and Lef1 (an homologue of Tcf1) are critical in recruiting the CCCTC-binding factor (known as CTCF), a well-characterized architectural protein and a versatile transcription regulator, to key parts of the genome of the CD8+ T-cells. By so doing, Tcf1 fosters key chromatin interactions - and associated crucial gene expression programs of the CD8+ T-cells.

[READ MORE](#)... and watch this mechanism in action [here](#).

Joseph M. Sanzari Children's Hospital Offers New Clinical Trial for Children and Young Adults Diagnosed with Aggressive or Recurrent Brain Tumor

Hackensack Meridian Children's Health is one of only a dozen pediatric networks in the country participating in a trial studying the treatment of an aggressive cancer of the brain. Joseph M. Sanzari Children's Hospital at Hackensack University Medical Center — a member of the global Pacific Pediatric Neuro-Oncology Consortium (PNOC) research group — is participating in a PNOC clinical trial for children and young adults with recurrent or progressive high-grade glioma (HGG), an aggressive, fast-growing type of brain tumor. The hospital is one of only 12 centers in the U.S., and the only center in the New York metropolitan area, to offer this trial.

The randomized, double-blinded, placebo-controlled clinical trial will evaluate local and systemic immunological changes, and the safety and efficacy of checkpoint inhibition therapy (CPIT) when delivered prior to surgery. CPIT works by “releasing the switches” — or checkpoints — that prevent the immune system's T-cells from identifying and attacking cancer cells.

Trial participants will be randomly divided into three groups. Group A will receive a one-time dose of immunotherapy medication nivolumab and placebo prior to surgery. Group B will receive a one-time dose of nivolumab and ipilimumab, another immunotherapy medication, prior to surgery. Group C will receive a one-time dose of placebo and ipilimumab prior to surgery.

After surgical tumor resection, all patients will receive three doses of nivolumab and ipilimumab administered every three weeks, followed by nivolumab every two weeks. [READ MORE](#)



**CDI Scientist
Dartois
Honored
with Gardner
Middlebrook
Award**

Véronique Dartois, Ph.D., member of the Hackensack Meridian Center for Discovery and Innovation (CDI), was honored with the Gardner Middlebrook Award for her years of tuberculosis research.

The prestigious award, which recognizes a lifetime's work of research on TB and other mycobacteria, was presented to her on June 26, 2022, during the 42nd annual meeting of the European Society of Mycobacteriology in Bologna, Italy.

Dr. Dartois received the 2022 Middlebrook Award in recognition for “her paradigm-shifting work on the pharmacology of anti-tuberculosis drugs,” according to the Society.

Dartois, also a professor at the Hackensack Meridian School of Medicine, is at the forefront of TB discovery and innovation — especially through the TB Drug Accelerator. She has authored several recent papers assessing the TBDA's major international initiative to turn the tide on the infection, which claims an estimated 1.4 million lives each year, mostly in the developing world.

Dartois and CDI experts are charged with the pharmacology aspects of the TBDA's work — specifically the pharmacokinetic and pharmacodynamics (PK/PD).

Prior to joining the CDI in 2019, Dartois was a faculty member of the Public Health Research Institute at Rutgers New Jersey Medical School. For a stint of about seven years before that, she was the Executive Director of Pharmacology for the Novartis Institute for Tropical Diseases in Singapore. She has 167 publications to her name, according to PubMed.

The latest distinction for Dartois is named after Gardner Middlebrook (1915-1986), a US physician, professor and worldwide authority on tuberculosis.

Dartois was also recently named as one of 65 new fellows of the American Academy of Microbiology in the Class of 2022, according to the AAM.

JFK Johnson Rehabilitation Institute Recertified

Hackensack Meridian JFK Johnson Rehabilitation Institute, a *U.S. News & World Report* nationally-ranked rehabilitation hospital, is proud to announce its pulmonary rehabilitation program has been recertified by the American Association of Cardiovascular and Pulmonary Rehabilitation.

“We are pleased to receive this prestigious recertification from the American Association of Cardiovascular and Pulmonary Rehabilitation,” said Sara Cuccurullo, M.D., chair, vice president, and medical director, JFK Johnson Rehabilitation Institute.

The cardiovascular and pulmonary rehabilitation programs at JFK Johnson Rehabilitation Institute are designed to help people with cardiovascular problems (heart attacks, coronary artery bypass graft surgery) and pulmonary problems (chronic obstructive pulmonary disease, respiratory symptoms) recover faster and live healthier. Both programs include exercise, education, counseling and support for patients and their families.

To earn accreditation, JFK Johnson's pulmonary rehabilitation program participated in an application process that requires extensive documentation of the program's practices. AACVPR Program Certification is the only peer-review accreditation process designed to review individual programs for adherence to standards and guidelines developed and published by AACVPR and other related professional societies. Each program's application is reviewed by the AACVPR Program Certification Committee, and certification is awarded by the AACVPR Board of Directors. [READ MORE](#)

Hackensack Meridian Children's Health Pediatric Neurologist Studying Concussion Recovery in Children

Pediatric neurologist **Felicia Gliksman, D.O., MPH, FAAN**, director of the Pediatric and Adult Concussion Center at Joseph M. Sanzari Children's Hospital at Hackensack University Medical Center, and vice chair of the Department of Neurology at Hackensack Meridian School of Medicine, is serving as principal investigator and investigator for two studies related to recovery from brain injury.

The first study is funded by a two-year, \$180,000 grant from the New Jersey Commission on Brain Injury Research. In this study, titled, "Speech Indicators of Dysfunction and Recovery following Mild Traumatic Brain Injury," Dr. Gliksman, who is an assistant professor of Pediatrics and Neurology at the School of Medicine, and Sona Patel, PhD, who is an assistant professor of Neurology, are studying changes in brain function. It is hypothesized that changes in speech characteristics will correspond with changes in behavioral, cognitive, neurological, physical, psychological, and sleep-related symptoms, and that these symptoms will recover to baseline function with time. Age and the severity of injury will help to determine the pace of recovery.

The second study is titled "Speech as an Indicator of Concussion Severity and Recovery in Pediatrics." This study will use speech technology to determine whether changes in speech characteristics correspond with changes in behavioral, cognitive, neurological, physical, psychological and sleep-related concussion symptoms in children. The goal of the study is to understand how speech in children may be impacted after a concussion and develop ways to detect injury and monitor recovery.

This study, which started in April 2022, will also analyze speech and recovery patterns in older children compared to younger children, as well as children who sustained a severe injury compared to children who sustained a mild injury. [READ MORE](#)

HMH Innovation VP Powell-Elliott Named to Becker's Women Power Players List

Sandra Powell-Elliott, the vice president of Innovation and Health Ventures at Hackensack Meridian Health, has been named to the *Becker's Healthcare 2022* list "Women Power Players in Health IT."

Powell-Elliott will also be a featured speaker at Becker's Hospital Review's 7th Annual Health IT + Revenue Cycle Conference, which will take place in Chicago from Oct. 4-7. She will discuss "How to be a Daredevil Innovator in Healthcare."

"Sandra is a forward-thinking leader," said Ihor Sawczuk, M.D., FACS, Hackensack Meridian Health's president of Academics, Research and Innovation, and also associate dean of Clinical Integration and professor and chair emeritus of Urology at the Hackensack Meridian School of Medicine. "We are proud of her accomplishments, and the insights and creativity she brings to the health network."

Powell-Elliott's role at Hackensack Meridian Health is to foster the internal development of an innovative culture, while also bringing innovative and transformative solutions from outside of the organization to the forefront of the organization's strategic planning efforts. Through the development of the Bear's Den investment and innovation program, Sandra's efforts have enabled HMH to invest in early stage, innovative ideas and technologies to better meet the needs of patients and the clinicians who treat them. [READ MORE](#)

Quadri Co-authors Paper in Journal Sleep

A Hackensack Meridian Health Research Institute doctor was co-author of a paper which used proteomic analyses to better understand a rare neurological disorder found most prominently in adolescent males.

The Kleine-Levin syndrome samples and controls were taken from cerebrospinal fluid and serum, according to the paper in the journal *Sleep* published in September, which included **Mohammed Quadri, M.D.**, vice president of strategy for Academics, Research, and Innovation at Hackensack Meridian Health.

The biomarkers identified through the univariate analyses could provide diagnostic potential, and also biological pathways for future research, according to the paper. [READ MORE](#)

Hackensack Meridian Health Doctor, Bioethicist Publishes Surgery Decision-Making Piece in New England Journal of Medicine



Hackensack Meridian Health doctor and bioethicist explores the difficulties of decision-making for surgeons in a new piece in *The New England Journal of Medicine*.

Making clinical decisions based on how a patient appears to a surgeon may be subject to "ableist" biases. A doctor's subjective "eyeball test" might make assumptions about a patient's quality of life and influence whether or not a patient is offered a surgical procedure, writes **Charles Binkley, M.D., FACS, HEC-C**, the director of Bioethics for the health network's Central Region, and also an associate professor of Surgery at the Hackensack Meridian School of Medicine, one of the paper's authors.

"From the Eyeball Test to the Algorithm - Quality of Life, Disability Status, and Clinical Decision Making in Surgery" contends that more data and an empirical framework involving algorithms would aid doctors, who must seek out more input than just their sole observation of the patient in deciding whether a surgical intervention is "worth it."

"The paper proposes that AI may actually de-bias some of the quality of life assumptions that affect physicians in their clinical decision making," said Binkley recently. [READ MORE](#)



RESEARCH UPDATES & EVENTS

FALL 2022

eResearch Guidance: How to Add Research Team Members to a Study

In order to add (or remove) research team members to a study, a Modification must be submitted for review and approval. However, two different scopes (types) of Modifications exist: “Study team member information” and “Other parts of the study”.

To add a Sub-Investigator (Sub-I) or change the Principal Investigator (PI): Select both options under Modification Scope (“Study team member information” and “Other parts of the study”). This allows the submitter to select the required Ancillary Reviews (COI and Research Credentialing) as well as edit the ‘Local Study Team Members’ page of the main study application, the protocol, and/or the consent form as needed.

To add a research team member other than a Sub-I or PI (such as a study coordinator, research assistant, data analyst or regulatory specialist), select “Study team member information” under Modification Scope. This allows the submitter to go straight to the ‘Local Study Team Members’ page of the main study application (if edits to the protocol and consent form are not needed).

When completing a Modification submission, please pay close attention to the instructions to ensure the proper Modification Scope and Ancillary Reviews (if applicable) are selected. In addition, please note while any member of the research team can create a Modification, only PIs or PI Proxies for the main study have the ‘Submit’ activity (to be able to submit the Modification for review). Need to submit a Modification on behalf of the PI, but don’t see the ‘Submit’ button? Work with the PI, Primary Contact, or other PI Proxies for that study to ensure you’re assigned as a ‘PI Proxy’.

Looking for Guidance Regarding the New eResearch System?

With a new submission system comes many questions: How do I submit a study in new eResearch? How does the Ancillary Reviews process work? What is a PI Proxy? How is access to eResearch granted to researchers? What are all the new mechanisms available to the research team?

The new eResearch system contains multiple sources to help guide the research community. The ‘Help Center’ contains guides and videos regarding the system and its submission process. The ‘Library’ contains policies, protocol and consent templates, and more. And the ‘Announcements’ section contains a list of all announcements sent out by eResearch including copies of the ‘Research Roundups’, upcoming presentations, and further guidance regarding the system itself.

As the research community continues to become familiar with this new system, guidance and education will continue to be provided

and disseminated. Furthermore, please reach out to the Research Integrity Office (201-880-3669; hmhrib@hmhn.org) for any questions.

Physicians Needed for Volunteer Research Committee

The Data and Safety Monitoring Board (DSMB) is an impartial group within the Research Integrity Office that monitors the progress of research studies through the review of safety and effectiveness data. The committee ensures that individuals participating as subjects in research at HMH are not exposed to undue risk and the Board looks for any differences in effectiveness between experimental and control groups. The DSMB has the authority to require protocol modifications related to participant safety and to recommend suspension or termination to the IRB and/or institutional officials for any research protocols that fall within its jurisdiction.

We are currently looking to recruit 1-3 physicians to this committee. The meetings are held the last Wednesday of each month at 12:30 pm. The meetings last 30-45 minutes total. Please contact Daniel Alderson at daniel.alderson@hmhn.org with interest or to learn more.

Responsible Conduct of Research Tip

Conducting research with animals is crucial (and a regulatory requirement) for innovating and advancing groundbreaking medical research. However, specific steps must be taken before that type of research can be conducted, such as approval by the Institutional Animal Care and Use Committee (IACUC). The committee will pay careful attention to the study design to ensure that the study is being conducted in the most efficient and scientifically sound manner possible. One useful tool is the [Experimental Design Assistant \(EDA\)](#). This tool helps improve the design of animal experiments, has been validated, and has been utilized by thousands of researchers worldwide.

Upcoming Events

There are many new and exciting research education events on the horizon!

The HMH Research Institute [Investigator Training page](#) outlines the available programming.

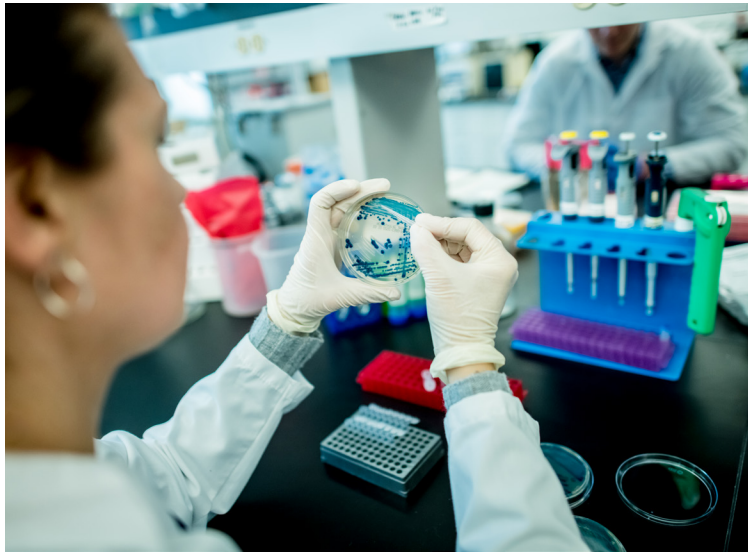
The upcoming topics for the Investigator Training Lecture Series are available [here](#).

For all dates of upcoming events, please see the [research calendar](#).

And don’t forget to check out our [library of recorded educational sessions](#) available to all HMH employees.

For any questions about educational programming, to suggest a lecture topic, or to volunteer to present, please contact tamara.friedman@hmhn.org.

KEEP GETTING BETTER



FEATURED RESEARCHERS

FALL 2022



Taya Glotzer, M.D.
*Professor of Medicine,
Hackensack Meridian School
of Medicine
Director of Cardiac Research,
Hackensack University
Medical Center*

As technology and science march forward, many fields have gained access to data they couldn't have imagined years ago. In the medical realm, new implanted devices and screening tests have made it possible to detect abnormalities that would have previously been overlooked. With all this new information, how best to use it remains a conundrum. At what point do you act on information that you receive that doesn't seem to be affecting the patient thus far? This is the question that launched Dr. Glotzer's research career in cardiac electrophysiology, and has been addressed numerous times throughout her decades-long research endeavors.

Dr. Glotzer completed her medical degree at the New York University School of Medicine and her residency, cardiology fellowship, and electrophysiology fellowship at NYU Langone Medical Center. She learned from her experience implanting and monitoring pacemakers and defibrillators that patients have arrhythmias that are entirely asymptomatic.

Atrial fibrillation (AFib) is a condition of the upper chambers (atria) of the heart that can intermittently "fibrillate" resulting in loss of contractility. This leads to an irregular heartbeat, but despite the irregularity, many individuals are unaware that it is occurring.

When the upper chambers are not contracting properly (fibrillating), blood can clot inside them, and these clots can travel outside of the heart blocking blood flow to the organs where they lodge. The most devastating consequence is when a clot lodges in part of the brain leading to a stroke. Therefore, the most important treatment for atrial fibrillation is blood thinners to prevent the formation of the atrial clots. All medications have risks, and in the case of blood thinners, the obvious risk is bleeding. Therefore

physicians must balance the risks of stroke with the risks of bleeding to determine which patients with AFib should be put on blood thinners.

Dr. Glotzer has spent much of her research trying to determine what duration of AFib requires the blood thinners. If someone has AFib for 1 hour on one day, should they be committed to taking blood thinners for the rest of their lives? Must all instances of AFib be treated with blood thinners? Where do we draw the line and make the decision to treat?

Those questions catapulted Dr. Glotzer into a prolific research career. In 2003, she collaborated with a research team that was asking an unrelated question about pacemakers, and they discovered that small amounts of AFib detected by pacemakers increase the risk of stroke and death. She was the first author on what became a very highly regarded paper (still cited today) on this topic. From there, Dr. Glotzer continued to collaborate with physicians in her field both within and outside of her institution. She has published several other papers trying to answer the question: How much AFib should be managed with blood thinners?? Which patients with Afib should be treated with blood thinners? As a result of the contributions she has made in the field of implanted device detected AFib, in 2022, she received the Researcher of the Year award from the NJ chapter of the American Heart Association.

Dr. Glotzer sat down with us to share a little more about her research experience, along with advice to other clinicians who are interested in becoming involved in research.

What drove you to pursue a career in medicine and more specifically a career in cardiac electrophysiology, a field of which such a small percentage are women?

The decision to become a physician was an easy one; my father was a general surgeon, and I tended to be pretty strong in math and science. During training, I loved cardiology, especially cardiac electrophysiology and its esoteric EKG language. My first job as an attending electrophysiologist was at Hackensack University Medical Center 27 years ago, and I've been here ever since.

A very small percentage of physicians in cardiac electrophysiology are female, and I did encounter some early challenges as a woman in a predominantly male profession. I give a great deal of credit to the
(continued)

FEATURED RESEARCHERS:

Taya Glotzer, M.D. *(Continued)*

“Women in Electrophysiology” group who provided me with advice and mentorship early in my career. I still maintain many friendships with women from that group and now mentor junior female colleagues. We are able to share our challenges of balancing raising a family, while still engaging in a busy clinical and research practice. I have also had a very supportive husband who has devotedly encouraged both my clinical and academic careers.

What has kept you so interested in research throughout your career?

First of all, research is both interesting and meaningful. These are real clinical problems that we are trying to solve that will impact patients in real ways. I care deeply about my patients, many of whom have been with me for decades. I consider it a privilege to be their doctor and want what is best for them. Research is one way to work towards attaining that end. Second, I very much enjoy interacting with my research colleagues from around the globe; they are smart, conscientious, hard-working people who are motivated to improve and save lives.

Can you briefly share with us a little bit about your recent research?

My initial work was related to determining how much AFib one should have in order to treat it with blood thinners, as discussed above. I am currently working on related topics such as screening for AFib in the population, similar to how we screen for cancers with mammography and colonoscopy. In the last few years, many devices have been developed that can measure pulse rate. Research questions are: Should we screen for AFib in the elderly population; perhaps when patients go to the pharmacy to pick up prescriptions? How accurate are the screening devices? Wearable technologies such as smart phones and watches can also detect AFib. Who should evaluate and confirm the findings of consumer wearable technology? How accurate are they? How should information from consumer devices be incorporated into the medical record? These are questions that Dr. Glotzer’s current research tries to answer.

I am also engaged in research regarding conduction system pacing. Conduction system pacing is a new technology designed to synchronize the contraction of the right and left sides of the heart, which we currently believe will prevent heart failure. Many studies are ongoing to answer this question. As a fellow of the Heart Rhythm Society, I have been involved in writing guidelines indicating which patients would be candidates for conduction system pacing.

Why do you consider research to be so important to the practice of medicine?

If you don’t explore and try new things, you will never improve patient care. At one time physicians believed leeches and bloodletting were effective; we know now that was severely flawed. The practice of medicine changes every year, and it is because of new treatments discovered through research that lead to improvements in how we practice medicine.

How do you balance your clinical practice with your research efforts?

I have become highly adept at time management. In truth, clinical practice and research are hard to balance, and I do often work on the weekends and into the evenings. But I also love research, and I enjoy the time I spend reading and writing about how to solve clinical problems.

What advice would you give to medical students and early-career physicians?

Don’t pick a career that you think will be more lucrative or easier; pick something that you love. You will be spending a lot of time doing it, so you are better off picking something that you really enjoy. Once you identify your passion, you can make all other aspects of your life fit around it.

In addition, always practice with the utmost honesty. It is okay to not know something; always reach out for help if you need it. We are all colleagues in medicine and we cannot be experts at everything. Work as a team, learn from each other, and support all members of the care team.

Finally, if you want to engage in research successfully, you need to take the initiative and do the work. Find a mentor who can guide and support you.

What are your hobbies and extraprofessional interests?

I run, play tennis, and recently took up golf. I love to do activities outside. I also love to read, historical fiction or fiction, an engaging story before bed.



FEATURED RESEARCHERS

FALL 2022

The CDI Experts: Psychologist Derry-Vick Researches Stress, from Lab to Clinic

Anxiety; stress; depression; mental health conditions. Our behavioral health is as critical to holistic well-being as any other factor, since these effects can exacerbate, or even trigger, other medical conditions.

Heather Derry-Vick, Ph.D., is a health psychologist and one of the most recent arrivals at the Hackensack Meridian Center for Discovery and Innovation (CDI). Her work focuses on the “psychosocial” aspects of disease – how the mental aspects of health can impact the sheerly physical.

“My interests broadly are at the intersection of physical and mental health,” said Derry-Vick recently, from her office within the Hackensack Meridian School of Medicine. “Behavioral research has always been the cornerstone of my work – I’m looking at the connections between the brain and behavior, and disease.”

“Heather’s work is a vital complement to other avenues of science at the CDI,” said David Perlin, Ph.D., the chief scientific officer and senior vice president of the CDI. “She aims to make a clinical impact as soon as possible, especially for cancer patients – a critical focus of the CDI’s mission.”

THE PSYCHOLOGIST IS IN

Derry-Vick is a clinical psychologist by training. She has seen patients with depression and anxiety in a variety of settings – those in primary care, those in medical rehabilitation programs, and a wide variety of niches in between.

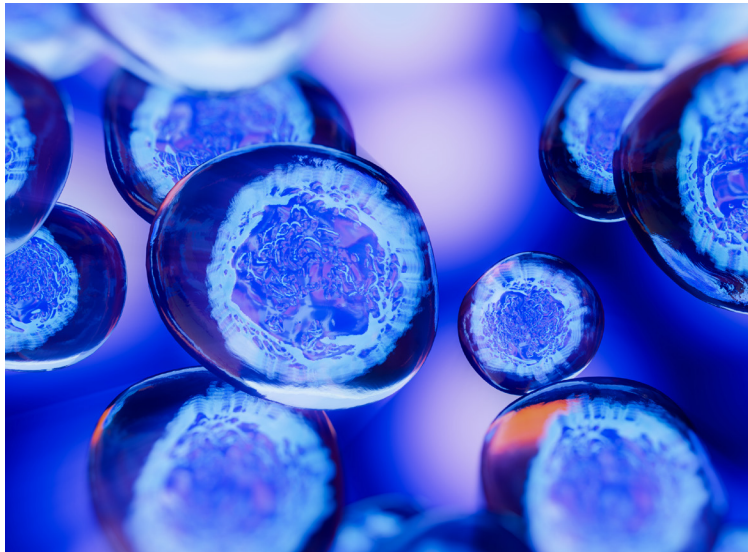
But it’s the research of discovering mental/physical feedback loops which has drawn her into forming her own CDI lab, looking to the ways that mental health challenges can worsen disease – and how these patterns can be disrupted to improve well-being.

Stress and anxiety can cause problems – and exacerbate others. “In stressful situations, the body goes through changes – think of ‘fight or flight,’” she said. “But it’s not just adrenaline pumping or blood pressure rising – the immune system and other functions are also impacted by stress.”

Derry-Vick has two main thrusts to her research. First, it’s aiming to understand how stress responses can be dysregulated for some people – by going on longer or being larger than a “typical” response, and how this impacts chronic conditions. Second, because people respond differently to stress, Derry-Vick also envisions finding out who is most susceptible to harmful responses or negative effects of stress, and studying ways to intervene.

These two fields of inquiry are broken down into projects underway in the Derry-Vick Lab. The primary work so far is based on stress management, and in testing new ways to help people with cancer to manage stress and anxiety at specific points in their care. Another line of her work is “biobehavioral,” which links psychosocial factors like stress and depression with physiological markers that impact disease development and progression – such as inflammation.

[READ MORE](#)



FEATURED RESEARCH ADMINISTRATOR

FALL 2022



Elli Gournas Paleoudis, M.S., Ph.D.
*Manager,
Investigator Initiated
Research Program*

Dr. Elli Gournas Paleoudis almost always gets a seat at the table. She has a well-earned reputation for being knowledgeable, hard-working, and forthright in her approach; for those reasons, her opinions are frequently sought. Researchers and administrators alike want her on their teams, involved in their initiatives, and there is no shortage of invitations for her to attend meetings and committees and to share her perspective.

In addition to supporting others' initiatives, she has many of her own. As the Manager of the Investigator Initiated Research Program, she is heavily invested in supporting investigator-initiated research at HMH, and not afraid to roll up her sleeves and work to make things the best they can be for researchers here. She is an early pioneer of the highly successful REDCap program and also serves as the HMH liaison for the FDA and the administrator for Clinicaltrials.gov. We asked her to meet with us virtually to share a little bit about her role and some tips for researchers.

Can you share with us a little bit about your job?

I primarily support our HMH investigators with study design and protocol development. Researchers will often come to me with an idea that I then help them refine. We think through the idea and choose the appropriate methodology together. This involves identifying the gap in the current literature that the researcher can address to make the study worth investigating and conducting. Once we have a more concrete idea ready, I guide the researcher in drafting the protocol and review it before it's submitted. I sometimes review supporting documents as well.

If the proposed study is a clinical trial, I assist with registering it with Clinicaltrials.gov. If the study involves a new drug or a drug that is being repurposed, I guide the researcher through the FDA application process.

Prior to your role here at HMH, your experience was primarily academic. In what way has your academic experience informed your work here?

Before joining HMH, I did my PhD in Health Sciences at the University of Leicester in the UK, where I focused on health policy and medical and research ethics and published work on incidental findings from clinical sequencing. Prior to that, I completed two master's degrees, one in Bioethics and one in Human Reproduction and Reproductive Technologies. My basic science background helps me understand the science in the studies that researchers here propose. I was also heavily involved in research throughout my training, especially with my Ph.D., and those research experiences inform my work today.

How does your strategy for guiding investigators differ between newer researchers and those with more experience?

The more experienced researchers come expecting more of a review or an additional set of eyes rather than assistance with the actual development. They usually rely on the available templates for creating the protocols and then send them to me once they've been drafted. On the other hand, the newer investigators usually require more basic support. I usually spend more time with them putting the application together, since they may not be familiar with all of the requirements at that point. There also might be more back and forth with them. However, I am finding that new investigators are coming to me with more and more knowledge from the get-go. I attribute this to the education available to the research community; it makes my job easier when researchers take advantage of the offerings.
(continued)

FEATURED RESEARCH ADMINISTRATOR: Elli Gourni Paleoudis, M.S., Ph.D. *(Continued)*

If you could give new researchers three pieces of advice to consider before embarking on their projects, what would they be?

My advice involves going back to the basics:

- Be aware of what studies are out there. It is true that there is value in replicating studies, but it is harder to publish a simple replication. Your best bet is to try to identify the gap in the literature. That doesn't mean that you need a completely novel concept; you could always apply an existing concept to a new population or utilize updated technology.
- Review all of the components of your application before you submit it. Sloppy protocols and incomplete documentation ends up delaying the process significantly. It is better for everyone if your team conducts a thorough review at the onset as opposed to trying to "band-aid" problems that are identified later on.
- Take advantage of the resources at HMH. Your best bet is to invest time in staying on top of updates or regulatory requirements by attending training sessions, reading the communications, and consulting with a member of the Office of Research Administration early on rather than scrambling at the last minute.

What are some of the most common missteps that you see when working with researchers?

Over the years, I have seen inconsistencies within the protocol document and between the protocol and the eResearch application. This issue has been minimized to some extent with the new system, since the application no longer asks for much information that is already in the protocol, but I still do see it pop up from time to time. It is important to have a strong grasp of what you are proposing to do and to ensure that you convey that consistently throughout. The second issue that I see pretty regularly comes back to what I mentioned earlier, with my advice. I often see that researchers unwittingly cause delays and more problems for themselves by rushing through the application and failing to stay up-to-date on updates or requirements.

What do you like most about your role?

I enjoy the creativity, interaction, and opportunities to work with investigators across the network. I am very fortunate to be able to learn about all kinds of specialties and fields of medicine from the researchers with whom I collaborate.

What are some of your favorite past times when you are not overseeing the Investigator Initiated Research Program?

I love spending time with my husband and two sons and especially like bringing the kids to outdoor activities in the area. I am also an avid reader.



HMSOM RESEARCH BULLETIN

FALL 2022

HMSOM Professor Writes for and Co-Edits Special Anatomical Record Issue

Anthony Pagano, Ph.D., was co-guest editor of a special issue of the Anatomical Record journal entitled “The evolution, development and functional morphology of the nasopharynx and its boundaries” (Volume 305, Issue 8, August 2022).

This special issue is comprised of 15 papers, of which Dr. Pagano is first author on three and second author on one. These contributions were written by paleoanthropologists, anatomists, and surgeons as far afield as France, Spain, Switzerland, Poland, the United Kingdom and various institutions across the United States.

One of Dr. Pagano’s key roles was the solicitation of contributions from a range of authors whose research is related to the nasopharynx. Topics covered by this special issue include:

- Evidence of early evolutionary history in nasopharyngeal embryologic development
- Computational airflow dynamics analysis of nasopharynx function in human and chimpanzee respiration
- Newly described fossil remains of the nasal cavities of Pleistocene humans from Spain
- The usefulness of the nasopharynx in reconstructing the evolutionary histories of humans and Neanderthals
- The importance of the nasopharynx to embalming techniques of the ancient Egyptians and evidence from mummies
- The 4,000-year-long history of study of nasopharyngeal anatomy.
- The clinical importance of nasopharyngeal anatomy in respiratory obstruction, middle ear infections and COVID-19.

The goal of this special issue was to call attention to a vitally important but often overlooked anatomical region. While much has been written on clinical issues affecting the nasopharynx, few have ever considered its impact on development and evolution of the adjacent facial skeleton, upper airway, vocal tract, middle ear and oral cavity (to name a few structures).

To read more, find the special issue here: <https://anatomypubs.onlinelibrary.wiley.com/toc/19328494/2022/305/8>



QUARTERLY QUESTION

FALL 2022

What are the penalties for failure to comply with the [Clinicaltrials.gov](https://www.clinicaltrials.gov) requirements?

- (a) Civil monetary penalties up to \$13,237 (as of July 2022) per study, per day
- (b) Civil or criminal judicial actions
- (c) Withhold current or future funding (for NIH studies)
- (d) All of the above

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.