



Hackensack  
Meridian Health  
Office of Research  
Administration

# RESEARCH ROUNDUP

APRIL 2022



## MESSAGE FROM THE **PRESIDENT OF ACADEMICS, RESEARCH AND INNOVATION**

The Hackensack Meridian Health network of researchers, clinicians and scientists continues to distinguish itself by publishing important findings - and by continuing to ask new questions. More than 1,000 papers were published in 2021 by HMH experts from across the disciplines - and our patients are better off with each new observation and breakthrough. This quarterly update outlines just a few of the latest.



## NOTE FROM THE VP

Watching the collaborations between so many talented people across HMH come together, like that of the experts of the Bio-R and the CDI during the time of COVID-19, shows the tremendous upside of our teamwork.

## **HMH RESEARCH NEWS**



## Sawczuk Promoted to President of Academics, Research and Innovation

**Ihor S. Sawczuk, M.D., FACS** has been named president of Academics, Research and Innovation, reporting directly to the chief executive officer.

In this newly created role of president of Academics, Research And Innovation, Sawczuk will be responsible for the strategic direction and growth of all aspects of academia, research and innovation across the network. This includes providing oversight, guidance and support to all academic hospitals, allied health and medical training programs, and ensuring quality, safety, consistency and efficiency throughout all curriculums. Hackensack Meridian School of Medicine will continue to be led by interim **Dean Jeffrey Boscamp, M.D.** and report directly to the chief executive officer.

In partnership with the chief scientific officer at the Center for Discovery and Innovation, Sawczuk will champion innovative research initiatives and introduce new products for commercialization, while maintaining pace with the health care industry and aligning with HMH's mission and values. In addition, he will provide guidance to establish metrics to monitor the progress and implementation of research standards, strategize process improvements focused on innovative operational models and facilitate the translation of research efforts across the network to improve patient care. *(continued)*

**KEEP GETTING BETTER**

## Sawczuk Promoted (continued)

An esteemed physician and sought-after educator, Sawczuk has been the recipient of numerous awards from prestigious academic and medical associations. He was the recipient of the Russell W. Lavengood Distinguished Service Award from the New York Section of the American Urological Association and was presented the prestigious Russell and Mary Hugh Scott Education Award by the American Foundation of Urologic Disease. In 1996, the office of the First Lady, Hillary Rodham Clinton, recognized him for his Chernobyl humanitarian efforts.

Sawczuk has been recognized by Becker's Hospital Review as one of the nation's physician leaders of hospitals and health systems to know two years in a row. He was honored by the National Ethics Collection of Organizations as a recipient of the 2017 Ellis Island Medal of Honor. He served as president of the New York Medical & Surgical Society for the 2018-19 academic year.

Under Sawczuk's leadership, Hackensack Meridian Health was recently named the top research center in the state by NJBIZ. In 2021, researchers at HMH published more than 1,000 papers in major journals with topics that spanned all specialties including COVID-19. In addition, more than 1,000 patients received the latest investigative treatments over the course of 10 clinical trials during the first wave of COVID-19.

**Mark D. Sparta, FACHE**, was also named president, Northern Region, reporting directly to the chief operating officer. Read more about these promotions on the HMH website.



## After Two Years of Teamwork, Finally to Meet: Bio-R Takes Tour of CDI

The two groups spent two years working closely and collaboratively to monitor the variants of the the SARS-CoV-2 virus - but they did it all from afar. So the two Hackensack Meridian Health departments were thrilled to make an in-person connection in February. The staff of the HMH Bio-Repository (Bio-R) took a tour of the operations at the Center for Discovery and Innovation (CDI).

"We had the most amazing tour and overview of what the CDI does and what they have been able to do with all the thousands of samples our team has sent over," said Yael Kramer, M.S., manager for the HMH Network Biorepository. "This experience gave an even deeper meaning and connection for our team. To capture a moment in time of this collaboration, [check out the HMH network video "COVID Variant Hunters - CDI and Bio-R" here on the CDI website.](#)



## 1,000 Papers for HMH Authors in 2021

Researchers at Hackensack Meridian Health published more than 1,000 papers in 2021, according to a network-wide count.

The publications included many major journals, including the *Proceedings of the National Academy of Sciences*, *Nature Medicine*, *JCI Insight*, *BMJ Open*, *Academic Medicine*, and others. The topics spanned all specialties, from clinical research to basic science in our laboratories, and many focused on the health challenge of our era, COVID-19.

The totals were amassed by Michael Oppenheim and Nicole Mastrogiovanni of the Hackensack Meridian School of Medicine.



## SUEZ North America Generously Donates \$100,000 to Hackensack Meridian Health Foundation to Advance Research at the Center for Discovery and Innovation

Hackensack Meridian Health Foundation is pleased to announce a generous gift of \$100,000 from SUEZ North America to support clinical research at Hackensack Meridian Center for Discovery and Innovation. (continued)

## SUEZ North (continued)

“We thank our friends and partners at SUEZ North America for their continued generosity, especially as we continue to battle against COVID-19,” said Robert C. Garrett, FACHE, CEO, Hackensack Meridian Health. “Our scientists at the Center for Discovery and Innovation have been on the frontlines of the COVID-19 pandemic and they continue to make extraordinary strides in the fight against the virus, cancer and other diseases, and we are incredibly grateful.”

The Center for Discovery and Innovation is an academic-based entrepreneurial center that rapidly harnesses innovations arising from a new renaissance in biomedical sciences to restore patient health. It comprises the Institute for Cancer and Infectious Diseases, the Institute for Multiple Myeloma and Lymphoma and the Institute of Restorative Health.

“At Hackensack Meridian Health, the Center for Discovery and Innovation has been at the heart of medical advancement during the COVID-19 pandemic,” said Nadine Leslie, CEO, SUEZ North America. “The Center for Discovery and Innovation’s work on vaccines, diagnostic testing and therapeutics has fueled the advances that will improve public health and outcomes for New Jersey patients today and in the future. Our team at SUEZ North America understands the importance of this ongoing work, and is proud to help fund research necessary for all of us to keep getting better.”

[READ MORE](#)

## John Theurer Cancer Center Investigators Publish Research on New Treatment Option for Large B-Cell Lymphoma

John Theurer Cancer Center at Hackensack University Medical Center investigators co-authored a publication in the [New England Journal of Medicine](#) that will change the paradigm in managing aggressive lymphoma who failed standard therapy. Hackensack Meridian John Theurer Cancer Center is a part of the Georgetown Lombardi Comprehensive Cancer Center, an NCI-designated Comprehensive Cancer Center.

The research, titled “[Axicabtagene Ciloleucel as Second-Line Therapy for Large B-Cell Lymphoma](#),” explored the use of CAR t cell therapy axi-cel or Yescarta - currently approved as 3rd line therapy in aggressive lymphoma - in a large global randomized trial against the current standard of care using high dose therapy followed by autologous stem cell transplantation (ASCT).

The trial named ZUMA-7 showed dramatic improvement in favor of axi-cel over standard salvage and ASCT with a >4-fold greater median event free survival (EFS) – which was the primary endpoint, a > 33% increase in overall response rate (ORR) and doubling of the complete remission (CR) rate. There were no concerning toxicities, and the benefit of axi-cel in 2nd line

therapy was confirmed across key prognostic subgroups including pts with high grade lymphoma and refractory to their initial chemotherapy.

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## John Theurer Cancer Center Investigators Confirm that Preserved Stem Cells Are Safe and Effective for Multiple Myeloma Treatment Up to 20 Years Later

Investigators from Hackensack University Medical Center’s John Theurer Cancer Center confirmed that cryopreserved stem cells collected before a first stem cell transplant to treat multiple myeloma are just as viable and potent for use in a second “salvage” transplant up to 20 years later when a patient experiences a relapse of the disease. The study, published in the *Journal of Transplantation and Cellular Therapy*, is the first to compare outcomes of initial and salvage transplants in the same patients.

Multiple myeloma is a cancer of the bone marrow, and autologous stem cell transplantation—the collection of a patient’s own stem cells from their bloodstream before chemotherapy, which are given back after chemotherapy to rebuild the blood-forming system—is a commonly used treatment. Multiple myeloma often comes back despite initial treatment, but it may not be for several years. For this reason, treatment guidelines recommend that enough stem cells are collected before the first transplant to support two transplants. The cells are frozen and stored in a vapor-phase liquid nitrogen refrigerator for storage below -150°C.

The study investigators assessed outcomes in 89 patients who received an initial stem cell transplant for multiple myeloma as well as a salvage transplant for relapsed disease at John Theurer Cancer Center between 2000 and 2021. The median period of time between the initial collection of the cells and the salvage transplant was 5.4 years, with some patients not receiving the second transplant until up to 19.7 years later. The researchers found that the amount of time it took for patients’ bodies to rebuild their levels of neutrophils (white blood cells) and platelets (blood-clotting cells) was not significantly different between the first and salvage transplants.

[READ MORE](#)



## Foundation for Health Advancement and Hackensack Meridian Health Partner to Support Healthcare Innovation

[Foundation for Health Advancement](#) (FHA) is pleased to announce the signing of an affiliation agreement with [Hackensack Meridian Health](#) that allows the organizations to work together to support breakthroughs in biomedical research and technologies within the Hackensack Meridian Health network, the largest and most comprehensive in New Jersey.

“Innovation requires an ecosystem of providers, researchers and collaborators and we are thrilled to work with this extraordinary organization to continue our commitment to transforming health care,” said Robert C. Garrett, FACHE, CEO of Hackensack Meridian Health. “Our work with the Foundation for Health Advancement will deliver significant breakthroughs in medicine and care delivery.”

The Foundation for Health Advancement (FHA) supports health-related research and education programs in New Jersey by providing grants to support early-stage university technologies with strong commercialization potential through its [Innovation Grant Program](#). FHA’s affiliate, the [New Jersey Health Foundation](#), provides grant funding for basic research and community health projects through its [Research/Community Health and Social Service grant programs](#).

“The addition of Hackensack Meridian Health adds strength to our Foundation’s entire network as we plan to work with our affiliated organizations to develop unique collaborations,” noted George F. Heinrich, M.D, vice chair and CEO of Foundation for Health Advancement. “We are very excited to collaborate on the goal of advancing health-related projects and companies within the state.” [READ MORE](#)

## JFK Johnson Rehabilitation Institute Study Identifies Nerve Damage in Post-COVID Patients

Researchers Call for Guidelines to Identify and Treat Post-COVID Nerve Injuries with Rehabilitation Medicine

Some COVID-19 patients develop severe and persistent nerve injuries that can add to the complexity of post-COVID rehabilitation as well as to the burden of disability for patients, according to a recent study.

The study by JFK Johnson Rehabilitation Institute, JFK University Medical Center, and St. Peter’s University Hospital identified peripheral nerve injuries in some patients who had been hospitalized and on ventilators for COVID. The study, published in the American Journal of Physical Medicine & Rehabilitation, calls for the creation of evidence-based guidelines that identify neurologic aftereffects of COVID and establish treatments.

“The patients we studied had severe nerve injuries in random places that wouldn’t be expected or related to their positioning

while on a ventilator,” said David P. Brown, D.O., a specialist in peripheral nerve injuries and neuromuscular conditions at JFK Johnson. “These patients have clear neurologic injuries, and it does appear from our research that the Covid-19 virus could have been the inciting factor.”

The study is called: Focal Peripheral Neuropathies Observed in Patients Diagnosed With COVID-19.

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## Hackensack Meridian Hackensack University Medical Center Announces Three Clinical Trials to Improve Urologic Care in Women

Investigators in Female Pelvic Medicine at Hackensack Meridian Hackensack University Medical Center Department of Urology have completed two studies and are conducting a third aimed at improving the standard of care for common urologic disorders in women. The studies address voiding dysfunction (problems with urination) and the management of urinary tract infections (UTIs) and have yielded compelling data that will be presented at professional conferences and published in academic medical journals.

“Problems with urination and UTIs impact the health and quality of life of many women. My colleagues and I are leading innovative clinical trials aimed at improving the care of these women and optimizing their outcomes,” explained Debra Fromer, MD, chief of Female Pelvic Medicine and Reconstructive Surgery at Hackensack University Medical Center and associate professor of Urology at Hackensack School of Medicine. She led studies to answer the following questions:

Can women with voiding dysfunction predict their voided volumes and post-void residual void volumes? “Women who have voiding dysfunction often tell us they have to go to the bathroom very frequently and every time they go, there’s a large amount of urine OR there isn’t a large amount and they feel like their bladder is still full,” Dr. Fromer explained. They are often asked to complete “voiding diaries,” where they measure how much urine they have voided and log it into a diary, which can be a very cumbersome process. Alternatively, they may be asked to undergo invasive urodynamic testing to assess their voiding dysfunction. The researchers wondered if the women could accurately predict how much they voided and how much they believed remained in their bladder afterward, to see if it could spare them from completing the diaries and/or invasive urologic testing. Their findings showed that the vast majority of women could not accurately predict how much they had urinated or how much was left behind. These results reinforce the importance of voiding diaries and testing in the management of women with urination problems. “Accurate assessment of urinary volume is important for determining how we treat each patient,” Dr. Fromer noted.

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## John Theurer Cancer Center Participates as Leading Center in Groundbreaking Study Showing Starting with Immunotherapy Over Targeted Therapies Anti BRAF Improves Melanoma Outcomes

### Study Is Stopped Early Due to Definitive Results

Melanoma is a disease that was changed by immunotherapy in particular checkpoint inhibitor combinations Ipilimumab and Nivolumab. About half melanoma cases carry mutations in key proteins that control cell growth such as BRAF, and which can be targeted with a combination of dabrafenib (BRAF inhibitor) and trametinib (MEK inhibitor), also part of standard of care now. One of the biggest questions in oncology nowadays is what's the best sequence of care when you have multiple options. This question was answered by a large phase III randomized study called DREAMseq comparing immunotherapy 1st (Ipi + Nivo) vs targeted therapies 1st (dabrafenib (and trametinib) in pts with advanced melanoma.

Hackensack Meridian Health John Theurer Cancer Center (JTCC), a part of the NCI designated Georgetown Lombardi Comprehensive Cancer Center, was a leading center for this pivotal US trial which was stopped early due to definitive results showing that the immunotherapy combination given 1st reduced progression by 20% and improved the 2y overall survival by 38%. The findings were presented November 16, 2021, at the inaugural American Society of Clinical Oncology (ASCO) Virtual Plenary Series.

The DREAMseq phase III, trial was conducted across 849 U.S. locations and was led by Michael Atkins, MD Professor at Georgetown Lombardi Comprehensive Cancer Center, on behalf of the ECOG-ACRIN Cancer Research Group and sponsored by the National Cancer Institute.

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## Study Shows Adherence to Oral Medications for Metastatic Breast Cancer Is Affected by Side Effects, Cost, Patient Knowledge, and Care Team Support

Investigators from Hackensack Meridian Health John Theurer Cancer Center (JTCC), a part of the Georgetown Lombardi Comprehensive Cancer Center, participated in the first study to evaluate factors that influence the ability of people with metastatic breast cancer to adhere to their prescribed regimen of oral anticancer medication. The researchers found that multiple factors affected adherence, including side effects, cost of the therapy, patients' knowledge about the medication, and communication with their care team.



The study; [Barriers and facilitators to taking CDK4/6 inhibitors among patients with metastatic breast cancer: A qualitative study](#), is being published in Breast Cancer Research and Treatment.

In the U.S., about 10% of breast cancers are diagnosed at the metastatic stage (cancer which has spread elsewhere in the body) and 20-30% of early-stage breast cancer progress to metastasis. Oral anticancer drugs are taken by mouth, and patients are responsible for remembering their medication schedule. Prior research has investigated adherence to oral anticancer drugs among patients with early-stage breast cancer, but until now, no studies had been performed in people with metastatic disease.

Inhibitors of enzymes called CDK4 and CDK6 are oral cancer therapies specifically for metastatic breast cancer; examples include palbociclib, ribociclib, and abemaciclib. Although not a cure, these medications have been shown to slow metastatic breast cancer progression and extend survival. Patients typically take them for as long as they remain effective. While convenient, these medications may have a high out-of-pocket cost and in some patients, cause side effects such as diarrhea, fatigue, and/or nausea.

[READ MORE](#)

## Leading Hackensack Meridian Children’s Health Nephrologists Are Principal Investigators in Clinical Trial of New Medication to Treat Children with Rare Kidney Diseases

Hackensack Meridian Children’s Health is the only pediatric health care network in New Jersey undertaking a new study that examines the effectiveness of a drug called sparsentan to treat rare kidney diseases in children. Chief pediatric nephrologists and Hackensack Meridian School of Medicine professors, [Ken Lieberman, M.D.](#) and [Guillermo Hidalgo, M.D., F.A.S.N.](#), are the study’s principal investigators.

The study, called “Study of Sparsentan Treatment in Pediatrics with Proteinuric Glomerular Diseases (EPPIK),” is open to pediatric nephrology patients throughout New Jersey at both Hackensack Meridian Children’s Hospitals - Joseph M. Sanzari Children’s Hospital at Hackensack University Medical Center and K. Hovnanian Children’s Hospital at Jersey Shore University Medical Center.

This EPPIK study is investigating the use of the medication to treat three specific proteinuric diseases — steroid-resistant nephrotic syndrome\*, Alport syndrome\*\*, and IgA nephropathy\*\*\*. These diseases typically develop in children or young adults, cause progressive loss of kidney function, and result in end-stage kidney disease.

Proteinuric kidney diseases are rare and result in a condition called proteinuria, or too much protein in the urine. High levels of protein in the urine can affect kidney function. And because proteins are needed to build muscle and bone, regulate the amount of fluid in blood, combat infection and repair tissue in the body, it isn’t healthy for proteins to enter the urine and leave the body. Up until now the three conditions being studied have been treated with other classes of medications, including immunosuppressive drugs. At times for extended periods of time. Hackensack Meridian Children’s Health researchers have participated in two previously published studies of sparsentan, which is manufactured by Traverre Therapeutics. This latest EPPIK trial is the first to be a 100-percent pediatric study. This trial joins our other trials currently enrolling or in the process of being opened for: anemia in chronic kidney disease and atypical hemolytic-uremic syndrome.

“These conditions have the likelihood of progressing to irreversible kidney failure, and previous treatments have not been successful,” said Ken Lieberman, M.D., chief of Pediatric Nephrology, professor, Hackensack Meridian School of Medicine, and EPPIK principal investigator at [Joseph M. Sanzari Children’s Hospital](#). “The EPPIK trial gives pediatric kidney disease patients throughout New Jersey access to a promising new treatment before it is available to the public.”

## Hackensack Meridian Health Research Will Keep Getting Better

Dr. Ihor Sawczuk, M.D., FACS, and representatives of Manatt, the firm working with HMM to structure a strategic plan for the network’s research program, unveiled an exciting new future: the Hackensack Meridian Health Research Institute. A virtual town hall event drew over 100 participants from across the network. At its onset, Dr. Sawczuk reviewed some of the significant changes that HMM research has undergone over the past few years, including several shining achievements. Manatt then unveiled plans for the new HMM Research Institute (HMHRI), which will unify the research efforts and resources throughout the network. The consultants offered their assessment of the current state of HMM research, including recent growth, challenges, and needs. They also outlined HMM’s vision for research and proposed development plans. Finally, they shared their recommendations, which included three overarching concepts: (1) establish a connected network research ecosystem; (2) grow differentiated research programs; (3) promote innovation and translation. The event concluded with a brief Q&A.





## In Memoriam of Dr. Bonita Stanton, 1951-2022

Bonita F. Stanton, M.D., a pediatrician who saved lives in the developing world before returning to the United States as a visionary medical educator at leading institutions and served as the founding dean of Hackensack Meridian School of Medicine in New Jersey, passed away on Jan. 19 after a sudden and unexpected illness. She was 70.

Dr. Stanton was known for her pioneering work in impoverished corners of the globe, where her research and care improved and saved countless lives. A prolific author and researcher, Dr. Stanton taught for decades in leading medical schools across the country and helped create the innovative curriculum at one of the nation's newest medical institutions, Hackensack Meridian School of Medicine based in Nutley, New Jersey.

Dr. Stanton launched her career in a disease-ridden and disadvantaged part of the world. For five years, Dr. Stanton lived in Dhaka, Bangladesh, conducting research and treating the poor. Her groundbreaking research addressed the prevention and treatment of diarrheal diseases in the urban slums of the city, where drinking clean water, as well as maintaining a healthy life, was a near impossibility. When the World Bank learned of the research, they asked Dr. Stanton to continue the work as part of a new approach to economic development in severely impoverished nations with a major focus on maternal-child health and education. It was the first time the World Bank had collaborated in a financial support program with other nations and donors, including USAID. It blazed new trails in global wellness.

The experience launched Dr. Stanton's dedication to community-based behavioral research and creating more equity in healthcare delivery, a passion that defined her career.

She made major research contributions toward global HIV prevention and was continuously funded by the National Institutes of Health (NIH) as a Principal Investigator from 1991 to 2016. She authored more than 350 peer-reviewed manuscripts and served as an editor of several textbooks, including Nelson's Textbook of Pediatrics. She was the consulting editor for "Pediatric Clinics of North America," and was a

member of the editorial board of Clinical Keys. She served on countless study sections for the NIH and Centers for Disease Control and Prevention, and served on numerous boards, task forces, and professional organizations.

In academia, she brought her lessons from the developing world back to the United States as she served on the faculty of University of Maryland, West Virginia University, and Wayne State University (Detroit, Michigan). In 2016, she distilled all her experiences and insights into a career-defining new role: creating a new medical school with a mission to fundamentally change health care. The U.S. could improve outcomes and lower costs by focusing more on the social determinants of health, issues such as safe housing and access to healthy food, which play a major role in health outcomes. The lessons from Dhaka, where mothers had struggled to keep their children hydrated with clean water, directly informed the mission of the new school, the Hackensack Meridian School of Medicine, as Dr. Stanton recently recalled.

"This (Dhaka) experience is fundamental to our vision for the School of Medicine and has driven my whole career since that point," she said. "It is a great opportunity to start a new medical school in collaboration with a health care system in order to create a partnership that is really going to change health care outcomes for the populations they jointly serve."

In six short years, the School has blazed new trails in medical education. Dr. Stanton's leadership inspired the school's Vision and Mission, assembled a remarkable leadership team, partnered in the development of HMSOM's governance, secured accreditation from five separate institutions, established the school as an independent Institution of Higher Education, and pivoted the institution through a pandemic. She relished the opportunity, delighted in welcoming the first class in 2018, and proudly sent 18 of its members to graduate this past June to enter residencies across the Hackensack Meridian Health network.



"We will remember Dr. Stanton's many contributions, and the foundation she helped set for our network's academic and research accomplishments," 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. "She was a one-of-a-kind leader, and we will always strive to match her exemplary life."



# RESEARCH UPDATES & EVENTS

APRIL 2022

## IRB Continuing Reviews Requirement Being Removed for Some Minimal Risk Studies



In accordance with federal regulations governing human subjects research, the HMH IRB is eliminating the need for annual Continuing Reviews for most studies that undergo expedited review (i.e. studies determined to

be 'minimal risk'). New applicable studies will receive IRB approval without an expiration date. Existing applicable studies will receive individual notices in eResearch, indicating that the expiration date has been removed and of removal of expiration dates from existing consent forms (if applicable).

Note that although Continuing Reviews are being removed for most minimal risk studies, an abbreviated check-in form will be sent annually (at a time closely related to the study's previous expiration date) to inquire whether the research is active or closed, to check whether any issues have occurred that the IRB needs to be made aware of, and to allow for CITI training records to be reviewed. Please note that this elimination of Continuing Reviews does not affect the requirements to submit Amendments and Reportable Events as needed. In addition, the IRB can determine on a case-by-case basis that Continuing Reviews are needed for a minimal risk study (which will be indicated accordingly within IRB approval letters).

For any questions, contact the Research Integrity Office via email at [hmhirb@hmhn.org](mailto:hmhirb@hmhn.org) or phone at 201-880-3669.

## eResearch No Longer Accessible to Researchers Without HMHN Emails

Due to elevated potential cyber security threats, eResearch will be moved behind HMH's firewall in the near future. This means that any current eResearch user account that is not registered

with an @hmhn.org email address will lose access to eResearch. If you are not currently registered with an @hmhn.org email address and would like to maintain access, please go into your eResearch account and update your email address within your profile to your @hmhn.org email address:

- Log into eResearch
- Click on your name in the top right
- Under Properties, edit your email address
- Scroll to the bottom and click Apply in the bottom right

Please reach out to the Office of Research Integrity at 201-880-3669 or [hmhirb@hmhn.org](mailto:hmhirb@hmhn.org) with any questions.

## New Responsible Conduct of Research Training Program Available to HMH Researchers

According to the NIH, "responsible conduct of research [RCR] is the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles for all activities related to scientific research." RCR training is mandated by the NIH for recipients of specific grants. Other institutions, such as the National Science Foundation (NSF) also have RCR requirements.

In order to maintain compliance with those requirements and to further promote research integrity here at HMH, the Office of Research Integrity has partnered with the Office of Compliance to create a structured program that will be required for those individuals who receive the relevant grants and will be otherwise available to all researchers throughout the network.

We especially encourage all research departments to participate in the opportunity to hold a department meeting focused on RCR practices. A written outline that provides the framework for an one-hour department discussion on data management planning and data accountability is available [here](#). A member of the Office of Compliance or Office of Research Administration is available to facilitate the meeting upon request, but the meeting can also be conducted independently.

To learn more about the HMH RCR training program, please click [here](#).





## HMH Research Day

The first annual Hackensack Meridian *Health* Research Day will be held virtually on May 4, 2022 from 9 a.m - 2:30 p.m. This is a symposium at which featured research from across the network will be presented.

The agenda is available [here](#). Registration is open to all HMH employees and can be accessed [here](#) or by going to [events.hackensackmeridianhealth.org/hmhresearchday](https://events.hackensackmeridianhealth.org/hmhresearchday).

This event is approved for CME credit. Nurses may use this credit towards their contact hours.

## HMH Resident/Fellow Research Days

Resident/Fellow Research Day is an annual event that provides opportunities for healthcare professionals, residents, and students affiliated with Hackensack Meridian *Health* to present original research studies and vignettes to the academic and professional communities. It is conducted to enable healthcare professionals to maintain proficiency in evaluating critical scientific data, and to promote and present examples of practice-based learning.

### Southern/Central Regions Resident/Fellow Research Day

Tuesday, June 14, 2022, 7:50 a.m. – 12:45 p.m.

Jersey Shore University Medical Center – Hybrid model - On site or Virtual

Keynote speaker: Jyothi Nagajyothi, Ph.D., Director/Member of Hackensack University Medical Center, New Jersey and Member/Professor at the Center for Discovery and Innovation

### Northern Region Resident/Fellow Research Day

Thursday, June 16, 2022 (Exact time to be determined)

Hackensack University Medical Center – Hybrid model - On site or Virtual

Keynote speaker to be announced shortly.

### Information for Both Days

The Call for Abstracts opened on Monday, March 14, 2022 and closes on Friday, April 15, 2022 at 5:00 PM. Please read the [General Guidelines for Abstract Submission](#) before writing your abstract. Click [here](#) to submit your abstract.

Notifications of the review of the abstracts with further instructions will be sent to all corresponding authors no later than May 13, 2022.

We look forward to receiving your abstracts, and a day of networking and learning.

### Research Seminars

For more information about upcoming events that are part of the Investigator Training Lecture Series, click [here](#).

For more information about upcoming events that are part of the IHS IPE Research Seminar Series, click [here](#).

To see the research events calendar, click [here](#).

For more information about research events, please contact [tamara.friedman@hmhn.org](mailto:tamara.friedman@hmhn.org).



# FEATURED RESEARCHERS

APRIL 2022



**EDUARDO CORREIA, M.D.**  
*Director, Neuro-oncology,  
Jersey Shore University Medical Center*



**SHABBAR DANISH, M.D.**  
*Chairman,  
Department of Neurosurgery,  
Jersey Shore University Medical Center*

Brain disorders are notoriously tricky to diagnose and treat, and there have been limited advances in the last few decades that have truly impacted the overall survival for some of the most aggressive diagnoses. Part of the problem is that the brain is a very complex and delicate organ, with many functional responsibilities packed into a relatively small and layered space. Research on the brain can also be challenging because unlike other tissues, brain specimens can be extremely difficult to procure. Regardless, Drs. Eduardo Correia and Shabbar Danish, a neuro-oncologist and neurosurgeon, respectively, remain optimistic and are forging ahead in their pursuits of better options for patients. Both physician-scientists joined HMH in the last year and brought with them a wealth of research experience and knowledge. We met with them to learn more about what brought them to HMH, why they love research, and what they are working on now.

**You are both recent additions to the HMH research community. What made you decide to join the HMH team? And how has your experience here been so far?**

**ESC:** I came from Memorial Sloan Kettering Cancer Center (MSKCC). It is a very large institution, and I had been looking for an opportunity to offer more individualized treatment to the patients. I also discovered that there was a gap in services for neuro-oncology patients from Monmouth to Atlantic Counties. This is a pretty significant population that could be greatly helped by HMH's extensive resources. It seemed like a perfect opportunity to start a program and help give patients the best care possible for brain tumors. I brought the clinical trial work that I had been doing at MSKCC with me, so that patients don't have to travel out of state to get access to landmark clinical trials or cutting edge research in order to achieve the outstanding clinical care that they need. My experience here has been wonderful. I've been able to realize my goal of providing innovative individualized treatment to patients with brain tumors. I know all of my patients by name, all of their therapeutic courses of treatment, and when is exactly the right time to put them on clinical trials.

**SD:** I have been practicing in New Jersey for over a decade at this point and had been carefully considering a move to HMH for over two years before actually making the move.

It was important to me to determine whether this was the right place to grow professionally and whether there was enough support behind potential growth across neuroscience within the network. Coming in as a chair to lead the changes was a great opportunity personally and professionally. As for my experience so far: my expectations have been surpassed. The environment is supportive, and I have the right resources and the right people to get the job done well and to continue to grow.

## FEATURED RESEARCHERS:

**EDUARDO CORREIA, M.D. &**

**SHABBAR DANISH, M.D. (Continued)**

**Could you please each share a little bit about your respective specialties and your corresponding research interests?**

**ESC:** I specialize in neuro-oncology and my research interests are reflected in my involvement in clinical trials in this sub-specialty. I am most drawn to two specific areas within neuro-oncology: immunotherapy and precision medicine. In my field, there has been a significant movement towards treatment based on the genetic profiles of the patients' tumors. My research interests involve studying genetic mutations in tumors to predict their behavior and then utilizing target agents on them. This often enables patients to avoid the unpleasant side effects of conventional chemotherapy in favor of a much more directed approach. Currently, I have an open clinical trial studying checkpoint inhibitors for primary brain tumors and an approved trial for recurrent tumors using a similar therapy. I am also working on initiating a clinical trial where patients with brain metastases will be enrolled based on the genetic makeup of their tumors, as opposed to their tumor subtypes. The research team has been very supportive of all of these initiatives.

**SD:** Prior to coming here, I was chief of neurosurgical oncology at Rutgers Cancer Institute for many years. I also served as director of stereotactic and functional neurosurgery, which covers movement disorders, including Parkinson's Disease, dystonia, and epilepsy. In my recent years, the majority of my research and writing has covered MRI guided laser therapy. This technology has been around for about a decade, and I was one of the earlier adopters. I have written about the practical applications of that technology and also about the thermal distributions of heat in target tissues. I have also been involved in some basic science projects that focused on heat diffusion and have used cadaveric specimens to understand the anatomy and trajectory of these procedures. I have also recently written on the use of robotics in brain stimulation procedures, which are used for various movement disorders. My hope is to transfer my work on these subjects to HMH, and I am working on creating the infrastructure to do so.

**Can you please each give me an example of a study that you've worked on recently?**

**ESC:** I have an ongoing clinical trial that is for the purpose of studying the effect of immune checkpoint inhibition, a treatment to enhance patients' immune systems to attack cancer cells, in patients with brain tumors. We are evaluating this approach in various ways. In this study, we are testing the theory that radiation offered in conjunction with immunotherapy can increase treatment efficacy compared to immunotherapy alone. We will also do some basic science analysis looking into immune system regulatory cells to see which subpopulation of immune cells are activated in either patients who respond to it or the ones who develop significant side effects without a clinical benefit.

Essentially, we are trying to identify biomarkers to predict which patients will respond to immunotherapy, since only about a third of patients with brain tumors tend to respond to this treatment.

**SD:** Two recent publications come to mind. One of them is an article that I authored on laser therapy for inoperable tumors in the brainstem, which is a part of the brain that is fairly inaccessible in surgeries. Over the course of 8-9 years, I looked at trajectories, anatomic variations, and dose distributions of heat within the brain. Another recent article investigates the variability of signal heterogeneities within laser procedures. These can affect thermal distribution within the tissue and the ability to perform the procedure. I investigated variables that affect signal heterogeneities and discussed how to use those variables to help make decisions during laser procedures.

**How did you begin your involvement in research, and what do you most enjoy about it today?**

**ESC:** I was a medical student in Brazil and wanted to do my residency in the United States, so during medical school, I completed internships in MSKCC in neurology. I ended up loving neuro-oncology. At that time (around 2012), I met the chair of neurology and worked with her on several projects. She invited me to do a research fellowship in brain tumor genomics at the Brain Tumor Center at MSKCC. In that capacity, I worked on genomics projects with data from brain tumor patients, analyzing brain tumor mutations to see if different genomic findings corresponded to different treatment responses. From there, I continued to develop my interest in research and remain very engaged in it. In my field, clinical work really goes hand in hand with research because there are very few approved options for these patients. In fact, there have been no new FDA approved treatments for them in the last ten years, and at this time, we only have two FDA approved drugs.

**SD:** I initially became involved in research as a student because I was inspired by a senior researcher. I continued to work on research projects as a resident and then went into a field that is married to the research world. As Dr. Correia mentioned, clinical practice is closely connected to research in neuroscience. Research is so directly relevant to what I do, and I also have this inherent desire to advance science and continually improve care.

**Do you have any extraprofessional hobbies or interests?**

**ESC:** I love to travel and to immerse myself in different cultures. I also really enjoy learning languages. When I travel to different places, I make an effort to speak in their native languages. I learned Italian during COVID and am looking forward to going to Italy at my next opportunity. I also recently got into winter sports and have been working on improving my snowboarding skills.

**SD:** My family keeps me busy. I have 2 kids, a 17 year old and a 13 year old. I also play bass in a local rock band and am involved in a lot of active and outdoorsy stuff - I'm on a hockey team and a pickleball league. I am also an avid boater and fisherman. I once caught a 450 lb. thresher shark!





# FEATURED RESEARCHERS

APRIL 2022

## The CDI Experts: Nagajyothi Hunts Disease Clues in Fat

Fat is basically a dirty word in the modern era. But when it comes to biological reality, it is a critical factor in mammalian health. In many humans, fat is the second largest organ, smaller only than the skin.

For **Jyothi Nagajyothi, Ph.D.**, this is a frontier in the battle against almost all diseases.

Nagajyothi, a member of the Hackensack Meridian Center for Discovery and Innovation (CDI), focuses on the fat (adipose) tissue, and the role it plays in disease progression, severity and recovery. From the vector borne-parasitic Chagas disease to airborne-bacterial tuberculosis, from COVID-19 to leprosy, to cancers and diabetes, the scientist seeks to better understand how this ocean of adipose tissue making up the human body modulates inflammation and other dynamics – driving ultimate outcomes.

“People want to get rid of it – they assume it’s all bad. But we need to understand what fats are good, and what fats are bad,” said Nagajyothi, who is also an associate professor of Medical Sciences at the Hackensack Meridian School of Medicine, and also professor in the Department of Microbiology and Immunology at the Georgetown University School of Medicine.

“Jyothi is an innovative researcher who is helping to lead our emerging understanding of how adipose tissue and its signaling to the immune system influences health and disease,” said David Perlin, Ph.D., the CDI’s chief scientific officer and senior vice president, who is also a professor at the Hackensack Meridian School of Medicine and the Georgetown University School of Medicine. “Our institution is richer for having her do her work here, where it complements so many other avenues of inquiry.”

**Of Fats And Disease** One of her key discoveries thus far: that adipocytes and adipose tissue serve as a reservoir for many pathogens, including SARS-CoV-2, which can be a risk factor in the development of metabolic syndromes such as obesity and insulin resistance. The work has also opened a link between the pathogenesis of Type 2 Diabetes Mellitus, cardiovascular diseases and severity of acute and chronic infectious diseases, all major causes of death in both developed and developing countries.

Fats provide nutrition – and sometimes fortifications – from which disease can persist and continue to attack the body. For instance, tuberculosis uses the lipids in the fatty microenvironment to defeat the body’s immune system, in a long war of attrition.

One infectious disease which is a key bellwether of this dynamic is Chagas disease, the parasite-spread infection which remains asymptomatic even as it causes long-running damage to the hearts of unsuspecting patients. Spread through the feces of the kissing bug, the disease is a scourge in Latin America, where an estimated 8 million people are infected, according to the U.S. Centers for Disease Control and Prevention (CDC). Nagajyothi’s work with colleagues has shown an exacting dynamic of how the parasite damages the heart, long-term, via adipose pathways. The team has also started to point the best way forward for clinicians to offset such damage. For one, it appears high-fat diets early in the infection can be protective, despite what logic may otherwise dictate.

Chagas became an especial focus almost by accident, while she was a postdoc at Albert Einstein College. She overheard a cafeteria conversation about the pathogen, which ultimately led to her starting a conversation with the scientists, ultimately leading to a collaboration.

Her research combined her expertise with fat, showing how the disease was impacted by adipose tissue. As it turned out, Chagas was a great example of showing fat dynamics in an infection. She vividly recalls first glimpsing the parasite itself, *Trypanosoma cruzi*, under the microscope.

“The first time I saw *T. cruzi*, I actually felt scared,’ she said, chuckling recently at the memory. “It was like small snakes wriggling around. It was a sight.”

**Adipose Linkages** The lab has also studied the infectious disease at the global forefront these last two years: COVID-19. She and the team, using animal models, showed that pre-existing Chagas infection may actually be protective against COVID.

Overall, fat is not a bad thing in all cases – and it can actually be helpful in modulating disease.

“There’s a similarity between these diseases – COVID, TB, and Chagas,” she said. *(continued)*

## FEATURED RESEARCHER:

**JYOTHI NAGAJYOTHI, PH.D.** *(Continued)*

The Nagajyothi lab has recently made a big pathway discovery: that the adipogenic adipokine called adiponectin, which impacts glucose levels and fatty acid breakdown, acts as a “double-edged sword” in health and disease. This has opened up new dimensions in understanding the feedback mechanisms of adipomes and adipokines in regulating immunometabolic pathways in various infectious and non-infectious diseases. Diabetes and its metabolic changes play factors in TB and other diseases, in key ways.

In addition, her lab is studying the immunoregulatory effects of diet and metabolic drugs on adipocytes and adipose tissue pathology and its consequences on the progression and severity in diseases including metastatic breast cancer.

In other afflictions, losing a lot of fat via dramatic weight loss can sometimes “activate” diseases which were otherwise stable or asymptomatic when surrounded by fat.

Adipose tissue, it seems, has so much of a part to play in virtually every battle the human immune system may face. And Nagajyothi is aiming at unlocking its secrets.

“Fat is not just my bread and butter, it is my fortune/serendipity,” she said. “The ultimate goal is to completely understand the fat/pathogenicity interaction.”

**India, Germany, The U.S., Beyond** Nagajyothi was born and raised in a rural small town in the south of India. It was a very conservative society, where girls were placed into arranged marriages shortly after the age of 18.

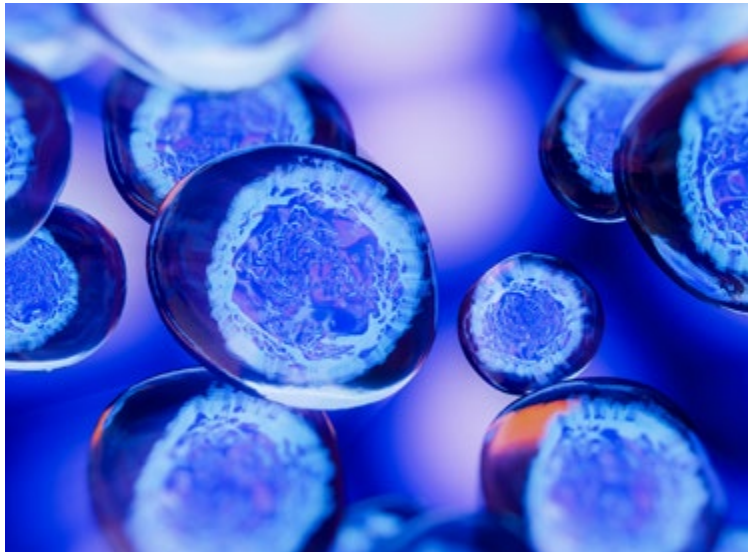
But her parents were set on her having an education of her own and becoming accomplished, encouraging her to pursue her studies and to play sports unlike many other girls. She was the only daughter of her older parents, so she was very protected – she was even still holding her father’s hand to cross the street in her mid-20s, as she recalls now.

But she pursued education. That’s what led her to continue her way out into the world: first her degrees in India, then a fellowship in Germany, and a burgeoning career in the United States since 2001.

Now married and living in New Jersey, her two children are finding their own paths and careers in other parts of the U.S.

The fundamental curiosity – of questions leading to yet more questions – is what drives her constantly forward.

“I always wanted the bigger picture – even if I didn’t understand what the bigger picture could be,” she said. “Basically, I’m a very curious person.”



# FEATURED RESEARCH ADMINISTRATOR

APRIL 2022



## DAVID CHOW, M.D.

*Medical Director, HMH Biorepository  
Medical Director, HMH Blood Bank  
Hematopathologist*

Dr. David Chow knows bodily tissues, inside and out. In addition to his work as a hematopathologist and the director of the HUMC blood bank, he also helms the [network biorepository](#). The biorepository is integral to HMH research and has already been crucial in making important findings. It is also a full-service operation, with services including cell banking, specimen processing, bioinformatics analysis, cryostorage, and more. Furnished with advanced equipment, an impressive inventory, and seasoned staff, the biorepository was designed to give researchers as seamless an experience as possible.

Dr. Chow met with us to discuss his path to the biorepository, the biorepository's recent growth, and what we can expect next.

### **How did you become interested in medicine and specifically the field of pathology?**

I actually did not intend to go into medicine before college, but I did like science and ended up majoring in biochemistry and biophysics. During my sophomore year, I participated in a program that offered the opportunity to shadow alumni in different fields. On a whim, I chose to follow a burn surgeon who was practicing at Cornell, and it was inspiring. I saw someone at the forefront of his field who was taking new research and techniques and directly applying it to his patients. That experience sparked my desire to become a physician. I became interested in pathology because of how quickly pathologists can translate cutting-edge science into clinical practice. During my residency, I became involved in the blood bank because there was a lot of patient interaction, and I really enjoyed working with patients. Then, during my fourth year, I also fell in love with hematopathology, so I decided to do fellowships in both subspecialties. The major challenge was that these two subspecialties are at polar extremes of the field, and few jobs marry those two areas of pathology together. Fortunately, Hackensack University Medical Center did, and I've been here ever since.

### **What led to your becoming director of the network biorepository, in addition to your other roles?**

The main role of the biorepository director is to work with researchers to identify tissues of interest and pair them with matching data. Before becoming involved in the biorepository, I had already collaborated on research projects with John Theurer Cancer Center as a sub-investigator. And as a pathologist, I deal with samples all the time. Because I was already involved with research and I have an understanding of how best to handle different types of tissue samples, I was asked to fill the role of biorepository director when there was an opening.

### **What does your role as medical director for the biorepository mean practically? What do you do in that capacity?**

My role is exciting because it's varied. One of my responsibilities involves interfacing with other principal investigators who are interested in doing research and want to know if samples exist for their intended projects. Sometimes they think that a certain type of sample can support their studies, and I let them know whether that is the case or whether that sample wouldn't work. Another part of the role involves ensuring that biorepository functions are standardized and that the quality of the specimens is consistent. For example, specimens collected in different hospitals within the network should not produce significant variations in their quality. We refer to this as minimizing "pre-analytical variables." Lastly, I work with Ya'el Kramer, the Director of Operations for the biorepository, to ensure that we are operating in absolute compliance with all rules and regulations.

### **Is there anything that you would like HMH researchers to know about the biorepository?**

I think that it might be helpful for me to shed some light on one aspect of the process, just to give researchers a bit of perspective. There is the misconception that the tissue acquisition - identifying and getting the tissue - is the hardest part of providing researchers with what they need, but that is not the case. The hardest part is actually matching samples with high quality data. Samples without data are essentially useless, and researchers often want numerous data points that may be difficult to capture in EPIC. Our biorepository staff usually needs to go into patient charts to retrospectively capture the right data, and that's the most time intensive part for us. *(continued)*



## FEATURED RESEARCH ADMINISTRATOR:

**DAVID CHOW, M.D.** *(Continued)*

**You and your co-director, Ya'el, grew the biorepository by leaps and bounds in the past few years. What has been your greatest challenge in building the biorepository, and how did you overcome it? Of what are you most proud?**

Ya'el and I only began to oversee and reorganize the network biorepository around 4 years ago. Prior to that, there were several biorepositories that were mostly cancer-specific across the network, and collection qualities varied. So the most challenging part was merging these separate collections into one uniform network biorepository. We picked the best parts of the legacy systems and made sure that everything meshed well. We also expanded what we can collect and updated our policies so that we are fully compliant with the newest regulations and guidelines. We are now working on improving the consenting process so that it is as streamlined as possible.

I am proud that we have been able to overcome hurdles and move things along in the right direction, and I am especially proud of the biorepository staff. During the pandemic, they pulled together and were able to collect a huge number of samples that are now being used to help us better understand SARS-CoV-2. These are mostly swab samples, which we never collected before. I think the pandemic showed how much the biorepository has changed in terms of organization and flexibility.

**Can you share an example of an exciting project for which the biorepository specimens were used?**

At the beginning of the pandemic, we made a decision to collect all positive swabs. Because of that, we were able to provide CDI researchers with valuable serial samples from inpatients during the first wave. Our researchers quickly identified new variants arising in real-time in an immunocompromised patient and published this data. In retrospect, we now know that the story of SARS-CoV-2 variants is one of the most important drivers of how the pandemic has unfolded, and HMMH's efforts have been an important part of that conversation.

**What is next on the horizon for the biorepository?**

We are working to automate our specimen processing, which will allow us to really expand our collection volume. We are going to further branch out in terms of the types of specimens collected and who we collect from. We also hope to continue facilitating both cancer and non-cancer related projects. Finally, we are in the process of establishing a third site at JFK so we will have a base in central New Jersey.

**Do you have any extraprofessional hobbies or interests?**

I enjoy hiking and traveling. I especially like experiencing new cultures, so when I travel, I try to avoid the resorts and touristy areas. I like to wander in different neighborhoods and try local cuisines. Pre-pandemic, I went on an amazing trip to Peru. I split my time between hiking to Machu Picchu and experiencing the vibrant metropolis of Lima. I think the most rewarding part of seeing different cultures is to see how we are ultimately so similar. It all comes down to family, friends, and good food!



# QUARTERLY QUESTION

APRIL 2022

**If a non-English speaking participant is consented with a short form,\* how many days after the consent may lapse before a fully translated consent must be provided to the participant?**

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.

\*A short form may not be used in situations in which non-English speaking individuals who speak a certain language are expected. For example, if the area is largely populated by Spanish speakers, then a Spanish short form may not be used.

A short form may be used when both of the following are true:

- A full-length version of the consent form in a language understandable to the subject is not available, and
- It is in the subject's best medical interest to be enrolled in the research before a translated consent form can be obtained