Hackensack Meridian *Health*

Office of Research Administration

JULY 2021

MESSAGE FROM THE **CHIEF RESEARCH OFFICER**

COVID-19 presented more challenges than could have been imagined over the last year-plus, and researchers at Hackensack Meridian Health rose to meet those challenges. The success of mass vaccination has not totally eradicated this pandemic, and we continue to be at the forefront of SARS-CoV-2 innovation. But inquiries on virtually every facet of health, from oncology to primary care, have never ceased. Discover some of these developments in the pages of this quarterly update.

NOTE FROM THE **VP**

Our many researchers across the network deserve to be recognized – for their COVID-19 work, and for what they continue to do in their "regular" duties. We have taken tours and recognized their work with Clinical Trials Day, and we try to let them know every day we appreciate their herculean efforts.

HMH RESEARCH NEWS

RESEARCH TAKES A TOUR OF BUSY BIO-R

The Hackensack Meridian *Health* Biorepository (Bio-R) facilitates discovery and innovative research to improve medical care by using high quality annotated biospecimens. The collected biospecimens are used for gaining a deeper understanding of diseases, finding better treatment options and progressing clinical and translational research. COVID-19 presented more challenges, and progress, than ever before. This included an 860 percent increase in BioR sample procurement in one year, the establishment of their wide-ranging bioinformatics department, and the establishment of a core facility. HMH Research leaders took a tour of the Bio-R on June 1 and thanked the personnel for their outstanding work. Included were: Yael Kramer, MS, manager of the HMH Network Biorepository (third from left), David Chow, MD, director of the HMH Network Biorepository (fifth from left), who along with their team led Ihor Sawczuk, MD, chief research officer and president of the Northern HMH region (fifth from right), Cheryl Fittizzi, RN, MBA, vice president of Research and Regulatory Affairs (fourth from right), and members of the Center of Discovery and Innovation on a tour of the biorepository.

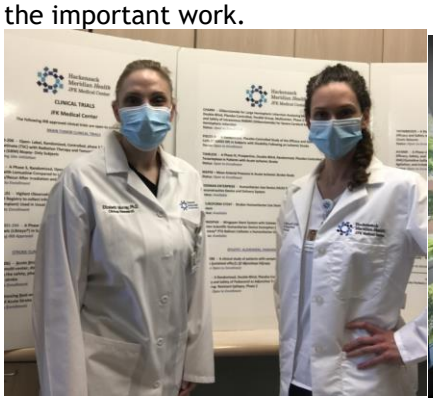
HMH and CDI Secure Research Accreditation

Hackensack Meridian Health and the Center for Discovery and Innovation have been accredited by AAALAC International. The distinction shows responsible animal care and use for research. The private, nonprofit organization promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.

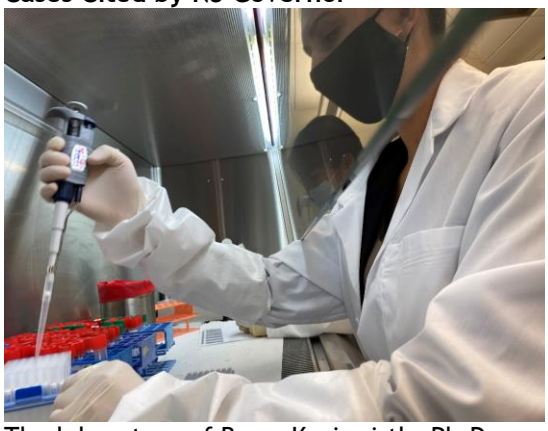
The team responsible gathered recently to display the plaque. Shown, from left, are: Avery Freed, CIP, director of the Human Research Protections Program; Cristina Jimenez-Ortigosa, Ph.D., manager, infectious disease lab at the CDI; Martin Gengenbacher, Ph.D., assistant member at the CDI; Steven Park, B.S., director of lab support operations at the CDI; Todd Keiser, director of the medical school facilities; Ihor Sawczuk, M.D., FACS, chief research officer and president of the Northern Region for HMH; Sean Fitzgerald, MPH, RBP, manager of biological safety and risk management; David Perlin, Ph.D., chief scientific officer and senior vice president of the CDI; Bruce Scharf, DVM, director of animal resources and attending veterinarian for the CDI; Michael Poulos, Ph.D., assistant member at the CDI; Juanita Vakerich, manager of the animal facility at the CDI; Chriselle Rivas, supervisor of the animal facility at the CDI; Cheryl Fittizzi, R.N., M.B.A., C.I.P., vice president of research and regulatory affairs; and Leigh Ann Tulleson, animal care use compliance specialist.

HMH Office of Research Administration Recognizes Clinical Trials Day

May 20 was Clinical Trials Day. Each year on this day, and especially during this time, Hackensack Meridian *Health* recognizes the work the research community does to improve human health. Sites across the network took time to recognize the important work.



CDI Work on COVID-19 'Breakthrough Cases Cited by NJ Governor



The laboratory of Barry Kreiswirth, Ph.D., a member at the Center for Discovery and Innovation, has been tracking COVID-19 through its many mutations, with diagnostics and variant tests.

The lab's work on "breakthrough cases" – those vaccinated persons who become infected with SARS-CoV-2 – was cited by Gov. Phil Murphy at the State's June 9 COVID-19 update for media.

The story was covered by many outlets, including *The Star-Ledger*.

READ MORE.

HMH Research Publishes Paper on COVID-19 Response

Hackensack Meridian *Health* experts published a paper showing how the research teams quickly responded to COVID-19.

The team outlined the establishment of the COVID-19 Research Review Committee (RRC) in the *Journal of Empirical Research on Human Research Ethics*, in a May paper.

In nine weeks, three network-wide RFPs yielded 238 proposals and 93 approvals – a rate of 39%, according to the paper.

"The RRC quickly established the ground rules: to produce better science, across disciplines across the network, and ensure we were working smarter, as well as harder," said Ihor Sawczuk, M.D., FACS, the network's chief research officer, one of the authors.

"We established a scientific review process that was transparent and standardized virtually overnight, and it worked really well at a time of need," said Elli Gourna Paleoudis, MS, Ph.D., manager of the Investigator Initiated Research Program at Hackensack Meridian *Health*. "Thanks to the Committee and the numerous reviewers that offered their time and expertise, we managed the volume of proposals we received while ensuring the quality of the ones which took shape." READ MORE.

Hackensack Meridian CDI Scientists Develop 'CATCHER' for Crucial Biomarkers

Tiny genetic markers, circulating in the blood, have shown great promise in diagnosing and treating disease. Yet identifying and harvesting these extracellular vesicles (EVs) have been a major challenge for science. Now a laboratory at the Hackensack Meridian Center for Discovery and Innovation (CDI) has discovered a highly sensitive methodology that can efficiently find and harness EVs – particularly exosomes and the micro RNAs they carry. These could be crucial clues to identifying diseases such as cancer early in its development. Read more

John Theurer Cancer Center Involved in Clinical Trial for First Personalized CAR-T Therapy for Advanced Multiple Myeloma

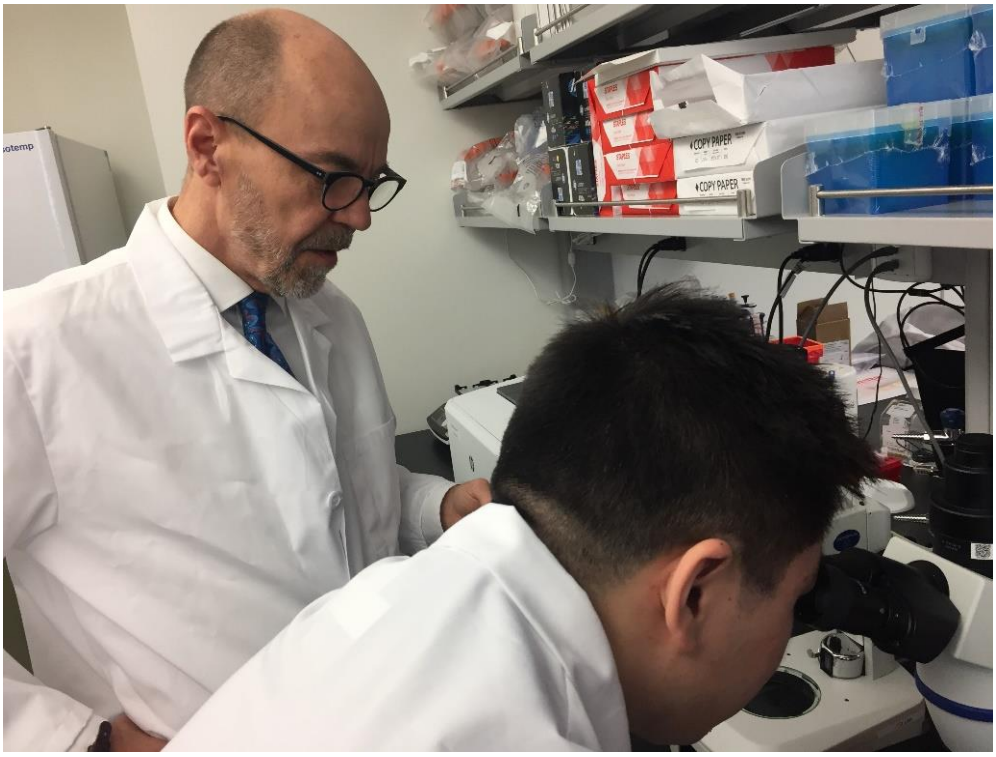
Abecma, a new CAR-T therapy also called idecabtagene vicleucel (ide-cel) that recently received approval from the U.S. Food and Drug Administration, was assessed in the pioneering phase II clinical KarMMA trial at Hackensack Meridian John Theurer Cancer Center at Hackensack Meridian Hackensack University Medical Center. Abecma is the first personalized cell therapy to treat patients with multiple myeloma who are no longer responsive to all standard previous types of therapy.**Idecabtagene vicleucel is the first approved patient-specific cell therapy, or CAR-T treatment, that targets a protein called B-cell maturation antigen (BCMA) found in malignant plasma cells. It is approved as a one-time infusion, customized using a patient's own T-cells, which are collected and genetically modified, and infused back into the patient. After they are injected back into the patient, the re-engineered immune cells seek and destroy BCMA-containing cells.** READ MORE

Mehandru Center for Innovation in Nephrology at Jersey Shore University Medical Center Publishes on Newly Identified, Potentially Life-threatening High Potassium Disorder

Researchers at The Mehandru Center for Innovation in Nephrology at Hackensack Meridian Jersey Shore University Medical Center and other authors recently had their new case report article "Metabolic Acidosis, Hyperkalemia, and Renal Unresponsiveness to Aldosterone Syndrome: Response to Treatment with Low-Potassium Diet," published in the *Saudi Journal of Kidney Diseases and Transplantation.*

Led by Nephrologist and Professor of Medicine Sushil K. Mehandru, M.D., the article describes three cases of Mehandru Syndrome, a potentially life-threatening electrolyte disorder that occurs in the absence of indicators or conditions that can cause high potassium levels, such as kidney disease, diabetes or high potassium diets or supplements. In each case, the high blood potassium was managed successfully with a low-potassium diet. READ MORE

CDI Scientists Discover New Tuberculosis Treatment Pathway



Scientists from the Hackensack Meridian Center for Discovery and Innovation, working with collaborators from across the globe, uncovered the mechanism of action of a novel anti-tuberculosis drug that they have helped develop. The new findings show how the enzyme inhibitor triaza-coumarin, or TA-C, is metabolized by the TB germs, which makes it effective in inhibiting the disease from within, like in a "Trojan horse" attack, according to the new paper in the journal *Proceedings of the National Academy of Sciences*.*

"This is a promising new direction of research," said Thomas Dick, member of the CDI faculty. "We are hoping this work can make a difference in the ongoing fight against TB."

"The scientists at the CDI who specialize in tuberculosis and other mycobacteria are at the vanguard of their specialty," said David Perlin, PhD., the chief scientific officer and senior vice president of the CDI. "Their promising new lines of research offer hope against a scourge that continues to kill in huge numbers, year after year." READ MORE

HMH Achieves Renewal of AAHRPP Accreditation in the Midst of the Pandemic

Hackensack Meridian *Health* has been recognized for its excellence in protecting the rights and welfare of research participants and for its strong research program. The AAHRPP (Association for Human Research Protection Program) Council reviewed our status report at their March 2021 meeting and decided to renew our accreditation. AAHRPP's mission is to accredit "high-quality human research protection programs in order to promote excellent, ethically sound research." It is viewed as the "gold standard" for research excellence, and accreditation is only granted to those human subjects protection programs that can demonstrate that they meet their high standards and requirements.

HM*H* received its original AAHRPP accreditation in September 2017. After the initial accreditation, the first re-accreditation takes place three years later. For HMH, three years later meant that we were to be evaluated in the midst of the COVID-19 pandemic - in September 2020. Given that there were no vaccines yet available and most of the country was in varying degrees of lockdown, AAHRPP veered from its normal in-person site visit and conducted its first ever remote visit for HM*H*. Members of the research teams, research administrators, IRB members, and others were interviewed by AAHRPP site visitors over two days.

Avery Freed, Director of the Human Research Protection Program, and Daniel Alderson, Manager of the Research Integrity Office, led the preparation for the visit, which required the review of numerous documents and discussions with many individuals involved in human subjects research across the network. After this most recent re-accreditation, the next scheduled re-evaluation assessment will take place in 5 years. Kudos to the Human Research Protection Program team for adding another feather to the research department's cap.

REGULATORY & PROCESS CHANGES AND REMINDERS

JULY 2021

OnCore for Clinical Research Management at HM*H*

Hackensack Meridian *Health* has implemented OnCore, a clinical trial management system (CTMS), to serve as a network-wide platform to manage clinical research and facilitate fiscal and operational compliance. OnCore is a suite of clinical and translational research modules consisting of software for research, patient registry, and biospecimen management. It is a product of Forte Research Systems, based in Madison, WI. OnCore has been successfully implemented in 44 institutions, 23 of which are NCI designated Cancer Centers and 21 are multi-disciplinary institutions. Recently, in addition to Hackensack Meridian *Health*, Forte has worked with leading academic institutions such as the University of Wisconsin, University of California San Francisco, and Yale University to do enterprise-wide deployments of OnCore that extend beyond Cancer Centers.

All clinical trials should be entered and managed through Oncore, and the following types of studies must utilize OnCore: Any human subjects study, data registry, chart review, or specimen collection research study conducted at Hackensack Meridian *Health* with a fully executed Clinical Trial agreement and/or budget must be entered into and utilize the OnCore system.

To Request Access to Oncore:
To access to OnCore, please complete this form.

User Support for OnCore
OnCore Training is required prior to gaining access to OnCore. The CTMS Administrator(s) is responsible for developing and coordinating major training initiatives. Research Services/Office of Clinical Research managers are responsible for individual team member/user training, as necessary. In addition, shadow training by trained team members is also an option. Training all of the users based on their roles through one-on-one or group training is documented under the user's contact record in OnCore. HM*H* Research Services/Office of Clinical Research has a specific set of standard operating procedures describing the step-by-step utilization of the OnCore Clinical Trial Management System.

Trouble Shooting
The CTMS Administrator(s) will investigate all user questions and issues and will resolve those that do not require Forte Research support. All user questions and issues should be sent via the RECAP OnCore Ticket system linked here.

The CTMS Administrator(s) will contact Advarra Product Support as needed to address any issues that they cannot resolve themselves.

Export Controls and How They May Impact Your Research

Federal export control laws govern how certain items may be transferred to foreign persons, nations, and/or entities. These laws apply to all research and activities at HMH regardless of funding.
Transfers can occur in many ways including, but not limited to:

- Shipping
- Mailing
- e-Mail
- Financial transactions
- Travel (w/ export controlled items)
- Discussions (about export controlled items)
- Visual inspection (of export controlled items)

Export controlled items are described under the Export Administration Regulations (EAR) and International Traffic in Arms (ITAR). Items may include (but not limited to):

- Articles
- Materials
- Supplies
- Software
- Technology
- Technical data
- Technical assistance
- Services

The majority of educational activities and research at HMH are excluded from export control regulations under the EAR or ITAR based upon public domain exclusions, fundamental research exclusions and exclusions for educational information. It is essential that researchers avoid entering into “handshake” or “side” agreements with sponsors that place restrictions on

dissemination of results and access by foreign persons because these restrictions can negate export control exclusions. When research and educational activities do not meet the fundamental research exclusions, they may require a license and additional monitoring by HMH's export control compliance.

A research project at HMH may require export control review if it involves any of the following:

- Sponsor pre-approval prior to publication of research
- Sponsor placing restrictions on foreign persons participation
- Involves a foreign sponsor(s)
- Includes foreign travel, international research, or collaborating with colleagues in foreign countries
- Traveling with export controlled items/HMH property including: laptops, tablets, cellphones, unpublished research data
- Receiving information or software from sponsor marked as "Export Controlled"
- Shipping any physical item(s) including software and/or transmission of technical data to a foreign country
- Any agreement that includes export control language
- Participation of a foreign person from an embargoed country or entity
- Travel to (or through) an embargoed country or entity
- Military research or research with potential military applications
- Encryption source codes or object codes

If any of the above apply to your project or if you have questions regarding export controls and how they may impact your research, contact exportcontrols@hmhn.org).

Guarding Against Undue and Prohibited Foreign Government Influence

The U.S. research enterprise is based upon the seven following principles to ensure the highest level of integrity and maintain public trust:

- Openness and transparency - enabling collaboration and disclosure of potential conflicts interests
- Accountability and honesty - acknowledge and correcting errors
- Impartiality and objectivity - results are protected from intentional/unintentional biases
- Respect - opportunities for those to be heard and contribute
- Freedom of inquiry - individual curiosity drives scientific discovery
- Reciprocity - mutual exchange of knowledge, materials, data, etc. benefits all collaborating
- Merit-based competition - the best ideas and innovations have the opportunity to advance

However, not all foreign governments promote the same values and are known to exploit the US research workforce to circumvent the costs and risks of conducting their own research. The US Government has taken an increased interest in this type of academic espionage, placing increased pressure on federal funders and US research institutions to be alert of these potential relationships with foreign governments.

HMH remains committed to the seven principles governing the conduct of research and recognizes the importance of international collaborations. However, not all collaborations are mutually beneficial for all parties. Below are some red-flags researchers should watch out for when entering a potential collaboration or external relationship with any entity:

- Certain conditions, contract terms, or other obligations associated with participation in foreign government-sponsored programs or entities
  - Contracts withheld or provided without third party certified English translation
  - Contracts that encourage/allow for continued employment at US research institution
  - Encourage/allowing of receiving Federal research dollars while concurrently working/receiving compensation from a foreign organization
  - Setting up or relocating a laboratory to a foreign country
  - Obligation to file international patents
  - Obligation to publish in particular journals, and/or list a foreign organization affiliation in any publication
  - Obligation to share information, even confidential (e.g. grant applications, peer-review information) with unapproved entities
  - Obligation to withhold information from HMH or Federal funders
  - Conflicts of time commitment (i.e. sum of all appointments >100% time)
  - Purpose or SOW conflict with principals of HMH
  - Obligated to participate in talent-recruitment activities
  - Obligation to hire/provide career advancement to individuals in specific programs
  - Obligation to provide pre-publication data/information
  - Obligation to prove loyalty or political alignment to a foreign govenmentment
- Participation in any foreign-government sponsored talent recruitment program that encourages or directs individuals to engage in behaviors that conflict with the seven principles

- Any obligation to conduct R&D activities on behalf of another research organization or entity without the knowledge/approval of HMH
- Foreign travel related to research responsibilities (especially if funded by foreign entity) without justification of benefits
- Extended travel that is inconsistent with funding received or HMH research responsibilities
- Association, affiliation, or collaboration by researchers with foreign entities identified on US government consolidated screening list
- Gifts that are provide with terms and conditions associated with research activities

What can you do to protect your research and reputation?
Always ensure your COI disclosure for research is accurate and transparent.
Speak with your department head before entering any new external consulting or affiliation agreement. HMH is your primary employer and supporter of your research portfolio. It is essential you are not over-committing to external relationships that can affect your work at HMH. Your department head should be aware and approve all external relationships related to your HMH institutional responsibilities. Ensure you are following appropriate institutional and research security protocols. Report potential security breaches to HMH IT Security.

What do you do if you are approached to participate in a research collaboration or offered an affiliation that raises red-flags?
Do not continue negotiations without HMH review by Export Control, legal and your department head. Contact, Dr. Michelle Benson at michelle.benson@hmhn.org for assistance or to report suspicious activity.

Resources:
JCORE Report on Recommended Practices for Strengthening the Security and Integrity of America's Science and Technology Research Enterprise.

New Form to be Utilized to Expedite Research Department Reviews and Promote Compliance

Beginning July 16, you will see a link for a "pre-registration form" in your eResearch applications. This is a new form that the Office of Research Administration and Research Compliance will be implementing in its efforts to expedite department reviews for studies and to ensure that HMH is compliant with all relevant research regulations and guidelines. Beginning August 2, the form will be required for all **new** research projects, both human subjects (as part of eResearch applications) and non-human subjects research (as part of IACUC and BioR applications). Prior to August 2, the form will be optional.

A few quick points about the new form:

- It is informative: As the researcher answers the questions, s/he will be provided with information about requirements for his/her research.
- It will help limit delays during the formal review process and promote research compliance: Once the form is submitted, department reviewers will be notified by email that the research project is being proposed, and it will enable them to be prepared for the review.
- It will be required for every new study: A representative of the study team must complete the form once for each study being proposed.
- It is easily accessible using the link below (and doesn't require a REDCap account): https://redcap.link/HMHPreRegistrationForm

Click here for a recording of a brief (5 minute) training that provides an overview of the form.

Click here for the training slides without the recording.

Click here to access a folder with sample forms completed for different scenarios.

If you have any questions about the form, please contact the following people:

- Technical questions about filling out the form in REDCap: Jasmyne-Rian Charles, Clinical Research Database Administrator, jasmynerian.charles@hmhn.org
- Questions about funding: David Candelmo, Manager, Office of Sponsored Programs, david.candelmo@hmhn.org
- Questions about budgets/contracts/data or materials sharing: Sergio Garcia, Clinical Research Business Manager, sergio.garcia@hmhn.org
- Questions about conflicts of interest/export control: Michelle Benson, Director, Conflicts of Interest Management, michelle.benson@hmhn.org
- General questions: ora@hmhn.org

Research Translations Requests to Language Services

Below is some important information about the process of submitting a research - related translation request:

Please email the appropriate contact in Language Services for your HMH region:
Elizabeth Lind (elizabeth.lind@hmhn.org) handles the Northern and Central regions
Jessica Ansbach (jessica.ansbach@hmhn.org) handles the Southern region

When writing to your Language Services contact to request translation of research documents, including consent forms, please include the following:

Subject Line: "Research Study" + [translation to which language]
In the body of the email, include the answers to the following questions:

1. What language are you requesting the documents to be translated?
2. What is your departmental cost center? If the study is unfunded and there is no funding for the translation, state, "No funding for translation - please use Network cost center".
3. Who should the translated documents be provided to? Include all who should be cc'ed.

Presentation Recordings Available Online

Recordings of our research education presentations (including Investigator Training Lecture Series presentations and other stand-alone presentations) are available in an easily accessible library online. Click here to access them.

If you are interested in learning about our exciting upcoming events, you can view the calendar here.

Tracking your eResearch Submission:

Once you have submitted your application in eResearch, you're able to track the status by using the following features:
o "Current State" (found in the top left corner of the submission's main page) indicates where in the submission process the application is: Whether it be in 'Department Review' awaiting any of department reviews such as Department Chair review, Contracts or Budgets review, COI review, etc. or in one of the IRB review states (such as 'IRB Staff Review', 'In Expedited Review' or 'Assigned to IRB Meeting').
o "Pre Review Status" tab lists all Department Reviews, indicating which ones have cleared and which are pending as well as indicates which departments/offices have been assigned those reviews.

FEATURED RESEARCHERS

JULY 2021

Gregg Klein, M.D.
***Orthopedic Surgeon*, Rothman Orthopaedics**
***Vice-Chairperson* of the Department of Orthopaedic Surgery, HUMC**
***Associate Professor*, Hackensack Meridian School of Medicine**

Dr. Gregg Klein solves problems. His goal: to identify an issue, implement an evidence-based solution, and reach a positive outcome. It's this acumen that led him to practice and research orthopedic surgery. Dr. Klein aspired to become a physician since his mid-teens. When he began medical school, the nature of orthopedics - diagnosing the problem, performing a surgery or procedure, and fixing that problem - appealed to him. He also became involved in clinical research during his time in medical school, since it's fundamentally a search for the best solution to a problem.

Dr. Klein discussed his research and offered advice to other physicians potentially interested in research in this recent conversation with us (which is edited for length):

You are on the editorial board of several scientific journals and are well published. What led to your involvement in research?
I became involved in research as a third year medical student to get my feet wet, learn a little bit more about what it involves, and improve my prospects for residency. Before beginning to work in research, I hadn't imagined that it would be a long term endeavor for me. But I actually really enjoyed it! Over time, I became more and more involved in different research projects - both individually and collaboratively.

Can you share with me some of your most exciting research projects?
Some of my recent work has been really exciting. I just learned that the manuscript has been accepted for publication. Essentially, the study involved looking at DVTs (deep vein thrombosis, a type of blood clot). The course of treatment for many DVTs is pretty clear, but there are certain cases for which the treatment path is ambiguous. I looked more carefully at those cases and set out to see whether there was a best way to manage them. I conducted a retrospective chart review and upon analysis, learned that many patients with distal DVTs did well with a simple aspirin. It worked effectively for them and didn't come with some of the complications of the more aggressive blood thinners, such as Heparin or Warfarin. Previously, some specialists in the field had suggested that stronger, more risky blood thinners would be needed; however, we were able to provide support to the contrary. I received an award from The Knee Society for this project, and the findings were presented at the American Academy of Orthopedic Surgeons conference this year.

I have also been involved in implant retrieval studies. We studied how certain types of implants wear more than other types of implants when they are in the body. We were able to study them in patients who required a second surgery. Once removed, the implants were sent to labs for analysis.

Over the course of my career, I have been fortunate to be involved in various types of studies related to orthopedics.

How do you navigate the physician-scientist role? Do you have any advice for budding physicians who are interested in becoming involved in research?
Being a practitioner and becoming involved in high level research is definitely challenging. It requires a very delicate balance, and the nature of the balance depends on your focus. While I am an Associate Professor at the Hackensack Meridian School of Medicine, I am primarily a clinician. Most of my daily activities are dedicated to clinical practice, and I devote many nights and weekends to my research. In my previous practice, I did not have the wherewithal for much support

for research. But since switching practices, I have support from the Office of Research Administration at HM*H*.

In terms of advice for future physician-scientists: Becoming involved in research can be challenging, but it is also incredibly rewarding. The process of having a question, executing a study, going through data, getting results, and seeing the publication is wonderful.

I imagine that you were forced to halt in-person visits and surgeries during the height of the pandemic. How did you pivot during that time?
That is correct - things were practically at a standstill for a good 2.5 months. Normally, I do 60 surgeries a month, but during the height of COVID, it dropped to maybe 1-2 a month. I was limited to the emergency cases.

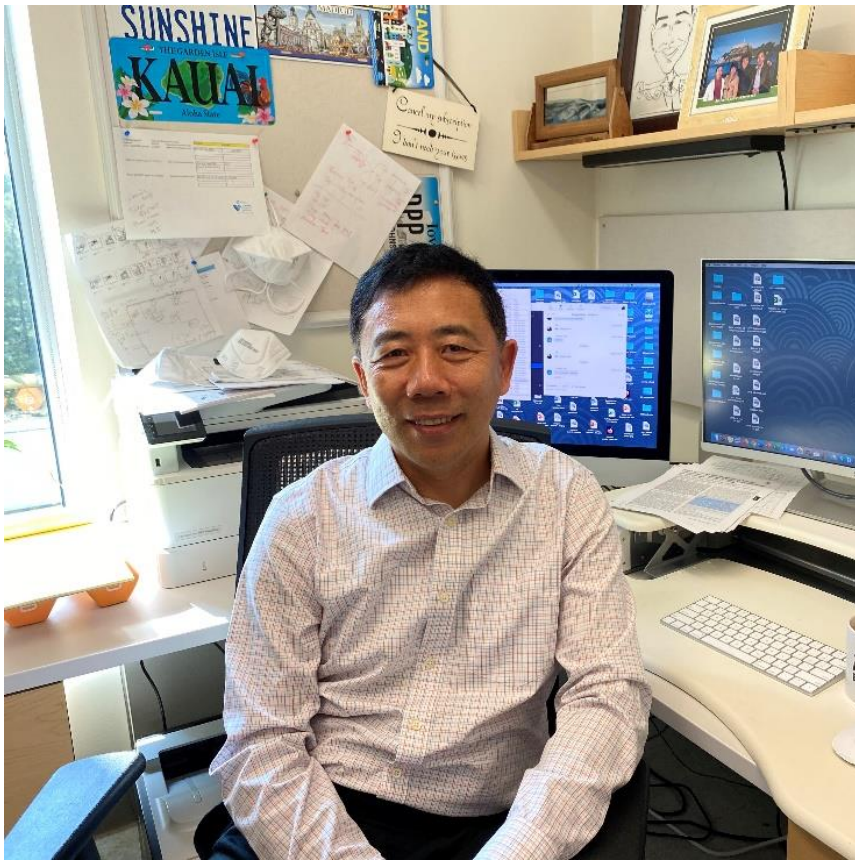
I took the time to regroup and to focus on ideas and concepts for research. I started some new projects and spent my free time working on them.

Your online profile for your practice mentions hobbies such as running, skiing, and golfing. Have you ever been injured? In general, what measures do you recommend to your patients to prevent injuries?
Yes, I have been injured - in fact, I have had two knee surgeries. To minimize the chances of injury, I tell my patients to be prepared with the right equipment, to stretch beforehand, and to exercise within their limitations. I advise them to take a slow and steady pace. Having said that, accidents happen that are unavoidable. Despite good intentions, things happen sometimes.

FEATURED RESEARCHERS

JULY 2021

Howard Xue, M.D., Ph.D.
***Member*, Center for Discovery and Innovation**



- **What brought you to the CDI? What was the major draw?**
It was the vision of Dr. Perlin. He wants to push forward innovation in basic science and emphasis on translational science into therapeutic applications. But another motivation is that it being in a young institute, I can contribute to shape the focus and direction of research programs. In fact, we are now moving toward to build strength in T cell immunity, which will likely create a nationally-ecognizable brand by making a strong impact on the field.
- **What is your major focus of research at the CDI?**
T cell immunity. We study the birth of T cells in the thymus, and their critical functions in anti-infection and anti-tumor immunity after mature T cells are deployed to tissues.

- **What brought you to the USA (circa 2006)?**

I came to the US in 2000 after I completed my Ph.D. studies in Biochemistry. From a young age, I dreamed of becoming a scientist, to better understand the governing rules in nature. I thought the US could be the best place for me to reach that dream.

- **What is the ultimate goal of your research?**

We are trying to identify key pathways that we can manipulate to achieve optimal T cell responses, such as optimizing T cell output from blood stem cells, enhancing memory T cell formation and function in vaccination, and the restoration of dysfunctional T cells due to exposure to tumor microenvironment.

- **What is your career high point up until now?**

“Today” is always a high point for me. I believe I am becoming more knowledgeable every day. The improvement may not be huge every day, but it is the cumulative effect that shapes my thinking. I hope to keep this momentum for the coming years.

- **What is your family life like (i.e., married, kids, etc.)?**

I’m married. My wife works as a physician at HMH. My son works at Google as an engineer. My daughter is in college, and is interested in medicine as a future career.

- **Do you have any hobbies?**
Badminton, travel

FEATURED RESEARCH ADMINISTRATOR

JULY 2021

Cheryl Fittizzi, MBA, RN, CIP
***Vice President*, Research and Regulatory Affairs, Hackensack Meridian Health Network**

Cheryl Fittizzi has been a key leader in research regulations and operations here at HMH for many years now. She began in the clinical realm and eventually expanded her research repertoire by assuming research roles that required increasing levels of regulatory knowledge and expertise. Given her breadth of experience, she can speak of a profound appreciation for the participant protection safeguards that now exist today. Ms. Fittizzi met with us to discuss some of the challenges that the research community overcame during the pandemic and some of the recent triumphs that we have celebrated (please note

You were originally a clinician (registered nurse), and you worked in that capacity for several years before moving to research. How did the shift to research take place?
I started in 1989 at HUMC, working as a nurse on the diabetic unit and then in the Emergency Room. At the time, they were establishing a new research department. They needed coordinators, and I took the opportunity to work as a research coordinator in a per diem capacity alongside my ER shifts. Eventually, I fell in love with research and moved to full time. While working as a research coordinator, I was approached to fill in temporarily as the Institutional Review Board (IRB) coordinator. I ended up really enjoying the role and stayed in that position. I didn't have an IRB mentor, so my IRB knowledge was initially self-taught. I grew the program over time - by instituting Standard Operating Procedures, regulatory compliance, research staff education, clear and efficient processes for research submissions, and continuing assessment of ongoing research projects.

What advice would you give to other clinicians who are interested in moving into the research regulatory field? How would you suggest they get started?
One approach is to partner with clinicians currently working in clinical research. They could also shadow someone who is involved in clinical research operations within our network.

What has kept you in research all of these years - is there something about it that you find especially meaningful?
In addition to the progress that I've seen in research regulations, there have also been huge leaps in terms of scientific innovation in certain fields - and this has produced significant benefits for patients. Research involves delving into unanswered questions and always trying to find better treatments and outcomes.
I can relate to this on a personal level, as well. My sister passed away from leukemia when she was only 11 years old. In those days, treatments were limited and largely ineffective. However, today, because of research, young patients who have the same condition as my sister now have a real fighting chance. In my mind, research represents hope.

Have you had any mentors who have been especially helpful to you during your career?
Yes, there were several people who provided excellent guidance and really helped me along my career path. One such person is Tisha Arakelian, currently the Clinical Research Manager for the Heart and

Vascular Health department. She worked with me in the ER and was the first person to transition over to the new research department years ago. She was the one who originally asked me if I wanted to join her in research and taught me the basics of being a research coordinator. Tisha fostered my early career and is one of the reasons why I am where I am today. Dr. Gary Munk, who recently retired from the Virology department, was also a strong supportive force. Debbie Grammer was the director of research at HUMC, and she helped me, as well. Finally, Tom Flynn, currently the VP of Corporate Compliance, really helped to grow an efficient and compliant research program.

Along with Dr. Sawczuk, you have led the HMH research community through the pandemic. What has been most challenging during COVID - especially early on? And what do you think has been key to the network's success in navigating research during this time?
The most challenging piece during COVID-19 was that there was no clear cut regulatory-approved standard of care treatment for the virus, so we had to rely solely on innovation for patient treatment. COVID-19 was also incredibly unpredictable initially. Other diseases came with a history, and this had nothing. There was no reference point on which to rely. Because of our location, HM*H* was hit especially hard early on. We were without many solutions, so we just focused on utilizing research to do the best we could for the patients across the network. I am really proud that we were able to do so much in so little time - we had clinical trials up and going very quickly, and we immediately started enrolling patients. It was really rewarding during a very difficult time.
As for the key to the network success, I attribute it to the spectacular teamwork from all of the partners across the network to deliver investigational treatments rapidly. We are built on the 5 Cs - compassion, creativity, collaboration, courage, and connection - and they really all came into play as we handled the pandemic.

You have been at HM*H* (including HUMC) for 32 years at this point. What is it about HM*H*/HUMC that has made you want to stay here for this long?
I like that it has never been stagnant. There is always change and improvement. It has been amazing to see the growth over the past few decades. I anticipate that as great as things are now, they will only continue to get better. That is an exciting prospect.

Research at HM*H* has grown exponentially over the last few years. What are some of the network's research milestones or accomplishments of which you are most proud?
I am extremely proud of HM*H*'s (specifically JTCC's) National Cancer Institute designation. To become a member of such a prestigious research consortium, a center must meet high standards for research that are aimed at coming up with better approaches to preventing, diagnosing, and treating cancer. I am also very proud of HM*H*'s AAHRPP (Association for the Accreditation of Human Research Protection Programs) accreditation for excellence in research, specifically in human subjects protection, and for our AAALAC (American Association for Accreditation of Laboratory Animal Care) accreditation for excellence in animal care and use for research. They were awarded to our Human Research Protection Program and to our animal research program, respectively. Finally, I am really proud of the high number of studies and clinical trials available to our patients. It is important to me that HM*H* patients have access to the most cutting edge options available.

Do you have any hobbies or things you enjoy doing when you're not leading the research program at HM*H*?
I really enjoy spending time with Frank and my three kids - Danielle, Anthony, and Ava Clare - and my dog, Freddie Mercury. We try to get outside when the weather is nice, and we especially enjoy the beach.

QUARTERLY QUESTION

JULY 2021

Who is ultimately responsible for the conduct of a study and the publications arising from it? What is a tool/document that can help ensure that responsibilities are properly delegated?

To answer the question, please click here.

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