RESEARCH ROUNDUP

Hackensack Meridian *Health*

WINTER 2023

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

The year 2022 was groundbreaking for the Hackensack Meridian *Health* Research Institute in virtually every way. More than $100 million in grants was a terrific start, but this year promises to bring even more incredible breakthroughs.

Ihor Sawczuk, M.D., FACS

NOTE FROM THE **VP**

The Hackensack Meridian *Health* network has so much talent - and so many different voices and expertise. The Hackensack Meridian *Health* Research Institute is bringing it all together, for the benefit of patients and team members alike.

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

HMH RESEARCH NEWS

HMHRI Opens the Center for Advanced Clinical and Translational Research at HUMC

The Hackensack Meridian *Health* Research Institute is proud to unveil the Center for Advanced Clinical and Translational Research (CACTR). It's a hub right on the campus of Hackensack University Medical Center which will be the location of untold number of clinical trials to come. The state-of-the-art facility boasts fully-equipped patient exam suites, allowing HMHRI clinicians and scientists to advance care like never before. A ribbon-cutting for the new space was held on Jan. 31, and featured, from left: Jason Kreitner, MHA, FACHE, SVP, Chief Operating Officer of Hackensack University Medical Center; Jeffrey Boscamp, M.D., the dean of the Hackensack Meridian School of Medicine; Ihor Sawczuk, M.D., FACS, president of Academics, Research, and Innovation, and founding chair of the Hackensack Meridian *Health* Research Institute; David Perlin, Ph.D., the chief scientific officer and executive vice president of the Hackensack Meridian Center for Discovery and Innovation (CDI); Mark Sparta, FACHE, president and chief hospital executive of Hackensack University Medical Center and president of the Northern Region of Hackensack Meridian *Health*; Lisa Tank, M.D., FACP, CMD, the chief medical officer of Hackensack University Medical Center; and Tracy Micalizzi, director of clinical research center operations for Hackensack Meridian *Health*.

JTCC Researchers Presented Pivotal Investigations at ASH

Researchers from Hackensack Meridian John Theurer Cancer Center (JTCC), a part of the NCI-designated Lombardi Comprehensive Cancer Center at Georgetown University, presented the latest data from their investigations assessing new diagnostic and treatment approaches for hematologic malignancies — including lymphoma, leukemia, and multiple myeloma — at the 64th Annual Meeting of the American Society of Hematology in December.

"While our cancer experts treat all types and stages of cancer, John Theurer Cancer Center is especially well known for our leadership in the management of people with blood cancers. We are proud to present so many studies at this year's meeting and demonstrate our commitment to improving outcomes and quality of life for people diagnosed with hematologic cancers," said Andre Goy, M.D., MS, chairman and executive director of JTCC.

The JTCC presentations addressed new therapies for lymphoma, leukemia, and multiple myeloma, as well as approaches to improving the effectiveness of treatments such as CAR T-cell therapy and bone marrow transplantation and novel diagnostics that use next-generation sequencing. READ MORE

Bear's Den Innovation Program Awards Winning Ideas from Team Members Across Network

Innovations and ideas from team members across Hackensack Meridian *Health* (HMH) will become a reality on the clinical front lines, courtesy of the successful Bear's Den Innovation Challenge: Reimagining Patient and Team Member Safety.

The six finalists of the program came from more than 100 high-level submissions from across the network. Following the presentation of each idea to the executive team and board members, it was determined that each idea had a unique contribution to advance HMH's ability to improve both patient and team member safety. The six finalists were all deemed winners, following a lengthy vetting process and a vote from top leadership at the network.

"To see such innovation from our incredible team members is hugely gratifying," said Robert C. Garrett, FACHE, chief executive officer of Hackensack Meridian *Health*. "We have professionals who are, indeed, always looking to 'keep getting better.'"

The Bear's Den Innovation Program is a unique accelerator at Hackensack Meridian *Health*, enlisting a panel of experts to evaluate inspirational health care ideas, inventions, and strategies from entrepreneurs, venture capitalists, health care partners, and HMH's own 36,000 team members. The Bear's Den helps make great concepts a reality through strategic partnerships, funding, and other support, and its quarterly meetings are thought-provoking dialogues - challenging the status quo to set better health care standards in New Jersey and beyond.

"The Bear's Den is an investment on a better future for everyone at this health network, and beyond," said Ihor Sawczuk, M.D., FACS, Hackensack Meridian *Health*'s president of Academics, Research, and Innovation, founding chair of the HMHRI, and associate dean of Clinical Integration and professor and chair emeritus of Urology at the Hackensack Meridian School of Medicine. "Here we have sometimes-simple solutions which will make a world of difference to patients and clinicians alike."

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Hackensack Meridian *Health*'s Dr. Ihor Sawczuk Named to 30-Year Fellowship Distinction by New York Academy of Medicine

Ihor Sawczuk, M.D., FACS, Hackensack Meridian *Health*'s president of Academics, Research, and Innovation, has reached an impressive milestone: He is a 30-Year Fellow of the New York Academy of Medicine (NYAM).

Dr. Sawczuk, also associate dean of Clinical Integration and professor and chair emeritus of Urology at the Hackensack Meridian School of Medicine, was honored by the NYAM at an event on November 16, 2022. Sawczuk was asked to join the NYAM Board Chair, Dr. Wayne Riley, on stage to provide his advice to the NYAM's newest class of Fellows and Members. Sawczuk received congratulations from well-wishers at the event, and also from Hackensack Meridian *Health*.

"This is an incredible distinction for a one-of-a-kind leader," said Robert C. Garrett, FACHE, the chief executive officer of Hackensack Meridian *Health*. "Over his career, Dr. Sawczuk has been an integral part of the growth of our health network - and the improvement of the lives of thousands of patients in New Jersey and New York. His newest role has only increased his positive impact at our health network."

Dr. Sawczuk, who grew up in New York City, has lifelong ties to the Big Apple. He completed his urologic training at the Squier Urological Clinic of the New York-Presbyterian Hospital, and his urologic oncologic training as a fellow of the National Cancer Institute in the Departments of Urology and Human Genetics of Columbia University, where he attained the level of Professor at the Columbia University College of Physicians and Surgeons. He attended the Medical College of Pennsylvania, and received his Bachelor of Arts degree from New York University.
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HMH Manager Represents Network at National Research Conference

Elli Gourna Paleoudis, Ph.D., manager, Investigator Initiated Research Program, represented HMH at an annually-held Investigator Initiated Trials Summit in Philadelphia this past November. This summit is hosted by Dynamic Global Events and aims "to share in-depth best practices on engaging with investigators, designing and executing the best study protocols, aligning research with the goals of the organization, and fostering collaborative relationships." Dr. Gourna Paleoudis presented on "Navigating Key Regulatory and Compliance Challenges" and served on a panel that addressed investigator-initiated research from both the sponsor and site perspectives. She and another panelist represented the sites, and two other panelists represented pharmaceutical companies.

Dr. Gourna Paleoudis's presentation addressed research compliance and common risks; how to meet FDA and ICH compliance requirements in protocol development; consenting, data collection and beyond; how to implement efficient procedures to support investigator-initiated trials; the increasing FDA scrutiny of clinical trials and ClinicalTrial.gov as an example of research compliance; and how to identify the risks involved with supporting investigator-initiated research. Her presentation was well-received and spurred an engaging Q&A session thereafter. This is Dr. Gourna Paleoudis's second year presenting at this summit.

David Perlin, Ph.D. Honored with Dr. Sol J. Barer Award

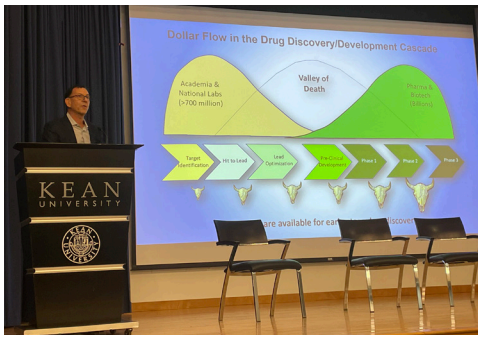
David Perlin, Ph.D., chief scientific officer and executive vice president of the Hackensack Meridian Center for Discovery and Innovation (CDI) has been honored with BioNJ's 2023 Dr. Sol J. Barer Award for Vision, Innovation and Leadership.

Dr. Perlin has served as the founding chief scientific officer of the CDI since its inception in 2019 to address unmet medical needs in infectious diseases, cancers, behavioral health, autoimmune, and neurocognitive disorders, as well as other acute and chronic health problems.

"Dr. Perlin is an exceptional leader whose expertise and dedication elevates and advances our health network mission to transform health care and serve as a leader of positive change," said Robert C. Garrett, FACHE, chief executive officer of Hackensack Meridian *Health*. "He is anticipating the incredible changes coming in the health care landscape - and finding ways to keep ahead of the curve."

"David is a colleague who is making a difference in all the best ways," said Sol Barer, Ph.D., current Chairman of the Board of Teva Pharmaceuticals, founder of Celgene, and a biotech innovator and leader who is the namesake of the award. "His is a mind which strives constantly for excellence, and he is relentless in his pursuits."

"We are thrilled to honor Dr. Perlin with the 2023 Dr. Sol J. Barer Award for Vision, Innovation and Leadership for his tireless work on behalf of patients, medical innovation and New Jersey's ever-growing life sciences ecosystem," said BioNJ President and CEO Debbie Hart. "Driven and passionate, Dr. Perlin is changing the lives of patients around the world … tackling the unimaginable. He is New Jersey's own innovation superhero."



CDI Scientists Present at NJADDC

David Perlin, Ph.D., delivered the keynote, and Thomas Dick, Ph.D., gave a presentation, at the New Jersey Academic Drug Discovery Consortium (NJADDC) 2022 annual meeting at the Institute for Life Science Entrepreneurship (ILSE) in December. The event is co-sponsored by Rutgers University Office for Research, ILSE, and BioNJ.

Perlin talked about the progress made by the Metropolitan AntiViral Drug Accelerator (MAVDA) which he co-leads, and he made a call for the New York and New Jersey region to "come together to build capacity and impact."

JTCC Researcher Sheds Light on Clinical and Economic Burdens Faced by Patients with High-Risk Chronic Lymphocytic Leukemia (CLL)

Lori A. Leslie, M.D., director of the indolent lymphoma and chronic lymphocytic leukemia (CLL) research programs at Hackensack University Medical Center's John Theurer Cancer Center, a part of Georgetown Lombardi Comprehensive Cancer Center, is the lead author of a recent paper focusing on the clinical and economic burdens faced by patients with high-risk CLL. The paper, published in Current Medical Research and Opinion, demonstrates that, compared to non-high-risk patients, those with high-risk CLL who are treated with first-line chemoimmunotherapy (CIT) have worse clinical and economic outcomes, including greater risk of next treatment or death, higher risk of treatment failure, and greater economic burdens.

"The availability of prognostic testing is enabling more precise risk-stratification of patients with CLL, and our findings validate the association between higher risk and worse outcomes," said Dr. Leslie. "Yet despite recent advances in testing technologies, assessment of genetic risk remains suboptimal. We hope our study results spur more widespread adoption of cytogenic and molecular testing in patients with CLL and other malignancies, as well as greater awareness of the clinical and economic implications of high-risk disease." READ MORE

JTCC and Genetic Testing Cooperative Researchers Demonstrate Value of Genomic Sequencing and Artificial Intelligence to Improve Cancer Diagnosis

Investigators from Hackensack Meridian John Theurer Cancer Center (JTCC), part of the NCI-designated Lombardi Comprehensive Cancer Center at Georgetown University and Genetic Testing Cooperative Inc. (GTC) published a groundbreaking study demonstrating the reliability of combining next-generation sequencing and artificial intelligence to accurately diagnose subtypes of blood cancers and solid tumors. This approach has the potential to become a part of routine cancer care and lead to improved patient outcomes. The study was published in the January 2023 issue of the *American Journal of Pathology*.

An accurate diagnosis of cancer is essential to ensure a patient receives the most effective therapy. But numerous studies have shown that errors in the diagnosis and classification of cancers continue to be a significant issue in current clinical practice. Relying only on the expertise of a pathologist and the way a tumor looks under a microscope can lead to significant discrepancies in cancer identification because of the subjective nature of the diagnostic process.

The JTCC and GTC researchers investigated a targeted transcriptome and artificial intelligence to diagnose blood cancers and solid tumors. DNA is the genetic code that carries the instructions for all the functions in the human body. In order for these instructions to be carried out, the DNA must be read and transcribed into RNA. A transcriptome is a collection of gene readouts in a cell. Analyzing the RNA of cancerous tissues by evaluating the transcriptome provides a tremendous amount of information about a cancer's biology and surrounding environment. READ MORE

JFK Johnson Rehabilitation Institute Is Researching A Breakthrough Wearable Medical Device To Accelerate Healing After Stroke

Hackensack Meridian JFK Johnson Rehabilitation Institute is researching a breakthrough medical device that delivers electromagnetic therapy to the brain to accelerate healing after a stroke.

JFK Johnson is one of 20 rehabilitation hospitals nationwide enrolling patients in the EMAGINE Stroke Recovery Trial, which aims to enhance recovery and reduce disability after neurologic damage caused by stroke. The wearable device, which can be used in a hospital setting, outpatient clinic, and at home would augment JFK Johnson's existing rehabilitation therapies.

"We're participating in this innovative research and other clinical trials because we're continually working to maximize the recovery of our patients and advance the science of stroke recovery," said Sara Cuccurullo, M.D., chair, vice president and medical director of JFK Johnson Rehabilitation Institute and principal investigator of the study. "We want all of our patients to reach their highest quality of life."

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. She is also physician-in-chief of the Rehabilitation Care Transformation Service at Hackensack Meridian *Health*.

The wearable device was given breakthrough status by the FDA after a pilot study showed promise. The study is funded by BrainQ, the technology company that developed the investigational device.

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RESEARCH UPDATES & EVENTS

WINTER 2023

Congratulations to Our Team Members on Their New Roles!

Susan Adler, MPA - Director, Post Award Clinical Research/Foundation
In her new role, Susan will be working closely with finance and accounting departments and will be responsible for creating policy and processes for the post-award phase of clinical research and Foundation funding.

David Candelmo, MBA, CRA - Director, Office of Sponsored Programs
In his new role, David oversees and assists researchers with grant proposal preparation, including identifying funding opportunities. His team also assists with award set-up, management, and close-out. They continue to guide and facilitate the grant process as a whole, including assistance with research proposals, contracts, sub-contracts, and agreements.

Tracy Micalizzi - Director, Clinical Research Center Operations
In her new role, Tracy oversees the clinical research team and the management of all study start-up, conduct, and close-out activities across all therapeutic areas. She also manages the fully equipped research centers at HUMC and JSUMC that are utilized to conduct study visits on multiple trials.

Elli Gourna Paleoudis, MS, Ph.D. - Director, Investigator Initiated Research Program and Support Services
In her new role, Dr. Gourna Paleoudis offers administrative and scientific oversight for HMHRI investigator-initiated research, including biostatistics. She guides investigators on all aspects of their investigator-initiated projects, including, but not limited to the design, conduct, and implementation and also serves as the HMH Clinicaltrials.gov Administrator, REDCap Administrator, and FDA Liaison.

Michelle Benson, Ph.D. - Research Compliance Officer
In her new role, Dr. Benson leads the HMH research compliance efforts and programming. She will oversee HMH's diverse portfolio of research and grant requirements, including implementation and oversight of network compliance programs such as: Conflicts of Interest (COI), Export Controls, Research Misconduct, Responsible Conduct of Research, Research Security, Data Management, and Scientific Integrity.

Please don't hesitate to reach out to these administrators for help with your research efforts.

New Email for the Office of Sponsored Programs

The Office of Sponsored Programs, led by David Candelmo, has established a new general email. From now on, the Office can be reached at sponsoredprograms@hmhn.org. More information about the Office's services can be found here.

Team Members Must Agree to Participate Before They Are Added to Studies

The Offices of Research Administration and Compliance reminds researchers to ensure that team members are willing and able to participate in studies before adding them. While this process no longer takes place in eResearch, it is imperative that it takes place between the PI and the team members before they are added to studies. Also, please note that team members cannot be added after the study has been reviewed for conflicts of interest.

The Biorepository Has Expanded

The network biorepository (BioR) has expanded once again. This time, they tripled their space at the Jersey Shore University Medical Center. The BioR, led by Dr. Dave Chow and Yael Kramer, has undergone significant growth in the last several years and offers a large array of biospecimens available for research purposes. More information about the BioR can be found here.

Annual Events Celebrating HMH Research

Resident/Fellow Research Day
This is an annual event that provides opportunities for residents and fellows 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. **The event will be held virtually on Tuesday, May 23, 2023 from 8:15 a.m. - 1 p.m. The abstract submission deadline will be March 26, 2023 at 11:59 p.m.**

The keynote speaker will be Lisa Carter-Bawa, Ph.D., APRN, ANP-C, FAAN, Director of Cancer Prevention Precision Control Institute, Center for Discovery & Innovation, Member of Hackensack Meridian *Health.*

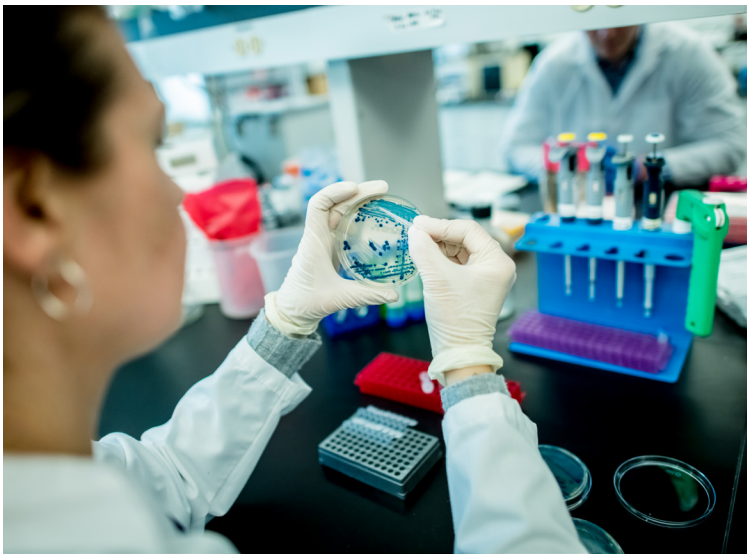
For more information, please email researchday@hmhn.org.

Annual HMHRI Research Symposium
The symposium highlights some of the most impactful research conducted at HMH as part of the HMHRI. This event serves as an opportunity to learn about the groundbreaking studies taking place within our network and to foster collaboration and networking. **The event will be held virtually and is scheduled for June 1, 2023 from 8:30 a.m. - 1 p.m.**

More information about the agenda and presenters will be shared in the coming months.

For more information, please email ora@hmhn.org.

To check out other upcoming research events taking place within the network, please see the research website and calendar.



FEATURED RESEARCHERS

WINTER 2023

The CDI Experts: Lisa Carter-Bawa Brings Years of Nursing to Cancer Prevention

Lisa Carter-Bawa, Ph.D., remembers how her patients could have been better. With improved conditions and food access – more favorable factors for staying healthy – they'd have a better chance to avoid a whole host of diseases, Dr. Carter-Bawa recalls now.

As part of her nurse practitioner practice in Louisville, Ky., Dr. Carter-Bawa would see diseases that could have been prevented - or at least better controlled – if patients would not have had to limited access to healthy foods without supermarkets; neighborhoods where there was little space to exercise; and environments where there were few doctors and little attention to preventive care.

It's part of the reason Dr. Carter-Bawa, already a seasoned clinician, went back to school for her Ph.D. – so that she could address the root causes of the health outcomes she was seeing and treating.

"I just remember thinking, there was so much more I wanted to do at the population level," she said recently.

One of the newest scientists to arrive at the Hackensack Meridian Center for Discovery and Innovation (CDI) won't be observing germs under a microscope, like many of the other experts at the institution. Instead, Dr. Carter-Bawa is going to direct the new Cancer Prevention Precision Control Institute (CPPCI) at the CDI – and she will be bringing her years of nursing expertise and behavioral research at the Memorial Sloan Kettering Cancer Center (MSK) to impact patients' lives almost immediately across HMH by looking at medicine through the vantage point of the patient.

It's a mission strengthening the "bench to bedside" ethos of the CDI.

"Lisa is bringing a terrific new, real-time focus to impacting clinical care," said David Perlin, Ph.D., the chief scientific officer and the executive vice president of the CDI. "Her work has important implications for improving clinical outcomes for patients with cancer." READ MORE

Suzanne C. Li, M.D., Ph.D.

Professor of Pediatrics, Hackensack Meridian School of Medicine
Pediatric Rheumatologist, Joseph M. Sanzari Children's Hospital

For some patients, symptoms of scleroderma can materialize briefly, be minor, and leave little damage behind. For others, the disease can be rapidly progressive, affect the child's ability to grow and play normally, and cause severe disfigurement or even death. Scleroderma is an autoimmune disease characterized by abnormal inflammation in different parts of the body that then triggers excessive fibrosis, resulting in the replacement of normal cells by scar tissue. It occurs in one of two forms: localized scleroderma also known as morphea, and systemic sclerosis. While scleroderma means "hard skin", both forms commonly affect other tissues. In localized scleroderma, deeper tissues near where the skin lesions are located are often affected in kids, resulting in problems such as arthropathy, hemiatrophy of the limb or face, seizures, and uveitis. In systemic sclerosis, besides skin and musculoskeletal involvement, the major internal organs such as the lungs, gut, heart, and kidneys are also affected - placing these patients at risk for life-threatening problems. Dr. Suzanne Li has spent years studying both types. Her foray into this area of research began nearly two decades ago and was motivated by one little four-year-old patient. The young girl presented with rapidly progressing disease, which motivated Dr. Li to study how best to treat patients to reduce the likelihood for severe damage. Today, Dr. Li is still continuing in that mission, having recently received a grant from the National Scleroderma Foundation for work on juvenile systemic sclerosis. She met with us to share more about the disease and what her grant could mean for the future of scleroderma in the pediatric population.

How did you become interested in medicine, and specifically in pediatric rheumatology?

In junior high school, I was really interested in science and research. I liked the idea that you could help society by discovering something new. In college, I was a chemistry major. I spent a summer in a lab extracting alkaloids from vinca plants, which are used for chemotherapy. It was interesting work, but I ultimately chose the *(Cont'd)*

FEATURED RESEARCHERS (Suzanne Li, M.D., PhD):

medical field because the problems that needed solving were more meaningful for me. In residency, I chose to focus on pediatrics because it offered the opportunity to positively influence kids and teens to help foster an interest in learning and help them develop healthy habits. Working with kids is also fun and interesting; they are always surprising you with their thoughts and perspectives. I was drawn to rheumatology by an outstanding clinician who was able to piece together different physical exam findings, symptoms, and lab findings to figure out what was wrong with some mysterious and challenging patients, and how to treat them. Patients with rheumatic diseases are often like a puzzle, so it's important to get a good history and do comprehensive physical exams because there are no straightforward diagnostic tests. You need to see the patient as a whole, which jibes with my subscription to the more traditional idea of spending time with patients. Lastly, I liked that the field was sorely in need of more research; there is still so much to learn.

Why do you think scleroderma is an important area of research? Can you share with us a little bit about some of your research on this disease so far?

The sclerodermas are some of the worst rheumatic diseases in terms of morbidity, yet our ability to treat this disease remains limited. Treatment has primarily focused on turning off inflammation to minimize fibrosis and damage as we don't have good anti-fibrotic treatments. Persistent fibrosis causes loss of normal cells, which leads to a lot of problems for the patients, depending on where the disease manifests. In some cases, the tissue can regenerate, but in others, such as with bone or lung tissue, the damage may be irreversible. There is still a lot that we don't know about scleroderma, especially in kids. We don't have a cure for it and don't even fully know what causes it.

I have been interested in working to identify effective treatment strategies. Other investigators identified methotrexate to be effective treatment for localized scleroderma, but I found widespread variations in dosing regimens, with even greater variation about concomitant glucocorticoid use. So, I worked with others in our pediatric rheumatology association, Childhood Arthritis and Rheumatology Research Alliance (CARRA), in a consensus process to develop three standardized regimens that shared the same methotrexate dose, and differed on inclusion of either oral or intravenous glucocorticoids. This made it much more feasible to be able to study which regimen was "best", with the idea that this would be an iterative process as new medications were identified. In our initial studies of patients treated with these regimens, we identified treatment failure was more likely in patients that have extracutaneous involvement (e.g., arthritis).

A lot of my focus has been on developing sensitive assessment tools for localized scleroderma to be better able to conduct treatment studies. We identified skin features specific to active lesions which helped us generate a more nuanced skin activity measure, and found ultrasound more helpful than MRI in identifying disease activity in tissues underlying the skin.

What are your plans for the grant that you were recently awarded?

The grant is to study juvenile systemic sclerosis (SSc). There is a real need for more research on this disease because of its significant mortality rate and potential to severely impact the patients' function and quality of life. There have been clinical trials in adults with SSc, but none in kids. And because there are many differences in disease features, including morbidity and mortality patterns between pediatric versus adult onset SSc, we need to study treatments in the kids to know which are the most appropriate to use.

The purpose of this study is to develop classification criteria for juvenile SSc as this is a key tool for conducting treatment studies. In rheumatology, we do not have diagnostic tests for our diseases, so we use classification criteria to ensure we identify a consistent patient population for study, one that has the disease of interest and not a different mimicker disease. Juvenile SSc is a very rare disease; in a prior CARRA Registry, approximately 12,000 pediatric rheumatology patients were enrolled, of whom only 64 had SSc. To be able to develop classification criteria, we need several hundred juvenile SSc patients. In addition, we want the developed criteria to be universally applicable so future treatment trials can be international.

For our study, we are planning to study 400 juvenile SSc patients. I sought out potential investigators through surveys of the international pediatric rheumatology community and by reaching out to physicians who had published on this disease. It was heart-warming to get so many enthusiastic responses. Ultimately, I was able to recruit more than 40 physicians from 20 countries and six continents. We are also very fortunate to have investigators with wide experience on our steering committee, including an adult rheumatologist who helped develop the adult SSc classification criteria. We intend for our investigator team to form a pediatric scleroderma consortium, with this as our first project. The consortium, we hope, will be able to partner with pharmaceutical companies in the future to conduct treatment studies.

I am really giving it my all to make this project successful. This is only the second year that the National Scleroderma Foundation is giving out grants related to pediatric scleroderma, and I want to encourage them to continue funding research in pediatric scleroderma. I've worked with the Foundation on other projects related to scleroderma, as well. I was one of the co-organizers for the first Pediatric Scleroderma Family Day, which we piloted at HUMC. Many HUMC staff members helped to make it a success. I've been involved in the organization of all the subsequent Pediatric Scleroderma Family Day conferences held at other sites.

Not all physicians become involved in research. What motivates you to conduct research, in addition to your clinical responsibilities?

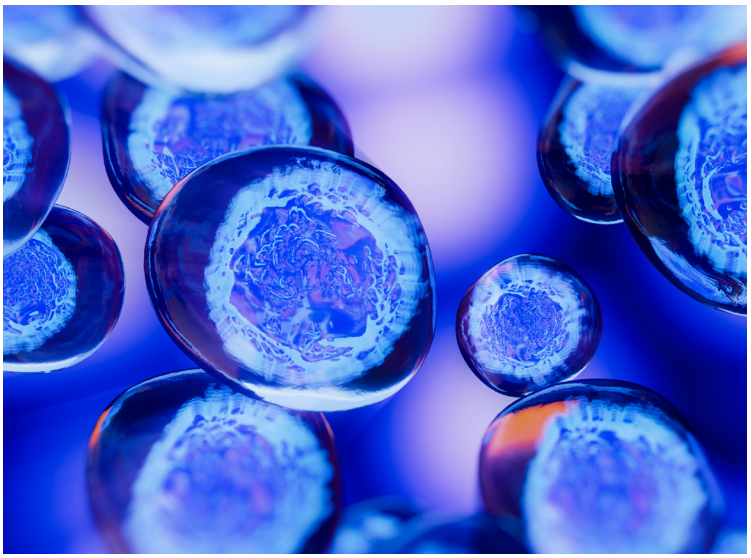
My mentor would say that you can learn a lot from one patient. Each patient is a little different, so if you look at your patients that way, you appreciate them and they spark your curiosity. You can ask yourself, why does this patient have this difference? Why don't their labs match the others? My interest in scleroderma research was because of that one patient, which prompted all this subsequent work. As physicians, we should be interested in continuing to learn. Research gives you a different perspective on care. Although clinical work offers you immediate gratification and disappointments, research provides a big-picture perspective. It's nice to have both.

What advice would you give to other physicians who might be interested in becoming involved in research?

First, find a mentor - or more than one, if possible. Everyone makes mistakes, but it's helpful to learn what to avoid from others. Second, read up when you are unsure of something. If you have a question about a patient, it's easy to do a quick literature search and see what's out there on the topic. It can give you ideas for things that haven't been addressed and connect with others; collaboration is more fun than working alone. Finally, be open-minded. You could be wrong, so it's useful to be open to other perspectives.

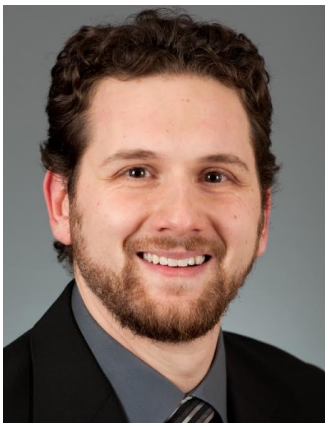
What are some of your hobbies and interests?

I like gardening, cooking, traveling, and getting together with family and friends.



FEATURED RESEARCH ADMINISTRATOR

WINTER 2023



Daniel Alderson, M.S., CIP

Manager,
Research Integrity Office

The Institutional Review Board (IRB) is the final gatekeeper before human subjects research studies can be conducted. Before it reaches the Board, the study has been worked on and reviewed by many people: the investigators and their teams, the Office of Research Administration support, the department Chairs, the ancillary reviews, and others. However, Daniel Alderson and his team are responsible for the final check to ensure that the study complies with the regulations pertaining to human subjects before it can be shepherded to the IRB. Althoughthis may seem like a formidable task, given the extent of the federal, state, and local requirements, Daniel arrived at HMH with a wealth of experience.

During his time here, Daniel has managed to streamline processes and boost compliance, despite the tremendous growth that the HMH research portfolio has seen. He sat down with us to discuss what led him to this field, common misconceptions surrounding the Research Integrity Office, and advice for researchers starting out.

Can you please share a little bit about your role within the research infrastructure here at HMH?
I am the manager of the network Research Integrity Office. This office has a few components, but the majority of the work is being the administrative office to the IRB and oversight of human subjects protocols. I also manage the HMH Data Safety and Monitoring Board, which reviews internal investigator-initiated clinical trials.

Practically, this means that I guide researchers, IRB staff, and the IRB itself in ensuring that any new human subjects research study (and their modifications, annual continuing reviews, or reportable events) is following our procedures and has the content necessary to meet the requirements of federal regulations and institutional policies governing the protection of human subjects. This includes reviewing protocols, helping researchers ahead of time to design ethically sound protocols, and helping to guide the IRB itself on ensuring that any given submission is being properly categorized and reviewed in the correct manner. Finally, I serve as an administrator to the new eResearch system, since all the work is dependent on eResearch. As such, I help with collective and individual education on the system.

How did you become interested in a career in research compliance?
My first position after college was in the pediatric and psychiatry departments at Rush University Medical Center in Chicago, conducting research rather than regulating it. It was during my time there that I was exposed to the concept of IRB review and what that entails. Research compliance, making sure that scientific research follows particular regulations, policies, and standards, actually seemed like a nice marriage of my research and law interests.

My first role in research compliance was as an IRB Analyst at George Washington University. I later moved to Boston Children's Hospital and specialized in the use of the single IRB model (using a single IRB for a multi-site research protocol). Finally, my position before this one was at Harvard Medical School, where I acted as a consultant for a national initiative to harmonize the single IRB approach. I have been at HMH since the summer of 2019 and have held this position since.

You have quite a bit of experience in this realm. How has your experience here at HMH differed from previous institutions? What is unique about HMH?
The big difference is the growth. My previous employers were large with established research portfolios, so they experienced limited growth during my tenures. However, HMH's portfolio expanded rapidly within a fairly short period of time. I was involved in merging IRBs from previously separate entities to create a centralized and harmonized IRB and upgraded submission system for the entire network. The growth also led to harmonized changes in policies and procedures, and increased staff. *(Continued)*

FEATURED RESEARCH ADMINSTRATOR:
Daniel Alderson, M.S., CIP *(Continued)*

What are some of the most common sources of confusion regarding the research submission process?

- The submission process timeline: Several offices review your submissions before it even gets to the Institutional Review Board, so budget time accordingly. There are a series of ancillary reviewers that look at your submission for different reasons - financial, training, contractual, ethical, etc. Plan for plenty of time for your submission to get through the whole process.
- Our goals: The goal of the Research Integrity Office is to promote research. Sometimes researchers can be hesitant when working with compliance and regulatory-based offices. Those of you who know us hopefully see us as very approachable and are happy for researchers to come ask questions early in the process. We want you to understand all of the steps in the process and to ensure that your protocol is sound from a human subjects protection standpoint.
- Our transparency: Researchers should never feel in the dark about submission guidelines for the IRB. We strive to be as transparent as possible in terms of the IRB review. We have a host of resources and guidance documents available on the Office of Research Administration website and eResearch, including the Human Research Protection Program Standard Operating Procedures.

What advice would you give to new researchers that are considering becoming involved in research?

First, familiarize yourself with the wealth of information we have available online, so that you can navigate the research submission process and system. Second, take advantage of all of the opportunities for collaboration within the network, both with researchers and with administrative offices. Because there are so many sites, there are a lot of opportunities for collaboration and connection across many stakeholders, including the IRB office, grants office, credentialing office, education, and more.

What do you find most gratifying about your role?

On a day-to-day level, I enjoy the challenge inherent in reviewing different protocols to ensure that they each meet the criteria for the protection of human subjects. Overall, I find it especially gratifying to play a part in advancing research within the greater HMH community.

What are some hobbies/interests outside of work?

I'm in the early years of parenthood, so I vaguely recall interests that included traveling and collecting vinyl records. I wish to pursue those interests again one day, but for now my focus is nursery rhymes and going to the park.

HMSOM RESEARCH BULLETIN

WINTER 2023

Hackensack Meridian School of Medicine's 'COVID Support Our Schools' Initiative Publishes Findings

An innovative program started to assist public schools amid the pressures and uncertainty of the first waves of the COVID-19 pandemic has culminated in a paper published by faculty from the Hackensack Meridian School of Medicine.

The paper, in the journal *Children*, concludes the COVID Support Our Schools (SOS) program helped underserved communities at a critical time - and its benefits could help with community health outreach beyond the time of a pandemic.

"Our initiative can serve as a framework for other institutions to establish a community – academic partnership," the authors write. "Such initiatives and community involvement can continue beyond the pandemic to address ongoing health care concerns and challenges such as vaccine hesitancy, health curriculum, and sports safety."

"We are so proud of the commitment to the mission and values of the school that the Human Dimension represents," said Jeffrey Boscamp, M.D., dean of the Hackensack Meridian School of Medicine, who was not one of the authors. "This was an example of really making an impact in the community at a time of unthinkable need."

COVID SOS was developed as part of the School's Human Dimension course curriculum, which is focused on outreach into the community. COVID SOS aimed to provide expertise about opening, and opening safely, to select school districts in underserved communities that had previously partnered with the Hackensack Meridian School of Medicine's innovative Human Dimension program. READ MORE

Diversity in Clinical Trials Research Underway

The need for diversity in clinical trials was acutely highlighted during the COVID-19 pandemic, when scientists made increased efforts to recruit patients from a diverse population for vaccine, treatment, and other studies. The general consensus is that clinical trials need to increase representation of patients from underrepresented demographic populations.

Faculty and students at the school are attempting to assess the extent of the inequity.

The group has gathered data from all clinical trials in New Jersey over the last five years. Analysis is currently underway to understand patterns about how representative the studies were - and to perhaps point a way toward better clinical trials in the future.

Updates will be forthcoming.

Second Annual Medical Student Research Day on May 5

The School's Office of Research and Graduate Studies and the Hackensack Meridian *Health* Research Institute are co-hosting the second annual Medical Student Research Day on May 5.

The event will feature the work of HMSOM students to highlight what the talented doctors-in-training have been investigating as they pursue their degree.

For more information, contact orgs@hmhn.org.

HMSOM Research Committee Reconstituted

The School's Research Committee has a new look - and a new agenda.

The committee has been reseated, revamped, and is expanding its charge.

Under its aegis, the committee will provide assistance, when appropriate, in reviewing grant applications and projects proposals, organizing Medical Student Research Day, and overseeing the Biomedical Incubator and Student Research Training Facility, as well as future graduate programs.

Vice Dean Stanley Terlecky, Ph.D., will continue to serve as Chair of the Research Committee.

QUARTERLY QUESTION

WINTER 2023

What is the difference between coded and anonymized data?

To answer the question, please click here.

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