



Hackensack  
Meridian *Health*

# RESEARCH ROUNDUP

SPRING 2023



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

The network's research operations continue to astound. We are expanding into new spaces, making trailblazing discoveries, and we're even planning a look into science in outer space! But all of these developments continue to keep an eye on the ultimate prize: the well-being of our patients.

Ihor Sawczuk, M.D., FACS



## NOTE FROM THE **VP**

The scope and breadth of research extends from COVID-19, to cancer, to community outreach. Being the largest health network in New Jersey has allowed us to help spearhead so many advances within the umbrella of the Hackensack Meridian Health Research Institute.

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



## HMH RESEARCH NEWS



## CDI, Axiom Space Sign Agreement to Pursue Science - In Space

The Hackensack Meridian Center for Discovery and Innovation (CDI) and Axiom Space, a Houston-based company currently building the world's first commercial space station, will collaborate to better understand the dynamics of biology and disease by conducting experiments in space. The CDI and Axiom Space will work together to study the influence of microgravity on the body with the intent to better understand human health and disease on Earth and ensure safe space travel. The initial collaboration may explore the impact of microgravity on the human immune system and how that affects the human body as it responds to space travel.

"The CDI and Axiom Space partnership is a critical deal which could benefit virtually all of us back on Earth," said Robert C. Garrett, FACHE, chief executive officer of Hackensack Meridian Health. "The sky isn't the limit when it comes to the expertise of our scientists."

"Space travel in microgravity places stress on the body," said David Perlin, Ph.D., chief scientific officer and executive vice president of the CDI. "By learning about factors that keep space travel safe, we can apply the knowledge to improve the terrestrial health of humans with a wide variety of conditions and diseases." (continued page 2)

KEEP GETTING BETTER

## CDI, Axiom Space *(continued)*

Since the mid-20th Century, a growing body of literature has found that humans and other Earth-evolved organisms age and respond to stimuli differently when removed from the natural atmosphere of the Earth and its gravitational pull. Exploring the science underlying these changes could lead to insights for humans in space in the future - and for health care here on Earth.

“By exploring partnerships with outstanding scientific institutes such as CDI, we are able to maximize the impact of the scientific research we enable across our portfolio of initiatives through Axiom Space missions to the International Space Station (ISS) today and through future missions to Axiom Station,” said Christian Maender, Executive Vice President for In-Space Solutions at Axiom Space. “We are building opportunity in space to better life on Earth.”

Axiom Space reached a critical milestone for its objective last year, completing the first all-private astronaut mission to the ISS. On April 25, 2022, the Axiom Mission 1 (Ax-1) crew and the SpaceX Dragon spacecraft safely splashed down off the coast of Florida. The Ax-1 crew’s arrival back to Earth officially concluded the first mission of its kind, thereby successfully demonstrating Axiom Space’s ability to integrate with the ISS and conduct meaningful research outside the planet’s atmosphere.

“The CDI has continually pushed the envelope for our health network, and beyond,” 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. “Their mission has been global for quite some time – but now they are pushing even beyond that.”

## Hackensack Meridian Health Partners with Neosoma for Innovation in Brain Tumor Treatment, Research

Hackensack Meridian Health and Neosoma, Inc., an innovative medical technology company focused on helping clinicians advance the treatment of brain cancers through the use of artificial intelligence (AI), announced a new strategic partnership to tackle some of the most difficult-to-treat tumors.

The collaboration will include clinical data sharing, clinical research, and strategic investment from the health network to support the Massachusetts-based company’s innovative method of imaging, tracking and collecting data on numerous types of brain tumors including glioblastomas.

“We are committed to investing in research and innovative therapies to live our mission to transform health care and give our patients the best possible outcomes,” said Robert C. Garrett, FACHE, chief executive officer of Hackensack Meridian Health.

“Partnering with Neosoma Inc. is a great way to continue to develop potential game changing therapies to treat these challenging cancers.”

“We have a terrific partnership with Hackensack Meridian Health already,” said Ken Kolodziej, the CEO and co-founder of Neosoma. “We’re very excited to expand the scope of our collaboration with the shared goal of improving treatment and outcomes for patients with brain cancer.”

The partnership will include HMH physicians using Neosoma’s software in clinical practice, starting with Hackensack Meridian JFK University Medical Center; physician input and feedback for development of future software including neurosurgeons, neuro-oncologists, neuroradiologists, radiation oncologists, and other clinicians; and data sharing for product R&D efforts including collaboration with Anthology Diagnostics for genomics data and capabilities, among other benefits. [READ MORE](#)



Hackensack  
Meridian Health



## Bear's Den Launches Second Challenge, Seeking to Decrease Length of Stay

The Bear's Den Changemaker Innovation Challenge: Decreasing Patient Length of Stay (LOS) has launched! The challenge is a network-wide open innovation competition and provides an opportunity to effect change, to look forward to the future and to think about what is possible.

LOS is a quality metric commonly used to measure a hospital's ability to efficiently and effectively deliver care. Together, the network continues to improve its ability to care for patients in the most efficient and effective manner, minimizing unnecessary delays in diagnosis, treatment and recovery. Reducing unnecessary or avoidable days of stay also reduces a patient's risk for complications, delays in getting the most clinically appropriate bed and the overall costs of care. The challenge prompts team members to ask themselves, “What processes or systems slowed down my ability to deliver care or support to patients?”

“What challenges do I experience, that, if fixed, could enhance more timely delivery of care or support to patients?”

Visit the Bear's Den page on MyHMH for additional information, including timelines, FAQs, the submission form and more. If you have any questions or comments, email the Innovation team: [OIC@hmhn.org](mailto:OIC@hmhn.org).

## Less Extensive Surgery Is Just as Effective as Full Lobe Removal for Some Early Lung Cancers

Hackensack Meridian Jersey Shore University Medical Center investigators were part of a multicenter international clinical trial showing that removing just the part of a lung containing an early-stage lung cancer was as effective as removing the entire lung lobe, without compromising the risk of recurrence or overall survival. The findings of the Phase 3 study, published in the February 9, 2023, issue of the *New England Journal of Medicine*, have the potential to change the standard of care for select patients with small cancers in the lung periphery that have not spread beyond their original location.



“The results of this clinical trial are very important and may change the way we manage early-stage lung cancer,” explained Thomas L. Bauer, M.D., MBA, chairman of surgery at Jersey Shore University Medical Center, who was one of the study’s lead authors. “We also witnessed a trend toward better respiratory function in patients who had less lung tissue removed, which could be especially beneficial for people with compromised pulmonary function.” [READ MORE](#)

## CDI Researcher Might Have Found Key to Why COVID-19 Kills More Men than Women

From the first months of the COVID-19 pandemic, observers noted that men are more susceptible to severe infections of the SARS-CoV-2 virus, with increased death rates.

One scientist at the Hackensack Meridian Center for Discovery and Innovation (CDI) has new findings which may answer why.



Jyothi Nagajyothi, Ph.D., a scientist at the CDI investigates infectious diseases relating to fat in the body, including COVID-19.

A new publication in the *International Journal of Molecular Sciences* indicates males fare worse than females with the disease because the virus more readily attacks females’ fat tissue, in lieu of lung tissue.

“Our data suggested that in female mice adipose tissue may act as a sink/reservoir for SARS-CoV-2 and thus spares the lungs from a greater viral load, preventing pulmonary damage due to infiltrated immune cells and activated pro-inflammatory cytokines,” they write.

The Nagajyothi Lab’s mouse models mimicking the human immune system showed that females lost more fat compared to males when infected with COVID-19. The males had more virus

in their lungs, while the females showed more virus in their fat tissue. The theory is that the adipose (fat) tissue in females may act as a “sink” or “reservoir” of the virus.

The latest paper follows a publication last year in *Frontiers in Cardiovascular Medicine* in which Nagajyothi and colleagues showed the virus infiltrated the lungs of males much more readily than it did in females. The latest paper goes a bit further, showing that an inverse relationship exists between the viral loads in the lungs and adipose tissue, and it differs between males and females. They found that SARS-CoV-2 infection alters immune signaling and cell death signaling differently in SARS-CoV-2 infected male and female mice.

“These data may help explain the higher COVID-19 susceptibility in males compared to females,” they conclude.

Photo: Jonathan Hillyer



## Hackensack University Medical Center Announces Opening of Helena Theurer Pavilion

Hackensack University Medical Center’s 530,000-square-foot Helena Theurer Pavilion is now open — and this state-of-the-art, nine-story surgical and intensive care tower is raising the bar on patient care excellence in the New York metropolitan area. The Pavilion features all-private patient rooms and the

latest “smart hospital” technology, with every detail optimized to deliver an outstanding patient experience.

“This is one of the largest hospital construction projects in the country and we could not be more proud to advance health care for the communities we are privileged to serve,” said Robert C. Garrett, CEO of Hackensack Meridian *Health*. “This new smart hospital expansion is a great example of Hackensack Meridian *Health* building the health system of the future.”

The Pavilion includes:

- 24 operating rooms
- 72 post-anesthesia care unit beds
- 50 Intensive Care Unit (ICU) beds
- 175 medical/surgical beds, including a Musculoskeletal Institute and intermediate care rooms
- 6 da Vinci robotic surgical systems, including one single port system
- 4 orthopedic robots for joint replacement procedures

[READ MORE](#)

## Hackensack Meridian Cardiologists Present at Prestigious ACC/WCC Cardiology Scientific Session

**Presentations in electrophysiology clinical science; complex clinical cases, including heart failure, cardiomyopathy and vascular medicine, as well as ischemic heart disease clinical science categories**

Cardiologists from Hackensack Meridian Health's Hackensack University Medical Center and Jersey Shore University Medical Center, the Hackensack Meridian School of Medicine and collaborators presented seven new clinical research and complex clinical cases as well as poster presentations at the ACC 23: American College of Cardiology/World Congress of Cardiology Scientific Session. The conference was held March 4-6, 2023, with virtual and in-person sessions in New Orleans, LA.

"We are honored to participate in the ACC 23 meeting where our cardiologists and their collaborators will present their latest research and teach continuing medical education," said Elizabeth A. Maiorana, MBA, MSN, RN, CCCC, vice president, Cardiovascular Care Transformation Service, Hackensack Meridian Health, prior to the conference. "Our goal is to advance patient care and extend patients' lives, and we welcome the opportunity to share insights and gain more knowledge as well." [READ MORE](#)



## Hackensack Meridian School of Medicine Fully Accredited

**The Liaison Committee on Medical Education (LCME) grants school full approval, a major milestone**

The Hackensack Meridian School of Medicine (HMSOM) has been granted full accreditation by the Liaison Committee on Medical Education (LCME), a major milestone capping a robust seven-year review process that affirms the highest standards in the training of future physicians. The school admitted its first class in 2018 and has graduated two classes, many of whom are serving residencies in Hackensack Meridian Health hospitals.

"This is the culmination of years of work that started with a vision to reinvent medical education to create a physician workforce to thrive in a new state of medicine," said Robert C. Garrett, FACHE, chief executive officer of Hackensack Meridian Health.

"We are reaching our goals to keep physicians in New Jersey, to diversify the physician workforce and graduate doctors who will humanize health care."

The LCME is sponsored by the Association of American Medical Colleges (AAMC) and the American Medical Association (AMA). The LCME is the accrediting body for all institutions conferring medical doctorate (MD) degrees in the United States and Canada. LCME accreditation is a voluntary, peer-reviewed process of quality assurance that determines whether the medical education program meets established standards, according to the organization. All aspects of the institution undergo rigorous review, including the entire curriculum, finances, infrastructure, and faculty. The full accreditation by the LCME confirms the high quality of the program.

"This tremendous accomplishment is a testament to the talent and perseverance of our faculty, staff, and students," said Jeffrey Boscamp, M.D., dean of the school. "We are meeting every standard required of us while pioneering, among a small cadre of other institutions, an accelerated medical education program, fully embracing an active learning pedagogy, and pioneering an award-winning investment in our local communities through the Human Dimension course."

Medical education programs leading to the MD degree must first hold institutional accreditation to be eligible for initial full accreditation and for continuing accreditation by the LCME. [READ MORE](#)



## Leading Scientists Gather at Inaugural MAVDA Meeting to Bolster Antiviral Drug Discovery Research

More than 70 scientists took part in the inaugural Annual Metropolitan AntiViral Drug Accelerator (MAVDA) scientific review meeting convened at the Hackensack Meridian's Center for Discovery and Innovation (CDI) in Nutley, NJ, on January 27, 2023. MAVDA is one among the nine Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern program funded by the National Institute of Allergy and Infectious Disease (NIAID) and involves world-class institutions in the New Jersey-New York metropolitan area, and beyond. The meeting was co-led by drug discovery expert Dr. David Perlin at CDI, and world-renowned virologist and Nobel laureate Dr. Charles Rice. *(continued)*

## MAVDA Meeting (continued)

The meeting participants include several senior world-class virologists, including Dr. David Ho (Columbia University), Dr. Stephen Goff (Columbia University), Dr. Yosef Sabo (Columbia University); drug discovery experts Dr. Jingyue Ju (Columbia University) and Dr. Tom Tuschl (Rockefeller University), Dr. Alejandro Chavez (UCSD); structural biologists Dr. Lawrence Shapiro (Columbia University) and Dr. Dinshaw Patel (Memorial Sloan Kettering Cancer Center, Cornell University); medicinal chemistry, pharmacology, and drug screening experts Dr. James Balkovec (Center for Discovery and Innovation, Hackensack Meridian Health), Dr. Joel Freundlich (Rutgers University), and Dr. Fraser Glickman (Rockefeller University). The meeting was also attended by scientific leads from innovative BioPharma including Julian Symons (ALIGOS), David Olsen (Merck) and representatives from Takeda (Tri-TDI).

The group of world-class experts is tackling one of the most major health crises of our time. The scientists came together to share ideas and developments in their drive to create new oral antiviral drugs to treat SARS-CoV-2 and its various variants, as well as other coronaviruses and other future viral threats.

“Translational science is extremely important to what we’re doing, and that’s why we’re here,” said David Perlin, Ph.D., chief scientific officer and executive vice president of the CDI and co-investigator on the MAVDA program. [READ MORE](#)

## JFK Johnson Rehabilitation Institute Presents at the Association of Academic Physiatrists National Conference

Hackensack Meridian JFK Johnson Rehabilitation Institute’s physicians and researchers introduced more than 20 research presentations at the annual meeting of the Association of Academic Physiatrists in February 2023. The research will advance the field of rehabilitation medicine and cover areas such as traumatic brain injury, Parkinson’s disease, post-COVID fatigue, stroke, and other illnesses, conditions, and injuries.

“We welcome the opportunity to present the important research we’re doing at JFK Johnson to a national audience,” said Sara Cuccurullo, chair, vice president and medical director of JFK Johnson Rehabilitation Institute, in advance of the meeting. “Our goal is to improve outcomes for our patients and also to advance the specialty of rehabilitation medicine to help patients everywhere.”

Dr. Cuccurullo is professor, chairman, and residency program director of the Department of Physical Medicine and Rehabilitation at Hackensack Meridian School of Medicine and Rutgers-Robert Wood Johnson Medical School.

One example of the research includes “Updates in the Evaluation and Management of Fatigue in Post-Acute Sequelae of COVID,” a presentation that will be made by Talya Fleming, M.D., Aba Zola, M.D., and Benjamin Abramoff, M.D. The study looks at long-term fatigue in some people who experience COVID. The in-person meeting was held from February 21-24, 2023, in Anaheim, California, and attracted an estimated 1,500 attendees. [READ MORE](#)

## CDI Scientist’s Data: Chagas Disease May Actually Help Protect Heart Against COVID-19

Chagas disease is a parasite-spread infection affecting 300,000 people in the United States. It’s largely a silent scourge, remaining mostly asymptomatic but causing long-running damage to the hearts of unsuspecting patients. Spread through the feces of the kissing bug, the disease is a major problem in Latin America, where an estimated 8 million people are infected, according to the U.S. Centers for Disease Control and Prevention (CDC).

Curiously, it appears to have a potential upside in the COVID-19 era, as it may actually be protective against SARS-CoV-2, the virus that causes COVID-19.

Jyothi Nagajyothi, Ph.D., a scientist at the Hackensack Meridian Center for Discovery and Innovation (CDI) investigates Chagas disease, as well as other diseases relating to fat in the body. The lab has also studied the infectious disease at the global forefront these last two years: COVID-19.

According to her recent paper, having a pre-existing Chagas infection is actually somewhat protective against SARS-CoV-2’s potentially damaging effects in the heart. The paper in *Frontiers in Cardiovascular Medicine* shows in mice that a Chagas-infected heart showed lower viral loads of SARS-CoV-2.

“The significantly reduced viral load in the hearts of coinfecting mice may be due to the altered immune and metabolic changes caused by *T. cruzi* infection during acute and indeterminate stages,” Nagajyothi and colleagues write. [READ MORE](#)

## Dr. Kountz Earns Award, Named Chief Academic Officer

David Kountz, M.D., MBA, MACP, won the 2023 Alliance of Independent Academic Medical Centers (AIAMC) Ethel Weinberg, M.D. Award. The AIAMC is an American national membership organization of approximately 70 major academic medical centers and health systems committed to quality patient care, medical education and research. The Weinberg Award is presented to an AIAMC individual member who best exemplifies the energy and commitment of its founder. Dr. Kountz, who has an extensive background with the AIAMC dating back to 2015, was recognized at an awards dinner in Nashville on March 24.

Kountz was also named Chief Academic Officer, Hackensack Meridian Health, and Sr. Associate Dean of Graduate Medical Education at Hackensack Meridian School of Medicine, effective March 19, 2023. Dr. Kountz had served as Co-Chief Academic Officer with Dr. Jeffrey Boscamp since 2016. In his new role, Dr. Kountz will continue efforts to harmonize GME across the network and with the School of Medicine; advance diversity, equity and inclusion in GME programs; and develop a multi-year GME strategic plan. He will also assist the Dean in fulfilling the diversity and inclusion mission for the School of Medicine. Dr. Kountz will be reporting to Ihor Sawczuk, M.D., president of Academics, Research and Innovation, and Jeffrey Boscamp, M.D., president and Dean of Hackensack Meridian School of Medicine.



## JTCC Community Outreach and Engagement Program Co-Sponsors First Major Community Outreach Event

The first major community outreach event that the Cancer Community Outreach and Engagement (COE) program at the John Theurer Cancer Center (JTCC) co-sponsored, a Family Fun Day focused on health, was held on April 16, 2023, at the Historic Calvary Baptist Church in Paterson, one of the largest African-American churches in the center’s catchment area.

Lisa Carter-Bawa, Ph.D., director of Cancer Community Outreach & Engagement at the JTCC, recognized Elan Shoulders, Manager of JTCC COE, for her tremendous efforts in making the event a success and shared her thoughts on the significance of the event.

“[Elan] has been critical to engaging the community faith leaders and working with the leadership at the Historic Calvary Baptist Church to plan and execute this event,” said Carter-Bawa.

“Despite the call for rain, she was prepared with a plan A and plan B. Elan and her team were incredibly creative in making items for their outreach table that would engage the community. There were over 100 individuals that stopped at the Cancer COE table specifically and engaged with our staff to learn more about cancer risk, prevention and early detection.

“As we move forward in the robust development of our Cancer COE program at JTCC/HMH, it is critical to remember that fostering trust in our underserved communities is key to the research that we as a scientific community perform. Events like these not only raise awareness about cancer risk, prevention and early detection, but foster relationships for those crosstalks between the community, clinicians and scientists. With outreach events in the places our patients - and potential patients - live, work and play, we are able to increase awareness of clinical trials, offer a venue for researchers to recruit, and improve the overall health of our community.”



## New Space Open for CDI

The Hackensack Meridian Health Research Institute cut the ribbon on a total of 20,000 additional square feet of space for the Hackensack Meridian Center for Discovery and Innovation (CDI) at the Interprofessional Health Sciences Campus, which includes the Hackensack Meridian School of Medicine, on May 3. This state-of-the-art new space will house nine laboratories and approximately 60 scientists and support staff and will be part of HMH’s major investment in oncology and immunology. Once completed, the total cost of the project will be approximately \$12 million. These upgrades bring the total space of the CDI to 128,000 net square feet.



## CACTR Unveiled with Ribbon Cutting

The Hackensack Meridian Health Research Institute was proud to unveil the Center for Advanced Clinical and Translational Research on the Hackensack University Medical Center campus on January 31, 2023.

This will provide the space and resources to conduct vital clinical trials for years to come.

## CDI Hosts Take Your Child to Work Day

Take Your Child to Work Day was a terrific event filled with fun experiments, games, ice cream and even a presentation from Dr. Perlin about the discovery of vaccines.

For those parents who missed being around, the event featured science, safety, awareness and teamwork.

The science activities included collecting samples from outdoors, followed by preparing slides to view under the microscope, growing bacteria, making smoke-filled bubbles, popping eppendorfs and making elephant toothpaste. The kids also received a booklet and some samples from the experiments we did.





# RESEARCH UPDATES & EVENTS

SPRING 2023

## Best Practices for Handling an FDA Audit

The idea of an FDA audit may be anxiety-provoking for some, but knowing what to expect and being prepared can bolster your team's confidence and make the experience seem less intimidating. Below are some tips from our institutional research auditor:

### Immediately, when you learn of the audit:

- Re-read the protocol and review the regulatory binder and subject charts.
- Alert all who need to know, including IRB, Corporate Compliance, Co-investigators, CRO, Sponsor, pharmacy, research leadership, etc.
- Schedule a comfortable room and space for the review.

### Before the Audit:

- Schedule a PI/Study Team prep meeting.
- Plan for the following details:
  - Who will greet the inspector & where?
  - Will the PI be available to receive the FDA form 482?
  - Who will be with the inspector at all times?
  - Where or how will you make copies for the inspector?
  - How will you recap each day of the inspection & to whom?
- Educate office staff on how to interact with the inspector and how to answer their questions.
- Remind team the inspector will show a badge and not to be taken off guard by this or to be overly anxious about this.

### During the Audit:

- Have as many of the research team members as possible at the initial meeting with the auditor.
- Bring into the room only the details the inspector asks for.
- Be hospitable, professional, calm and courteous.
- Don't offer to buy lunch, but it is OK to offer coffee or water, and orient the auditor to area, including the rest rooms.
- Share what is requested but refrain from being overly chatty or offering information not asked for.
- Never become defensive or argumentative.
- Display a passion for excellence.
- Have someone in the room at all times with the auditor to make copies or run questions to the team.
- At minimum, ask at lunch and at the end of the day if there are any questions or concerns. Remember that it is OK to let the auditor know that you will get back to them. Do not feel pressured to answer or make up an answer on the spot.
- Ask for clarification if anything asked for is unclear to you.
- Take careful notes, especially at the end of the day/audit summation.

- At the end of the audit, always convey grace/thankfulness and collegiality, no matter the outcome.

### After the Audit:

- Promptly (within 15 days for a 483) and completely address and respond to findings in writing to avoid a warning letter.
- Contact and collaborate with Corporate Compliance, Research Office, IRB, etc on Corrective and Preventive Actions (CAPA) response before sending out the response. Remember the response is coming from the institution, not simply the PI. The PI should review before the response goes out, but the response itself should be sent by central administration.
- Put into practice your CAPA.

## Roll Out of DOA Log SOP by JTCC Holds Promise for Reducing Errors in DOA Logs During Audits

The Delegation of Authority (DOA) Log is among the most important documents in an audit. It is often the first item that an auditor will review and also one of the most prone to potential mistakes. It holds the key to who is responsible for what and is critical to ensuring that there is accountability for all research responsibilities and that qualified individuals are conducting them.

In an effort to further improve the processes for DOA log documentation, the JTCC developed an SOP that involves using a combination of a JTCC Oncology Research Study Personnel Master Signature Page and a separate Protocol-Specific Delegation of Authority Log (PS-DOA). Sponsor-provided delegation logs are no longer used. Prior to any study-related activities being undertaken, individuals must sign the JTCC Oncology Research Study Personnel Master Signature Page and be added to the PS-DOA by regulatory staff and PI.

An audit of the DOA logs was conducted several months ago and fewer mistakes were detected than previously. Another audit will take place this summer to confirm the findings.

## Keep an Eye Out for Our Upcoming Educational Events

More information about the types of education available and a calendar with dates and times of events can be found [here](#).

A [video library](#) of past events is also available for reference.



## Resident/Fellow Research Day 2023

The Office of Academic Affairs and Hackensack Meridian Health Research Institute presented the virtual HMH 2023 Resident/Fellow Research Day on May 23. Lisa Carter-Bawa, Ph.D., APRN, ANP-C, FAAN, gave the keynote, entitled “Research with a Purpose: The Impact of Community Participation.”

The event boasted original research, case reports, a poster session, and presentation of awards. The event attracted a wide audience of fellows and residents, but also physicians, nurses, students, and health care professionals involved in research activities.

**Find out more about this event in the Summer edition of the Research Roundup, coming soon.**

## Second Annual HMHRI Research Symposium 2023

The Second Annual HMHRI Research Symposium was held virtually on June 1. The symposium highlighted some of the most impactful research conducted at HMH as part of the HMH Research Institute. The HMHRI leads and organizes a connected ecosystem bringing together clinicians, scientists and educators to respond to the health problems of our time, in real-time. The HMHRI is dedicated to accelerating discovery, innovation, and translation of scientific breakthroughs that address unmet clinical needs. This event served as an opportunity to learn about the groundbreaking research and innovation taking place within our network and to foster collaboration and networking.

**Find out more about this annual event in the Summer edition of the Research Roundup, coming soon.**



### May 20 Was Clinical Trials Day

Clinical Trials Day is celebrated around the world on May 20 to recognize the day that James Lind began what may be considered

the first randomized clinical trial. Aboard a ship on this day in 1747, in pursuit of a treatment for scurvy among sailors, the Scottish doctor tested the theory that citrus fruits could cure the deficiency. His work ultimately discovered a cure - and saved untold lives.



Here at HMH, there are hundreds of leading-edge clinical trials available to our patients. Throughout the network, scientists

are pursuing treatments for diseases that run the gamut from tuberculosis to Alzheimer’s disease, from multiple myeloma to coronary artery disease.

We raise our hats to all of the researchers who contribute every day to the vast body of knowledge that enables millions of people to live better and longer lives.

## OnCore Training and Policies

### OnCore Training

For new users, please complete an [Access Request Form](#) and a trainer will contact you regarding training sessions.

### OnCore Policies

As a user of OnCore, please familiarize yourself with the following policies in PolicyStat regarding its use:

- OnCore (CTMS) Utilization for Clinical Trials
- Protocol Administration in OnCore
- Subject Administration in OnCore

For more information, contact OnCore Support Email: [HMHOnCoreSupport@hmn.org](mailto:HMHOnCoreSupport@hmn.org)

## COI Disclosure Software Upgrade: COMING SOON!

Research Compliance is upgrading their COI Disclosure software to Huron (eResearch). This software will serve as HMH’s single-disclosure system and integrate with the Huron module for IRB protocols. The upgraded system will streamline COI reviews and reduce administrative burden for HMH disclosers. The estimated go-live is August 2023. Stay tuned for training sessions and announcements. If you have any questions regarding Huron COI module, email [COI@hmn.org](mailto:COI@hmn.org).

Can’t wait to try out the new system? HMH Research Compliance is seeking volunteers for beta testing. Benefits of being a volunteer include:

1. You get first access to the new system
2. Your 2023 disclosure will be completed (no need to refile in 2023)
3. You have an opportunity to provide feedback on the user experience
4. Additional training and support

To be eligible to volunteer, you must meet the following criteria:

1. Be willing to attend virtual training sessions (weekly for up to 4 weeks)
2. Actively engaged in HMH research, meaning:
  - Individuals responsible for the design, development, testing, evaluation, reporting, review and oversight of research;
  - Individuals who are directly involved in research intervention or consenting or evaluation of human subjects; or
  - Individuals who share responsibility in the design, development, testing, evaluation, conduct, reporting, review and oversight.

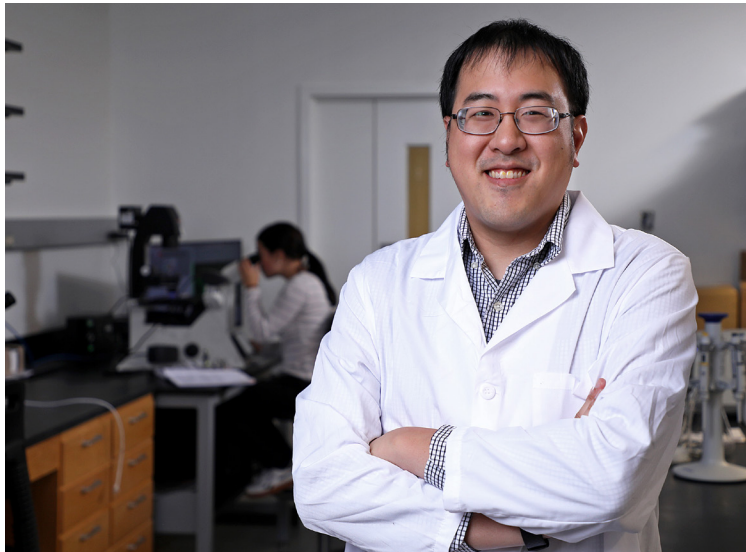
-and/or-

3. HMH Director or above

You can sign-up by filling out the [Google Form](#). Space will be limited.

## The HMH Nursing Newsletter is a Great Resource

The Nursing Newsletter includes useful nursing-related articles and research. Nurses throughout the network are encouraged to check it out. The spring edition is linked [here](#).



# FEATURED RESEARCHER

SPRING 2023

## The CDI Experts: Tong and the Pursuit of Perfectly Targeted Cancer Drugs

Picture this: a cancer patient has their tumor tissue sampled, collected, and sent to a laboratory. The tissue is grown in a dish, and can be cloned into organoids. The scientists analyze the entire genetic sequence – then tactically aim drugs at the cancer’s molecular vulnerabilities. Whatever works in the organoid should work on the patient, giving doctors the edge back in the hospital.

It could soon be regularly happening at Hackensack Meridian Health.

“Can I test in real-time, a drug screen in an organoid and know as soon as possible exactly what combination of drugs is going to work for that patient’s unique cancer?” said Kevin Tong, Ph.D., the assistant member of the Hackensack Meridian Center for Discovery and Innovation (CDI), from his lab. “It’s the definition of ‘personalized medicine.’ It’s a dream. But I think we can make it come true.”

This may be the future of cancer treatment at Hackensack Meridian Health, via the science of the CDI and particularly the mission of Tong, a recent arrival to the CDI whose lab has focused on molecular profiling of cancers, particularly colorectal cancer. But while he continues to use his expertise to study the mutations and tactics of cancer, he is also looking toward these organoids under a microscope which could provide a key strategy to defeating tumors on an individualized basis.

“Kevin Tong is a scientist who has had a terrific start to his career,” said David Perlin, Ph.D., the chief scientific officer and executive vice president of the CDI. “We’re thrilled he brought his work to the CDI, where it will complement so much of the other fundamental investigations of cancer here.”

### Colorectal Cancer

Colorectal cancer is a mercurial, heterogeneous beast to tackle. It is a disease which has a variety of root causes in genetic mutations and environmental factors, and has always been a puzzle for clinicians and scientists. Key breakthroughs were made in the 1980s by Burt Vogelstein, M.D., now of Johns Hopkins, who developed a “Vogelgram” showing the genesis of colorectal cancer based on genetic mutations, and their progression through human biology. It was the first model of its kind done for any kind of cancer, by most accounts.

Of course, the picture has become increasingly complex in the ensuing 30-plus years of cancer biology. Tong is one of the investigators seeking to find new details within the Vogelgram, accurate though it may largely be, in a large cross-section of cases.

One particular pathway that Tong has focused on is the “serrated” form of colorectal cancer. One aspect of this more-difficult variety of the tumor is the BRAF-mutation-driven variety – and particularly the loss of a critical tumor suppressor known as SMAD4.

Several projects revolve around a novel mouse model, a Tong creation, which aggressively generates serrated tumors that emulate human varieties of the cancer.

Tong and his laboratory have found that SMAD4 might actually play a greater role earlier in serrated colorectal cancer – that SMAD4 is critical to prevent serrated tumors from even starting.

### Organoids

Tong did his postdoctoral work at Rutgers University. But when an opportunity arose at the CDI to further accelerate his work, he seized it. “What sold me on the CDI was the translational aspect of the work,” said Tong. “Here you have a network supporting you – and you get to move the work as close to the clinic as you possibly can. That’s what it’s all about.” Just a few weeks ago, Tong received the first patient samples from clinical settings in Hackensack Meridian Health and has successfully established organoids from them. But it’s just the beginning.

Coupled with the access to the rapidly-growing Bio-Repository at HMH, the ambitious project has just become that much closer to a “personalized medicine” reality, he mentioned.

“We know everybody wants to do this in health care,” he said. “But we want to be ahead of it. We want to help drive it forward.”

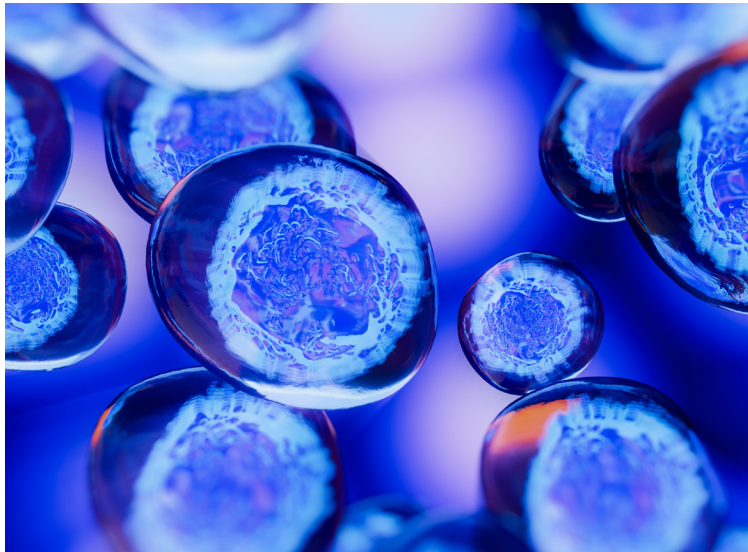
### Personal

Tong grew up outside Princeton. He has a sister four years younger than him who works at Princeton. Both of his parents are retired computer engineers who worked for telecom giants.

From a young age, he was a “techie,” involved with computers, video games and the like. He also was an avid hometown sports fan of the New York Giants and the New York Mets. At the same time, he was a “music geek” – he spent long years studying piano and guitar, and he was in the high-school marching band.

He has been married five years and the happy couple can commute together; his wife Caitlin works at Modern Meadow, the biotech company that is in the same building as the CDI.

Tong said he is excited to keep pushing his work forward – and has found the place to do so. “My dream is to translate my research to help patients,” said Tong. “What’s better than that?”



# FEATURED RESEARCH ADMINISTRATOR

SPRING 2023



## Ernest W. Richards, Ph.D., FACN

Director, HMH Oncology  
Clinical Research

Assistant Professor,  
Department of Oncology  
Hackensack Meridian  
School of Medicine

Oncology research has been marching ahead at an impressive clip. Promising treatments are becoming available to patients with conditions from which there was once little hope of recovery. Prognoses are improving and patients are living longer and with better quality of life. At the forefront of all this progress has been Hackensack Meridian Health.

Progress is paved through clinical trials, and clinical trials can be complex, both with respect to methodology and also in terms of the regulations and guidelines associated with their execution. Each clinical trial must be conducted with the utmost care to ensure the integrity of the data and compliance with the law and best practices.

Dr. Ernest Richards, Director of Oncology, Clinical Research for the network, leads this effort. He oversees all oncology research throughout HMH and is responsible for the ongoing conduct of a portfolio of 400+ oncology clinical research trials and a team of 135+ clinical research professionals that manage them. His primary focus at the moment is at the John Theurer Cancer Center (JTCC) with relation to the ongoing National Cancer Institute consortium designation with Georgetown.

Dr. Richards took some time to share about his career path, why he loves working at the site level, and what excites him the most about oncology research today.

### **Please tell us about your background. What was your path from a Ph.D. in Clinical Nutrition to research management and operations?**

I earned a Ph.D. in Clinical Nutrition from Rutgers University and then completed a postdoctoral fellowship at the Baptist Medical Centers at the Alabama University Medical School in Birmingham, Alabama. During my post-doc, I focused on clinical nutrition support of trauma

and geriatric patients. From there, I moved to Abbott Laboratories, where I was responsible for the nutritional support division, including products like Ensure, and developed specialized nutritional support for patients with cancer and HIV. I hold four patents from my time there. After Abbott, I moved further into the industry realm to a contract research organization that is now known as PRA Health Sciences. I moved from a project manager role to eventually becoming Vice President of Operations for the NJ office. Ultimately, I decided that I wanted to go back to the site, where the action happens and you can see the direct impact of the research you're involved in. I secured a position at Meridian Health in 2007 and was tasked with the role of harmonizing a cluster of hospitals that all had separate Institutional Review Boards (IRBs) into one centralized research program with one IRB. Shortly before the merger with Hackensack, I was hired to run the JTCC cancer research program and eventually was asked to serve in my current role for the network. In sum, I have been able to experience the full circle of entities involved in clinical research - the site, the pharmaceutical company, the contract research organization - and have come full circle back to the site. When it comes down to it, I most enjoy being able to see the impact of the work my team is doing.

### **In what way has your experience been different at the JTCC and in your current role than in your other positions, such as at Meridian Health, where you've overseen research?**

At Meridian, I managed numerous therapeutic areas that were important to Meridian at the time: neurology, psychiatry, women's health, cardiology, et cetera. In my current role, my focus is strictly on oncology. Another difference between my work at Meridian and what I'm doing now is the scope of the research. Meridian had an active research program, but it was small relative to the JTCC. Coming to the JTCC was attractive because there was the opportunity to develop something remarkable and really grow.

### **You oversee a large team of research staff and hundreds of sponsored and investigator initiated clinical trials at a time. What is your strategy for oversight, since you can't be involved in the minutiae of every single trial on a daily basis?**

I surround myself with capable people and hire strong managers. I learned that early on in the CRO industry. No one person could have managed the volume that that team was responsible for, and I can't do it at the JTCC either. I have six or seven managers in key areas, and they allow me to use my expertise without having to be in the weeds all the time. It also helps that I'm a multitasker at heart and am used to juggling many balls in the air while keeping them moving. Having the ability to multitask effectively and staying very organized is key to success in this type of role.

## FEATURED RESEARCH ADMINISTRATOR:

**Ernest W. Richards, Ph.D., FACN** *(continued)*

### **Can you share with us some of the exciting projects going on in oncology?**

There are huge things happening in the world of oncology. It is the most exciting time in the field ever. This is in large part due to precision medicine and the multiple treatment options now available to patients because of it. Today, oncology research is focused on genetic mutations; that is where the promise lies because you can target the therapy. We're at the forefront of the continuing evolution of drug development for cancer. Things like immunotherapy are routine, where just a few years ago, they weren't. CAR-T cells are now commercially available, and this is, in part, because of the team at the JTCC - because we built the clinical trials. CAR-Ts are available for hematologic cancers and solid cancers now, too. The results have been amazing: we review the patients in our clinical trials weekly, and one of the patients who enrolled in a clinical trial with a survival prognosis of two months has now been on the trial for 24 months!

### **Given your varied and considerable experience in the field, what advice would you give to new researchers that are considering becoming involved in research?**

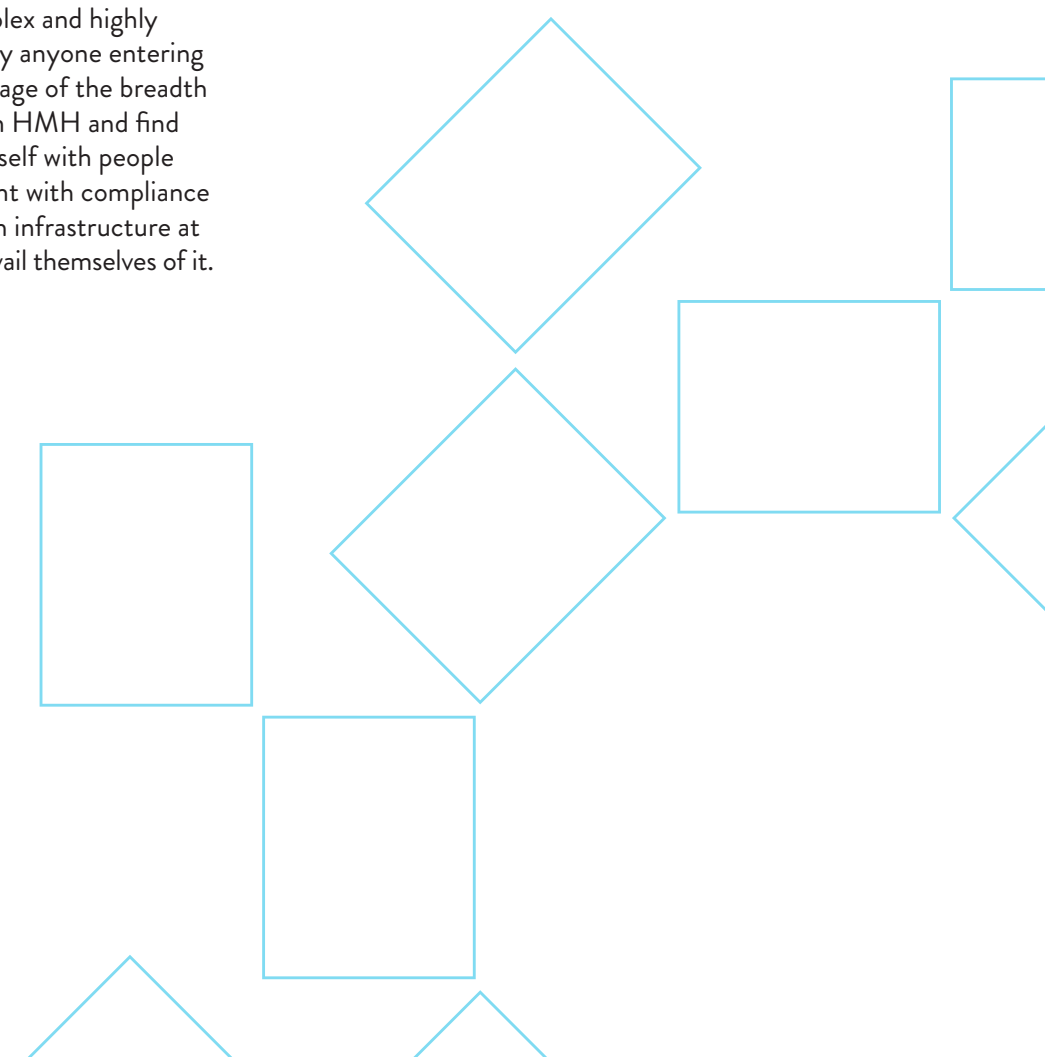
Today's world of clinical research is very complex and highly regulated. New physician researchers, or really anyone entering the field for the first time, should take advantage of the breadth of clinical research expertise that exists within HMH and find a partner from whom to learn. Surround yourself with people who are knowledgeable so you don't get caught with compliance and regulatory issues. There is a huge research infrastructure at HMH; new researchers should make sure to avail themselves of it.

### **What do you find most gratifying about your role?**

I truly consider the role I play to be a privilege. Working with the incredible oncologists within our network and the capable clinical research teams allows us to bring forward options to patients that are limited in the avenues they have available to them.

### **What are some of your interests and hobbies outside of work?**

My husband and I live on the beach in Sea Bright. Each night, I cross over the bridge to get to the Shore, and the view of the Atlantic Ocean helps to demarcate my work life from my home life. As might be expected, given my location, my hobbies include anything beach or water related. I love boating and swimming. I also enjoy traveling and have a bucket list of places to go, including France, Italy and Egypt.





# HMSOM RESEARCH BULLETIN

SPRING 2023

## Medical Student Research Day Dazzles with Ideas, Science

The Hackensack Meridian School of Medicine's second annual Medical Student Research Day on May 5 featured fresh presentations from students who are looking at medicine - and the science to push it forward - in a whole new way.

The event was an afternoon affair which included more than 80 research posters by students, two featured student presenters, and a keynote address from Rachel Rosenstein, M.D., Ph.D., an assistant professor of internal medicine, and also an assistant member of the Hackensack Meridian Center for Discovery and Innovation (CDI).

The crowd numbered over 130 for the entirely in-person event.

***"This event shows how vibrant a learning environment exists at this school," said Stanley R. Terlecky, Ph.D., vice dean of research and medical sciences at the School. "We are a place that questions, and innovates, because of the talent we have attracted from across the country."***

### Among the highlights:

- Dr. Rosenstein's talk was titled "Chance Favors the Prepared Mind: Studies of Skin Immunity and Inflammation," and examined translational studies linking human skin disease, sequencing, and the response to therapies.
- Aishwarya Sridhar (M2), working with Andrew Ip, M.D., of John Theurer Cancer Center, was one of the featured student presenters. The work focused on a case study of refractory diffuse large B-cell lymphoma following CAR T cell therapy. The results indicated that CAR T cells may persist in the body long after infusion, and clinicians should use sequencing to monitor patients.
- Meghana Singh (M2), offered another featured student presentation. Working with Michael Stifelman, M.D., professor and founding chair of urology at the School, Singh's work showed a retrospective and prospective review of robotic pyeloplasty (a surgical procedure to remove a blockage preventing urine from reaching the bladder). The data suggested that single-port surgeries of this kind are a safe and acceptable alternative to multi-port varieties of the procedure.

- The 80 posters spanned the gamut of topics and were a product of partnerships with experts across Hackensack Meridian Health. These included: a new methodology to predict newborn outcomes with ultrasounds; a look at preventing injuries in lacrosse; assessing the prevalence of rashes in patients with certain cancers; analyzing new possible cancer treatment compounds; health screenings of public school students in Paterson during the COVID-19 pandemic; and many others.

The event was co-sponsored by the Hackensack Meridian Health Research Institute, the School, and the Hackensack Meridian Health Foundation.





# QUARTERLY QUESTION

SPRING 2023

**What is the difference between coded and anonymized data?  
What clinical trial phase generally takes place after FDA approval?**

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

The first person to submit the correct answer will receive a Hackensack Meridian *Health* gift.