



AdventHealth Research Institute | 2023

Annual Report

Table of Contents

Welcome	4	Pharmacy Investigational Drug Services (IDS).....	50
AdventHealth Research Institute (AHRI) Overview.....	5	Translational Research Institute (TRI).....	52
Introduction to AHRI in the Rocky Mountain Region.....	6	Transplant Institute.....	55
AHRI in the Central Florida Division	8	AHRI in the Great Lakes Region	57
AdventHealth for Children.....	10	AHRI in the West Florida Division	59
Cancer Institute	14	The Office of the Vice President of Research.....	63
Digestive Health	22	Philanthropy	67
Genomics and Personalized Health	26	Research Participant Recruitment.....	70
Heart, Lung and Vascular Institute.....	30	Participate in Research.....	72
Neuroscience Institute	34	2023 Publications.....	73
Nursing, Whole-Person and Academic Research	40	Acknowledgments	105
Orthopedic Institute.....	46		

Welcome

Advancements in medical science come in two forms. The first is the incremental increase in knowledge — continuous improvement, the broad implementation of best practices and better outcomes. And then there are the breakthroughs — new ways of conceptualizing, diagnosing, preventing and/or treating disease. At the AdventHealth Research Institute, we conduct research that aims to achieve both the steady march and the rapid advancement of care. Under the banner of this year's theme, "We Are the Breakthrough," we highlight the big wins and novel approaches we have achieved and the teams that do this form of research. Knowledge is ever-increasing, but these researchers and this team pole vault over the bar — moving rapidly to surpass yesterday's medicine. Come along with us as we leap ahead and fly over the barriers to a whole life.



A handwritten signature in black ink that reads "Steven R. Smith, MD".

Steven R. Smith, MD
Senior Vice President and Chief Scientific Officer, AdventHealth

How do you make the complex simple?

This question is a key challenge in leadership, scientific discovery and even research administration.

Breakthroughs that may seem simple in hindsight, reflect highly intense and complex work by committed Research Institute teams who never stop pushing to heal the body, mind and spirit. Whether that's breaking through the mechanisms of complex metabolic processes, navigating the myriad regulations governing research or de-mystifying clinical trials to inspire hope for a patient, efforts like these combine our team's passion for science with our commitment to extend Christ's healing ministry to all.

Thank you for exploring more about us in the pages that follow. We hope you'll see the tireless effort of our investigators and teams and the power of research innovations to create wholeness for our communities.



A handwritten signature in black ink that reads "Rob Herzog".

Rob Herzog
Vice President, Research



AdventHealth Research Institute (AHRI) Overview

AdventHealth's vision is to be a preeminent, faith-based, consumer-focused clinical institution that delivers exceptional patient care. The AdventHealth Research Institute (often referred to as "the Research Institute" or "AHRI") plays a key role in helping our organization create an exceptional quality of care by bringing groundbreaking research, vigilant patient-centered oversight and scientific knowledge closer to our patients and community system-wide.

Elevating our ability to serve and enrich our community is integral to the Research Institute's vision to expedite groundbreaking and globally recognized, whole-person health care research that leverages our population's scale and diversity to improve our communities' health and wholeness.

Our diverse portfolio of clinical trials, involving more than 1000 investigators and staff, has strengthened the medical community through various means, such as improving our understanding and treatment of diabetes. To better understand neurodegenerative diseases and the latest innovations in immunotherapies and CAR-T treatments, while also gaining deeper insights into our portfolio, we aim to sustain our musculoskeletal studies and ultimately enhance quality of life as we age. Our clinical trials have also placed cutting-edge research into the hands of patients in need, connecting them to results and possible treatments faster, without compromising safety or quality of care.

As AdventHealth further expands its expertise and leading-edge research discoveries, we remain true to our mission of Extending the Healing Ministry of Christ and our quest to help people achieve wholeness in body, mind and spirit in the Central Florida Division, West Florida Division, South and East Florida Divisions and several regions within the Multistate Division. We share that knowledge across our system and beyond—building a solid scientific foundation we can use to define and extend the borders of standard clinical practice in the 21st century. Guided by this vision, our leadership collaborates to create bi-directional benefits for the community, our health system and our physician, PhD and nursing researchers.

AHRI Leadership Team



Steven R. Smith, MD
Senior Vice President,
Chief Scientific Officer,
AdventHealth



Rob Herzog
Vice President
Research



Christopher Davis, PhD
Executive Director
Research Operations



Shauni Dusan
Executive Director
Research Data Services Core



Bret Goodpaster, PhD
Scientific Director
Translational Research
Institute



Patricia Robinson, PhD, APRN
Scientific Director
Nursing, Whole Person and
Academic Research



Delores Barnes
Director
Oncology, Neuroscience and
Pediatrics Clinical Research



Ashley Brower
Director
Research Administration &
Strategic Communications



Christina Jackson
Director
Office of Research Integrity
and Compliance



Rossitza Kassabova
Director
Research Finance



Kirk Erickson, PhD
Director
Translational Research

Introduction to AHRI in the Rocky Mountain Region

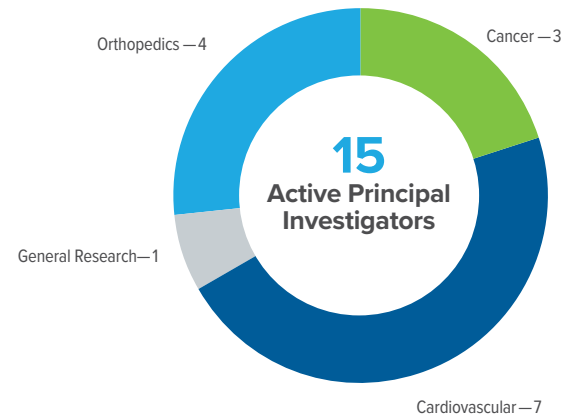
Overview

The Rocky Mountain Region, one of the newer additions to the AdventHealth family, continues to provide exceptional care with leading-edge treatments and a dedicated whole-person care system throughout Colorado. The region comprises five hospitals: AdventHealth Avista, AdventHealth Castle Rock, AdventHealth Littleton, AdventHealth Parker and AdventHealth Porter.

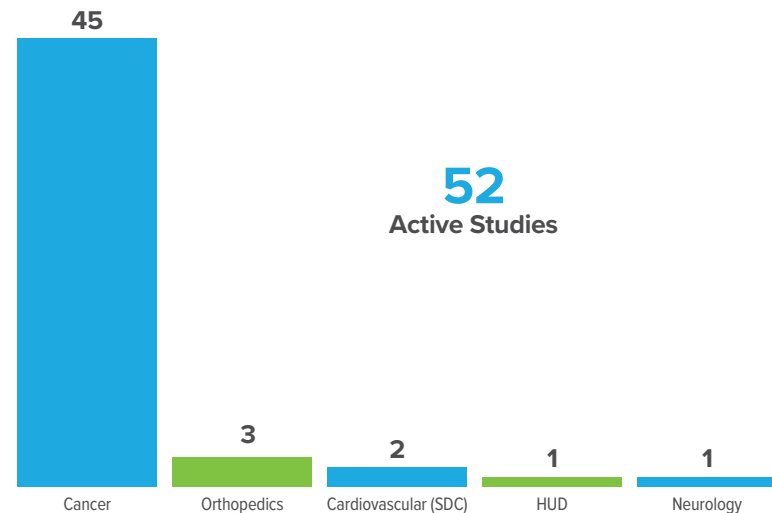
The Rocky Mountain Region strives to provide the latest research to our community and build a solid foundation for their future growth in research. From the Nationally Accredited Program for Breast Centers that AdventHealth Parker and AdventHealth Littleton have maintained for their remarkable care for oncology patients to the nationally recognized physicians at Colorado Joint Replacement at AdventHealth Porter, our physicians are committed to making a difference in our patients' care through innovation and research.

By the Numbers

Active Principal Investigators in the Rocky Mountain Region



Active Studies in the Rocky Mountain Region



Investigators



**Douglas Dennis, MD,
FAAOS**

Douglas A. Dennis, MD, FAAOS, is a board-certified orthopedic surgeon serving adults at AdventHealth Porter. He is an adjunct professor of bioengineering at Denver University, an adjunct professor of biomedical engineering at the University of Tennessee, and an assistant clinical professor in the Department of Orthopaedics at the University of Colorado School of Medicine. Dr. Dennis is keenly interested in knee and hip arthroplasty, resulting in three decades of study on the kinematics of knee replacement and how it relates to total knee arthroplasty design. His current focus on hip arthroplasty analyzes how spinopelvic mobility patterns affect the 3-D functional position of the acetabulum in THA. This research has generated over 400 publications in the orthopedic literature. Dr. Dennis is the past president of the American Association of Hip and Knee Surgeons and Knee Society, a member of the Hip Society, and serves as Executive Director of Operation Walk Denver, an organization committed to performing free joint replacement in developing countries for those patients without access to medical care.

Medical Degree: Medical College of Ohio

Residency: Ohio State University

Fellowship: Fellowship Training with Mack L. Clayton, MD, founder of the Denver Orthopedic Clinic



**Jason M. Jennings,
MD, DPT**

Jason M. Jennings, MD, DPT, is a board-certified orthopedic surgeon at Colorado Joint Replacement in Denver, Colorado. He serves on many well-known associations and committees, including the American Association of Hip and Knee Surgeons Research Committee.

Dr. Jennings' research focuses on hip and knee replacement surgery and rehabilitation. He has authored over 100 scholarly articles and received the 2019 James A. Rand Award from the American Association of Hip and Knee Surgeons for his efforts in total joint-related research. He also co-authored the Rose Excellence in Research Award paper in 2020, awarded by the Academy of Orthopaedic Physical Therapy Research Committee. Dr. Jennings was selected as one of two North American surgeons for the prestigious John N. Insall Knee Society Travelling Fellowship in 2017. Lastly, in 2023, he was inducted into The Knee Society, an academic, by-invitation-only membership organization comprised of approximately 200 internationally recognized leaders, innovators, mentors, researchers and educators.

Dr. Jennings is the principal investigator of more than 20 ongoing research projects, including a clinical trial on the use of a synthetic form of cannabis to decrease narcotic utilization after total knee replacement surgery. This prospective, randomized, double-blinded, placebo-controlled study is ongoing at Colorado Joint Replacement. Currently, there have been no studies in the orthopedic literature to support the use of cannabis for pain control after knee replacement surgery. This study may assist with guidelines for treating these patients.

Medical Degree: University of South Florida

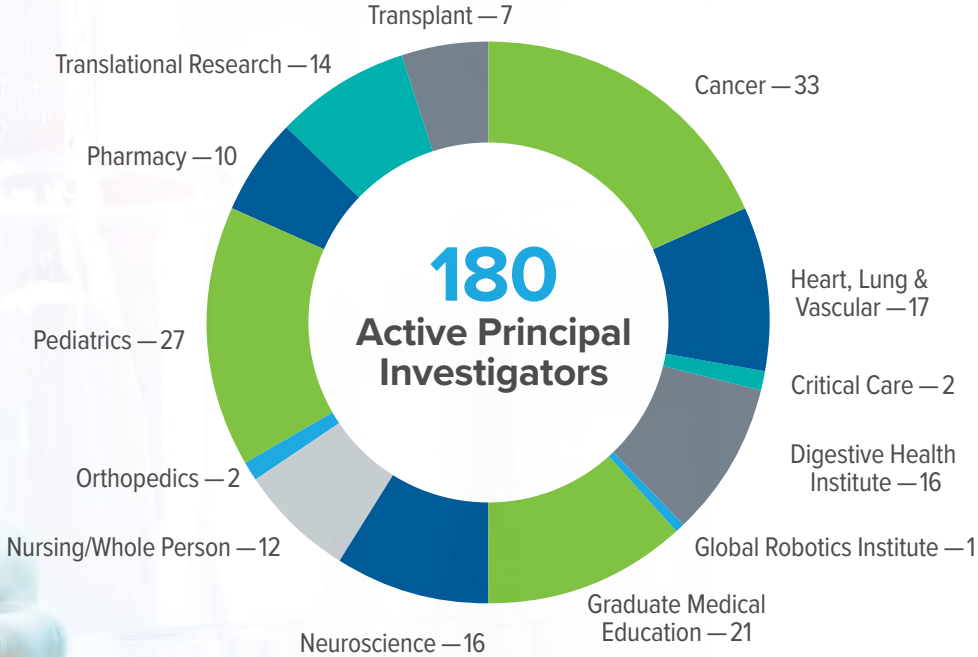
Residency: Duke University

Fellowship: Colorado Joint Replacement

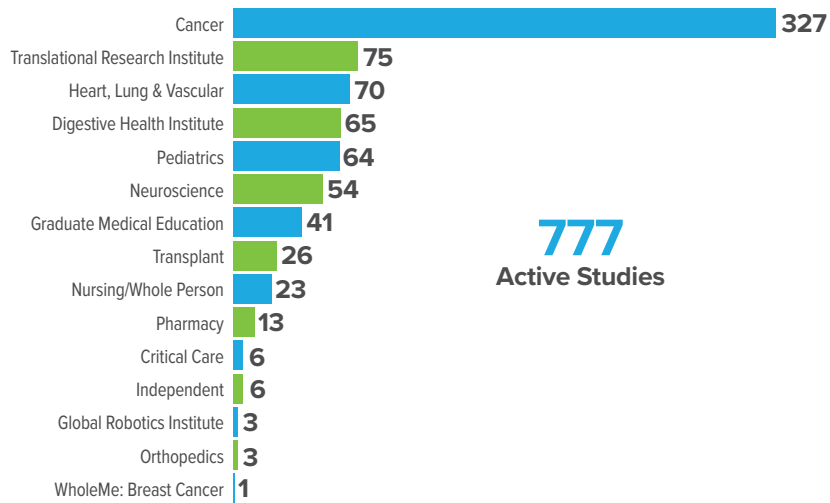
AHRI in the Central Florida Division

By the Numbers

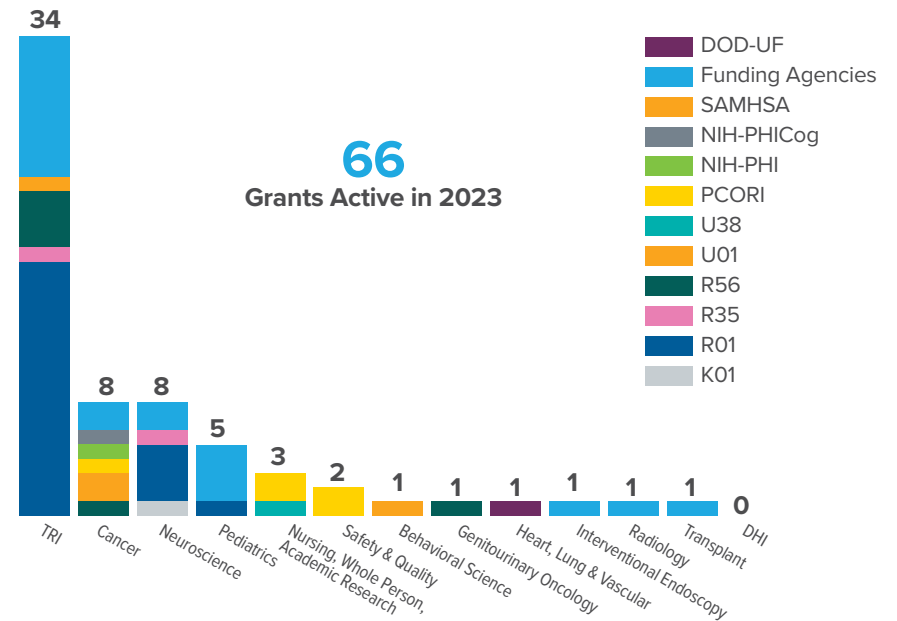
Active Principal Investigators in the Central Florida Division



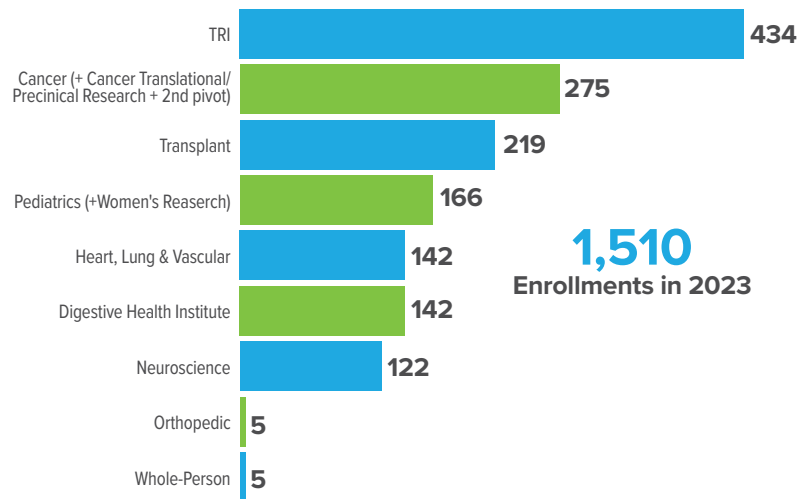
Active Studies in Central Florida Division



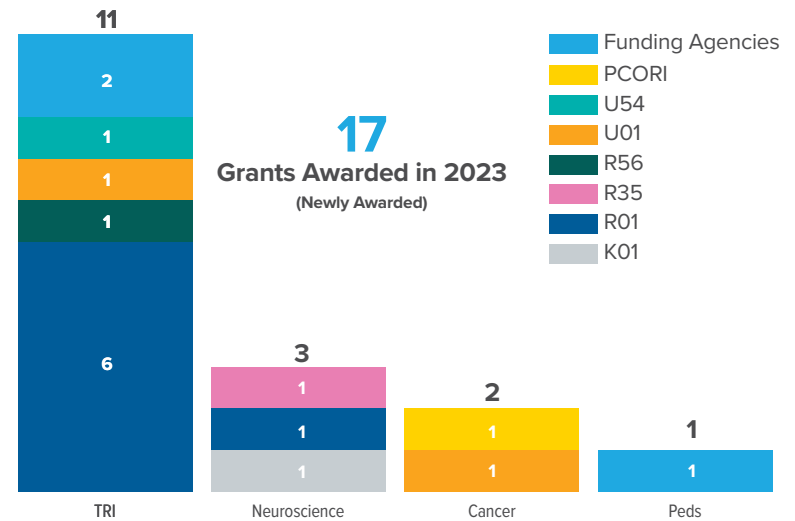
Grants Active in 2023



2023 New Enrollments in Central Florida Division



Grants Awarded in 2023





AdventHealth for Children

Overview

AdventHealth's Center for Pediatric Research is defining the future of pediatric health care through research, and data analysis, as well as improved clinical performance and quality of care. Our vision is to achieve an outstanding national reputation in pediatric care through education, research and innovation while prioritizing equity and diversity for all patients.

The research department fully supports all investigator-initiated, grant-funded and sponsored clinical trials comprising a portfolio that crosses many pediatric areas. Subspecialty care includes head and neck tumors, a mental health program, a Level IV comprehensive pediatric epilepsy center, a Level IV neonatal intensive care unit (NICU), a pediatric cellular therapy program with a cancer and blood disorder specialty, a pediatric liver transplant program and a complex care clinic for patients with more complicated diagnoses. The center seeks out and participates in industry-sponsored research in various pediatric subspecialties and focuses on investigator-initiated projects that significantly impact survival and outcomes through clinical trials today and standardized care tomorrow.

Areas of Focus

- Asthma
- Autism
- Cardiology
- Dermatology
- Epilepsy
- Genomics and rare diseases
- Hematology
- Hepatology
- Neonatology
- Neurology
- Orthopedics
- Obesity
- Sepsis (infections)
- Urology
- Vaccines

Featured Researchers and Research



Leslie Pineda, MD,
MPH

Leslie Pineda, MD, MPH, is the principal investigator for the STAR Study, a Phase 2, two-stage, multisite, randomized, double-blind, placebo-controlled, multiple-ascending dose study of RLS-0071 to assess the safety, tolerability, pharmacokinetics (PK) and preliminary efficacy in newborns with moderate or severe hypoxic-ischemic encephalopathy (HIE) undergoing therapeutic hypothermia.

HIE, also known as birth asphyxia, is a rare disease that affects newborns suffering an abrupt, unexpected loss of oxygenation due to placental rupture, umbilical cord problems or other factors. The initial loss of oxygen and the following dysregulated inflammatory process cause damage to the brain and other organs. This acute disease often results in death or moderate-to-severe cognitive and physical disability, with life-long impacts on both the newborn and the newborn's family. Derived from activity discovered in an astrovirus coat protein that evolved to block inflammatory processes, RLS-0071 has dual-targeting mechanisms to inhibit both humoral and cellular components of the immune system. RLS-0071 inhibits complement activation and reduces cell-mediated inflammation by blocking myeloperoxidase (MPO) activity and neutrophil extracellular trap (NET) formation. Additionally, RLS-0071 has antioxidant characteristics that reduce free radicals that would otherwise be harmful to tissue. The anti-inflammatory properties of RLS-0071 can potentially mitigate disease progression and tissue damage by limiting inflammation and oxidative stress through these key mechanisms.

For the STAR study, our institution is collaborating with ReAlta Life Sciences, Inc., a clinical-stage biotech company dedicated to harnessing the immune system's power to address life-threatening rare diseases. "ReAlta is so pleased to have the AdventHealth NICU team participating in the STAR Study. As one of the highest enrolling out of the 14 sites in the United States, we appreciate Dr. Pineda and her team's willingness to go the extra mile for the babies." Lori Upham, HIE Program Leader. NCT05778188

Orlando boy among first in the world to receive life-changing Type 1 diabetes drug



Anderson Ata, age 10, is living his best life, going to school, playing basketball and having fun. You'd never know he was extremely sick earlier this year. His parents, both dentists in Orlando, knew something was wrong last New Year's Eve. Anderson came to them cold and shaking.

Konda M. Reddy, MD Anderson's father, Dr. Joseph Ata, said the family found their way to **Dr. Konda Reddy** of AdventHealth. Dr. Reddy is the first doctor in Orlando to administer Tzield, a new Type 1 diabetes drug. Tzield's genius is that it can delay the onset of symptoms for years. "This monoclonal antibody therapy is approved for stage one and stage two of the disease. That's why the early diagnosis is very important," Dr. Reddy said.

Patients are given a series of injections over 14 days, and then they're done. Anderson says his life hasn't changed that much since getting the drug, other than not eating much candy, which he says his parents didn't

"At AdventHealth for Children, we believe in the power of collaboration and innovation to drive breakthroughs in pediatric health care. By nurturing a culture where clinicians and researchers work hand in hand, we transform cutting-edge research into tangible care – inspiring hope and healing for our communities. Our investment in talent and research empowers us to pursue bold ideas, ensuring that every child we serve receives the exceptional care they deserve.

"We're committed to investing in talent and research that redefines what's possible in pediatric health care. By empowering our teams to pursue bold ideas and innovative approaches, we're not just shaping the future of medicine, we're creating breakthroughs that transform lives and uplift communities. Together, we're forging a path towards a healthier, brighter tomorrow for every child we serve."

— Rajan Wadhawan, MD

allow anyway “because they’re dentists,” he said with a laugh. His dad says the real blessing is that he doesn’t really know what it’s like to have Type 1 diabetes because of this revolutionary new drug.

Anderson is a trailblazer for Tzield. He’s the first person in Orlando and only seventh in the world to receive it. When asked how he feels about being first, his answer is wise. “Good? Almost? Well not that good because that means a lot of people are still not getting the drug,” Anderson said. That’s something the Ata family hopes changes soon.

In the meantime, Dr. Ata says they’re grateful for the gift of time it’s given Anderson. “Even if we only get two years, even if we only get three years, even if we get one year, it will have been worthwhile, because just his past six months of being able to enjoy life fully has been a treasure,” Dr. Ata said.

— Used with permission by and from FOX 35

New Investigators



Chenue Abongwa, MD

Chenue Abongwa, MD, is a board-certified pediatric oncologist trained in clinical investigations. He obtained an MS in Clinical Investigations during his Pediatric Hematology-Oncology fellowship in 2014. This research training incorporated practical experience in designing, conducting and analyzing clinical trials for children with cancer into the didactic coursework. Dr. Abongwa designed a clinical study titled “The Efficacy of 68-Ga

DOTATOC PET in Children and Young Adults with Brain Tumors.” The results were published in the American Journal of Nuclear Medicine and Molecular Imaging. He also published a manuscript titled “Favorable Outcome to Glucocorticoid Therapy for Engraftment Syndrome in Pediatric Autologous Hematopoietic Cell Transplant” in the journal Pediatric Transplantation based on work conducted for his MS in Clinical Investigations thesis. Dr. Abongwa has since published other papers.

With heightened activity in translational research in pediatric neuro-oncology as new therapies are sought, he believes this research training will enable him to keep abreast of these changes and initiate clinical or translational projects in the future. Dr. Abongwa participates in children’s oncology group trials in children with cancer and plans to develop an investigator-initiated trial. He was drawn to AdventHealth by its focus on high ethical standards.



Sean Keyes, DO, FAAOS

Sean Keyes, DO, FAAOS, is a board-certified, pediatric orthopedic surgeon with advanced training in pediatric sports and trauma from Cincinnati Children’s Medical Center. Dr. Keyes, a dedicated sports medicine physician, provides medical team coverage for Florida Citrus Sports for college bowl games, such as the Camping World Bowl, Cheez-It Bowl and Florida Classic. He recognizes the increasingly competitive nature and pressures on growing kids and is a source for injury and re-injury prevention methods. Dr. Keyes is the national secretary for the American Osteopathic Academy of Orthopedics Sports Committee. He and his team are the medical providers for local high schools, including Bishop Moore Catholic, Edgewater and Jones High Schools. Dr. Keyes treats athletes on various levels, including patients who fly in from all over the country to have surgery with him due to his work with the BEAR implant.

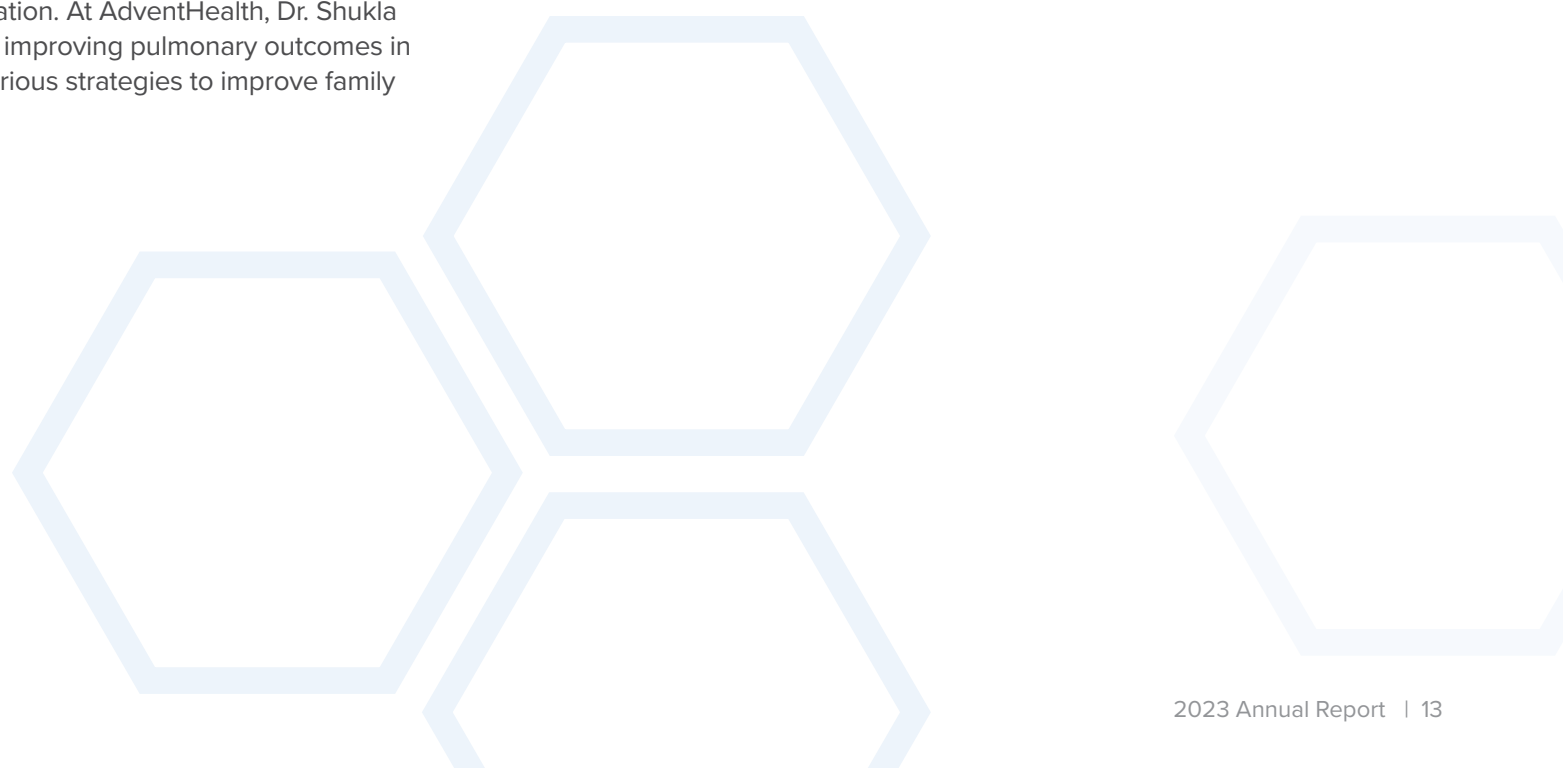
Dr. Keyes is the principal investigator of the Miach Orthopedic BEAR Implant Registry. “The BEAR Implant is a novel device aimed to restore and facilitate healing the torn ACL. We perform an ACL repair during the procedure, and hydrate the implant with the patient’s whole blood. The implant turns into a hydrogel or a blood clot that we place around the torn ACL. This procedure creates a microenvironment inside the knee that keeps the enzymes out, allowing the ACL to heal. This device is the first to come to market that reliably shows restoration of a torn ACL.” – Sean Keyes, DO. To learn more, visit BearImplant.com.



Samarth Shukla, MD

Samarth Shukla, MD, is a neonatologist with over eight years of clinical experience. He trained at Cohen Children's Medical Center of New York and Feinstein Institute for Medical Research. Dr. Shukla's research initially evaluated strategies to improve outcomes in infants exposed to maternal drug use. Dr. Shukla transformed this bench research into clinical care when he joined the University of Florida Health in Jacksonville, Florida. Working with the most fragile patient population, he strives to improve the quality of care delivered to newborns and enhance their outcomes. Dr. Shukla has engaged in clinical studies aimed at increasing parent participation in neonatal care and improving outcomes in babies with drug withdrawal. Another study looked at the impact of early administration of steroids to extremely low birth-weight infants on bronchopulmonary dysplasia as well as mortality. Dr. Shukla has led and participated in several projects to increase maternal breast-milk provision, reduce antibiotics use and reduce central line infections. He has co-chaired the Florida Perinatal Quality Collaborative's statewide initiative to improve newborn skin-to-skin care.

AdventHealth for Children treats many patients from diverse backgrounds. Thus, it is an ideal place for conducting clinical studies on patients who widely represent the national population. At AdventHealth, Dr. Shukla aims to conduct further research on improving pulmonary outcomes in premature infants and evaluating various strategies to improve family participation and clinical outcomes.



Cancer Institute

Overview

The AdventHealth Cancer Institute (AHCI), one of Florida's largest cancer care providers, is recognized worldwide for its comprehensive, state-of-the-art care and reputation as a cancer care destination. Patients can access the latest treatments and technology through a multidisciplinary care model with cancer subspecialists. Our vision is to be nationally recognized for providing our patients with access to value-based, personalized care through highly specialized, comprehensive and innovative, destination cancer programs.

AHCI research initiatives span clinical, translational, population health research, value-based care, precision medicine and pharmacogenomics. The Institute offers a wide range of clinical trials and leading-edge treatment options that are not widely available. In addition, our specialists study FDA-approved and investigational medications and devices to pursue novel, efficient, enhanced, cancer treatment options to improve care and quality of life. Patients also have access to spiritual and psychological support, educational programs and specially trained oncology nurse navigators who help guide them through personalized treatments.

Areas of Focus

- Brain and spine cancers
- Breast cancers
- Digestive tract cancers
- Gynecologic cancers
- Head, neck and skin cancers
- Leukemia, lymphoma, myeloma and blood cancers
- Lung and esophageal cancers
- Urologic cancers



Featured Researchers and Research



Arlene A. Gayle, MD

Arlene A. Gayle, MD, is a hematologist oncologist and cellular therapy physician at the AdventHealth Cancer Institute, with expertise in treating patients with malignant blood disorders and cellular therapy. She is a member of the Protocol Review Committee and the FLASCO Multiple Myeloma Consortium. Dr. Gayle is also an inspector for the Foundation for the Accreditation of Cellular Therapy. She is the principal investigator for several clinical trial research studies, including SYNTRIX for patients with r/r MDS. This study is a phase 1 oral dual CXCR1/2 inhibitor (SX-682) that delivers a “one-two punch” directly to (i) mutant MDS stem cells and (ii) the immunosuppressive marrow microenvironment. SX-682 is the only agent in development targeting both these components. The hypothesis is that in MDS, SX-682 will lead to the normalization of cytopenias but with only a mild side-effect profile compared to other therapies. If successful, SX-682 could transform the existing treatment landscape in MDS and change the disease trajectory, a truly unmet need in treating patients with MDS. If SX-682 is successful, this would be a breakthrough for MDS.



Wassim Mchayleh, MD

In Cancer Care and Research, Everything Matters.

Wassim Mchayleh, MD, is the clinical Director of the Breast Cancer Program, Hematology and Oncology at the AdventHealth Cancer Institute. When physician-scientist Dr. Wassim Mchayleh joined AdventHealth’s cancer research team, his first goal was to improve the breast cancer research portfolio by increasing the number of profile, practice-changing studies available to patients. Dr. Mchayleh and his team built strong partnerships and credibility with pharma by demonstrating their ability to enroll patients across diverse populations. This now very large and high-profile breast research portfolio offers patients some of the top national and international clinical trials and treatment options available in the country.

The patients’ faith and trust are everything.

Dr. Mchayleh is clear- patients are everything in clinical trials. “We don’t treat patients like numbers or screen patients randomly. From the beginning, we discuss clinical trials as treatment options so patients understand a trial’s value and why it was carefully selected not to compromise care. Our patients put their faith and trust in us and we ensure their knowledge and expectations for the clinical trial are clear and caring. We treat our patients like family,” says Dr. Mchayleh.

Patient apprehension in research.

Dr. Mchayleh’s team recognizes that some patients are apprehensive about participating in research, perhaps due to family history or pressures. “We have frequent conversations with our patients to ensure they understand we are not judgmental about their participation decisions. They are not guinea pigs, nor will their treatment ever be compromised.” Fostering diversity in research is historically challenging and a priority for

“The Cancer Institute believes clinical/translational research drives progress in the war against cancer. Creating a culture of research as the standard of care brings innovative new therapies to our patients and creates a commitment to improving state-of-the-art treatment options for all patients. Our most valuable resources are human resources. Recruiting top talent with subspecialty expertise remains a primary focus of the Cancer Institute. We rely on this talent to drive innovative clinical research addressing the most important questions facing cancer patients.”

— Mark A. Socinski, MD

clinical trials, but Dr. Mchayleh asks his patients from diverse populations to help him change that dynamic. “I tell my patients that starting with our relationship, together we can make the future better, regardless of whatever happened in the past,” he says. “At every visit, they feel the trust, they feel the caring, they feel the passion and positive energy. In cancer care and research, everything matters.”

Novel clinical trials close to home.

“Having practice-changing clinical trials available here, at AdventHealth, saves patients from leaving the state to seek novel treatments. These trials are at the same level and top executions as NCI cancer centers across the nation.” Dr. Mchayleh is grateful to the research institute for having the breadth of research resources, support and infrastructure to make the research happen. He says, “IT (research) takes a lot of work, commitment and a big whole team to conduct successful trials. Here, we have that structure, academic level and the resources to make a real difference to our patients.”

EMBER-4 STUDY (Eli Lilly) — AdventHealth is Number 1 Site in U.S.

Dr. Mchayleh is the AdventHealth site PI for a very large randomized trial involving about 6,000 high-risk patients with hormone-positive breast cancer. The trial is testing a new hormone blocker from the class of serds, the selective estrogen receptor degraders, which is a new class of endocrine therapy against the standard-of-care, which could be tamoxifen or aromatase inhibitors. The trial selects patients with a high risk of recurrence and randomizes them to receive either the new endocrine therapy or stay on the standard-of-care therapy.

Eli Lilly, the study sponsor, indicates that AdventHealth is **the number one study site in the U.S.** in enrollment and diversity enrollment, a priority in clinical trials. Our success in minority enrollment highlights our patients’ high level of trust and recognition of the important role they play in the trial. Our patient population includes Hispanics, African Americans, Pacific Islanders, and Caucasians. All ethnicities are represented, which makes our site extremely attractive for research.

The results of this study will be practice-changing, and Dr. Mchayleh and AdventHealth will be included in all relevant publications. The global, multicenter, single-arm study included patients treated at 32 sites in North America, South America, Asia and Europe. All patients involved in the study were at least 18 years old and had an ECOG performance score of 0 or 1. Based on the study findings, investigators noted that zanidatamab is a potential new therapy for HER2-amplified BTC. Further, another study of zanidatamab has been announced. The study is a randomized, multicenter, phase 3 study (NCT05152147) investigating the use of zanidatamab in combination with chemotherapy, with or without tislelizumab in the HER2-positive, unresectable, locally advanced or metastatic gastroesophageal adenocarcinoma population.



Mohamedtaki Tejani, MD

Mohamedtaki Tejani, MD | Based on the largest clinical trial of patients with HER2-amplified biliary tract cancer, a novel anti-HER bispecific antibody may be the next option.

Substantial clinical benefit has been exhibited in the phase 2b HERIZON-BTC-01 study (NCT04466891), which is investigating treatment with zanidatamab (ZW25) in patients with HER2-positive biliary tract cancer (BTC).¹ “This powerful study demonstrates that a HER2-targeted therapy is effective in this rare tumor type. “The benefit seen with zanidatamab in terms of tumor responses is clinically meaningful in this subset of patients with limited treatment options,” said Dr. Mohamedtaki Tejani, the AdventHealth hematologist/oncologist leading this study.

The key takeaway from this study is that it is critical for patients with biliary tract cancer to have molecular tumor profiling right at diagnosis. Patients cannot benefit from targeted therapy if their tumor-specific biomarker is not known.

Findings also showed that zanidatamab dosed at 20 mg/kg and administered intravenously every two weeks displayed a manageable safety profile when administered to patients with HER2-positive BTC in the study. The results were consistent with preliminary efficacy data from the phase 1 study of zanidatamab in patients with HER2-amplified BTC, in which the objective response rate (ORR) was 38%.

The global, multicenter, single-arm study included patients treated at 32 sites in North America, South America, Asia and Europe. All patients involved in the study were at least 18 years old and had an ECOG performance score of 0 or 1. Based on the study findings, investigators noted that zanidatamab is a potential new therapy for HER2-amplified BTC. Further, another study of zanidatamab has been announced. The study is a randomized, multicenter, phase 3 study (NCT05152147) investigating the use of zanidatamab in combination with chemotherapy, with or without tislelizumab in the HER2-positive, unresectable, locally advanced or metastatic gastroesophageal adenocarcinoma population.

“The results from this study are quite compelling. We do not have FDA approval to use zanidatamab for this patient population yet, but I believe it will be a treatment option soon. Our next hope is to make this treatment option available earlier during patients’ disease trajectory,” said Dr. Tejani.

“The AdventHealth Cancer Institute continues to participate in breakthrough clinical trials. Our performance and previous clinical trials in breast oncology have made our center attractive for the early development of novel, breast cancer treatments. We were chosen to participate in the first-in-human phase 1 trial of a first-in-class, complete estrogen receptor antagonist (CERAN). We were the first center in the world to put a patient in the OP-1250 Phase 1/2 clinical trial in 2022, and this drug has been further developed as an investigational agent with the proper name, palazestrant. In 2023, our center opened another phase 1 clinical trial using palazestrant in combination with other highly active agents, ribociclib and alpelisib, for treating patients with progressive breast cancer.

It is exciting to witness how palazestrant and other investigational agents have benefitted many of our patients and provided Central Floridians with treatment options that may become the standard treatments of the future. Our institute is committed to finding better treatment options to offer our patients in collaboration with our pharma research partners that help bring these breakthrough treatments to Central Florida. Always, our patients are the real heroes of this story, for selflessly volunteering for studies seeking treatments that will benefit them and potentially scores of patients after them.”

—Carlos Alemany, MD



Mark Socinski, MD

Mark Socinski, MD, Executive Director (Thoracic Cancer), Medical Oncologist | New Research Shows Having an Inflammatory Side Effect During Monoclonal Antibody Treatments for Lung Cancer is Linked to Improved Survival Rates | AdventHealthMD

For those with advanced, non-small cell lung cancer (NSCLC), having an inflammatory side effect, called an immune-related adverse event (irAE), from a monoclonal antibody treatment correlates with patients living longer, according to findings in a recent JAMA article co-written by Mark Socinski, M.D., thoracic medical oncologist and Executive Medical Director of the AdventHealth Cancer Institute.

The American Society of Clinical Oncology lists NSCLC as the most common type of lung cancer in the United States, accounting for 82% of all lung cancer diagnoses. For people with localized NSCLC, which means the cancer has not spread outside the lung, the overall 5-year survival rate is 63%. In advanced NSCLC, most patients' standard-of-care treatment is the combination of chemotherapy and immunotherapy.

This new research shows that patients who have irAEs after introducing an immunotherapy drug, in this case, a monoclonal antibody called atezolizumab, are directly linked to improved survival. This published paper looked at three large, global, phase 3 trials, and Dr. Socinski worked on all of them. Mark Socinski, MD, is a thoracic medical oncologist and Executive Medical Director of the AdventHealth Cancer Institute.

"We found if you had a mild to moderate irAE — suggesting the immune system is invigorated, reactivated, no longer sleeping and is fighting the cancer — it controlled the cancer better," said Socinski. "There was some spillover to normal tissue with some side effects, such as a rash, diarrhea and colitis, and that's actually a good thing."

Socinski explained that if a patient's irAEs have mild to moderate side effects, it's not necessarily bad. Physicians provide supportive care to manage and minimize these types of side effects, which can also indicate the immune system is engaged. "It follows the paradigm of no pain, no gain," said Socinski. "For example, having a rash might not be comfortable. But, having an irAE means your immune system is in overdrive and working. If it's working on your skin, it's also working on the cancer and controlling it."

One of the hallmarks of cancer is the evasion of the immune system. Several checkpoints can turn on or off the immune system. In the last decade, the main checkpoint important to controlling cancer growth has been the PD-1/L1 pathway. When the immune system locates certain tumors and attempts to attack them, the tumor expresses PD-L1 and puts the immune system's T-cells, a type of white blood cell, into a state of dormancy.

Blocking the PD-1/L1 pathway with antibodies unlocks the immune system's dormancy and wakes the T-cells to fight cancer. Several monoclonal antibodies can block the pathways, including atezolizumab, which is studied here. When the immune system is awakened, it sometimes attacks normal tissue, called immune-related adverse events (irAEs). Upon evaluation, this study concludes that mild to moderate irAE from monoclonal antibody treatments correlates with improved survival rates.

Currently, Socinski is studying this type of immunotherapy treatment with mild to moderate irAEs in a large database to determine if it can be extended beyond lung cancer



**Imran Mohiuddin,
MD, PhD**

Imran Mohiuddin, MD, PhD, is a radiation oncologist specializing in treating tumors and cancers of the central nervous system. Dr. Mohiuddin’s research aims to advance the efficacy and safety of radiotherapy in managing brain and spine pathologies. At AdventHealth Orlando, he leads the CNS radiotherapy section, which comprises conventional radiotherapy, radiosurgery and brachytherapy service lines.

Dr. Mohiuddin is the principal investigator on several clinical trials investigating how these modalities can improve outcomes in aggressive and common brain cancers. He is also actively recruiting participants for several other cutting-edge clinical trials with incredible potential to transform the treatment of CNS malignancies.

Dr. Mohiuddin traces his radiotherapy interests to his neurology focus while engaged in the MD-PhD Medical Scientist Training program in medical school. Only a few top candidates are selected to participate in the MD-PhD each year at most LCME-accredited medical schools in the United States. In addition to earning the MD degree, candidates also extend their training for an extra three to five years of research, leading to the PhD portion of their degree. Dr. Mohiuddin’s studies of how the immune system works in the brain are very important in oncology. “One of the biggest breakthroughs right now is using immune modulatory therapy or checkpoint therapy to help people live longer by recruiting the immune system to help fight cancer,” he says. “So, as an AdventHealth specialist focusing on the brain, I can read the oncology program from a radiation perspective. My immunology background comes in handy to understand the big picture. It dovetails with our research in brain tumors, which are among the most difficult to treat and require a multidisciplinary team.” Dr. Mohiuddin also helped build and head the Gamma Tile program, a type of surgically targeted radiation performed in conjunction with neurosurgery. “This program allows radiation to be inserted into the brain during surgery, thus sparing the patient additional, post-surgery radiation treatments typically needed in more conventional approaches. AdventHealth is one of the top-enrolling patients for the Gamma Tile study, and we look forward to accelerating the program as we advance.”



Rushang Patel, MD

Rushang Patel, MD, is board-certified in internal medicine and board-eligible in medical oncology and hematology. Dr. Patel brings a wealth of clinical knowledge and in-depth research experience to both patient and practice, having worked on projects for the United Nations International Children’s Emergency Fund (UNICEF), Alembic Pharmaceuticals and Sanofi-Aventis, as well as having conducted studies focused

on the mechanisms of cancer formation due to toxic chemicals and identifying new targets for designing cancer drugs.

Dr. Patel serves as the PI for the ANTLER clinical study. Recent advances in genome editing are ushering in a new era in lymphoma therapy at AdventHealth, highlighted by the ANTLER trial, a study of allogeneic CAR-T cell therapy for high-grade B-cell lymphomas. This innovative approach leverages CRISPR-Cas9 and other gene-editing technologies to engineer T-cells from healthy donors, equipping them with chimeric antigen receptors (CARs) that target lymphoma cells. This allogeneic strategy circumvents the time-consuming logistical processes associated with autologous CAR-T therapies, offering an “off-the-shelf” treatment option, potentially broadening the availability and reducing the time to treatment with CAR-T therapies. This trial and related clinical trials put AdventHealth at the forefront of integrating cutting-edge genomic engineering techniques with outstanding patient care to create breakthroughs in treating hematological malignancies.



**Vipul Patel, MD,
FACS**

Vipul Patel, MD, FACS, is the director of the Global Robotics Institute at AdventHealth Celebration. On March 28, 2023, Cision published a press release featuring Dr. Patel and the partnership between CytoVeris Inc., a medical device company, and AdventHealth on a clinical study to improve prostate cancer outcomes. Dr. Patel will collaborate with CytoVeris to adapt and develop its imaging platform for assessing prostate cancer margins.

This new, multi-year, clinical research study will explore how CytoVeris’ AI-powered imaging device, MarginASSURE, can help surgeons detect cancer in near real-time during robotically assisted radical prostatectomy (RARP) surgery. The study will only involve American-based surgeries at the AdventHealth Celebration facility and will be led by Vipul Patel, MD, and his team. Dr. Patel is world-renowned for his contribution to

the field of robotic-assisted surgery and is one of the most experienced robotic surgeons in the world, having personally performed over 16,000 robotic prostatectomies. “In the operating room, every move is critical. Robotic devices are changing how we (surgeons) operate by providing more precision, resulting in better patient outcomes,” Patel said. “This study will attempt to demonstrate the capability of MarginASSURE and its ability to detect cancer in near-real time in a label-free manner through the development of advanced tissue characterization technologies that can identify cancer tissue, assess margins and identify critical tissue structures.” The CytoVeris system is based on proprietary Multi-Spectral Tissue Auto Florescence (AF) imaging technology that analyzes tissue’s “optical fingerprint” due to its intrinsic biomolecular and morphological characteristics without using dyes or imaging agents.

“We are excited to extend our technology to help surgeons and their patients undergoing prostatectomy, in collaboration with Dr. Patel, one of the world’s leading surgeons, and the outstanding team at AdventHealth,” said Patrick Curry, COO of CytoVeris. “Having demonstrated the technology in breast and bladder cancer surgery, this is the next impactful indication in our platform.”

The American Cancer Society reports that prostate cancer is second only to skin cancer among the most common cancers in American men. This year’s estimates suggest that the United States will see 288,300 new cases of prostate cancer, resulting in 34,700 deaths. Among men diagnosed with prostate cancer this year, approximately 90,000 will undergo RARP surgery. Post-surgical, positive margin rates are generally only in the 20% range, which can lead to complications and poorer patient outcomes. The success of the MarginASSURE study can significantly impact the positive outcomes of literally thousands of patients in the years ahead.

New Investigators



Jawad Francis, MD

Jawad Francis, MD, is a highly experienced medical oncologist, researcher, and medical director of the AdventHealth Lake Mary Oncology program. He previously held professional, clinical and research leadership positions at Mercy Health in Ohio. During his post-doctorate research fellowship in cancer

experimental therapeutics at Loma Linda University in Loma Linda, California, and clinical oncology fellowship at Roswell Park Cancer Center in Buffalo, New York, he recognized that the most fundamental research must focus on innovating and discovering new pathways to fight cancer. Dr. Francis believes a multidisciplinary approach and clinical research are the best ways to improve patient treatment outcomes. His research has primarily focused on phase II and phase III trials in solid tumors, including NSCLC, head and neck SCC, breast, GI, GU and melanoma. Dr. Francis was the principal investigator for a phase I study in breast cancer with Spectrum Pharmaceuticals, which enrolled the largest number of participants in the country. Dr. Francis is very excited to contribute and advance cancer care in Central Florida.



Philip Pancari, MD

Philip Pancari, MD, is a hematologist focusing on hematologic malignancies, specifically cellular therapy approaches, including allogeneic stem cell transplantation and chimeric antigen receptor T-cells (CAR-T). He trained at Fox Chase Cancer Center/ Temple University in Philadelphia, Pennsylvania, and remained an academic faculty member for several years post-graduation. Dr. Pancari served on several NCCN guidelines committees and was robustly engaged in research, including as principal investigator on several prospective interventional studies. He was also a participating member of a research review committee that critically reviewed proposed clinical trial protocols for further discussion amongst a team of experienced researchers. Dr. Pancari came to AdventHealth to join a growing cellular therapy and stem cell transplant program, aiming to have a robust practice encompassing all types of hematologic malignancies within a highly supportive environment – with the concurrent ability to participate in exciting clinical research. He is particularly interested in investigating aggressive lymphoid malignancies and immunotherapeutic methods and treatments, including novel approaches to CAR-T, bispecific antibody T-cell engagers and targeted therapies. He looks forward to serving as both investigator and clinician at AdventHealth, benefiting his patients and advancing knowledge in the treatment of blood cancers.

Clinical Research Unit (CRU)

Advanced cancer patients in central Florida can access first-in-human treatments through phase I clinical trials.



Karolina Kilowski, DO

In 2023, the AdventHealth Celebration Clinical Research Unit (CRU) continued to grow rapidly. **Karolina Kilowski, DO**, from the gynecologic oncology section, joined **Guru Sonpavde, MD**, and **Lindley Mosqueda, APRN**, as a phase I CRU investigator in 2023.

A growing and robust pipeline of phase I clinical trials is offered to patients with advanced cancers who may have exhausted other treatment options. Immunotherapy, targeted therapy and antibody-drug conjugates (ADCs) are all available. Most of these trials bring patients in central Florida and beyond access to first-in-human treatments.



Guru Sonpavde, MD
Medical Director
of Genitourinary
(GU) Oncology and
Executive Medical
Director, AdventHealth
Cancer Institute CRU

The CRU is supported by an onsite infusion center, research pharmacy, clinical laboratory, and tissue processing and storage facility to assist with banking samples for pharmacokinetic and pharmacodynamic studies for patients enrolled in trials.

In 2023, the CRU enrolled the first global patient on a clinical trial evaluating a next-generation PARP inhibitor — a trial for which Dr. Sonpavde has also been designated as the global principal.



Lindley Mosqueda,
APRN

The following presentations of phase I trials at major global oncology conferences in 2023 featured Dr. Sonpavde as co-author based on trial participation and accrual at the CRU.

ASCO June 2023

Jeffrey Melson Clarke, Tom Stinchcombe, Lin Gu, Hirva Mamdani, Scott Joseph Antonia, George R. Simon, Guru P. Sonpavde, Neal E. Ready, Jeffrey Crawford, Michael Campa, Elizabeth Gottlin, Ryan Bushey, James Emmett Herndon, Edward Patz. Results from a first-in-human phase 1B study of a complement factor H inhibitor (GT103) in patients with non-small cell lung cancer (NSCLC). Abstract 9128 (poster presentation).

ESMO October 2023

C.A. Perez, J.T. Henry, N. Lakhani, J.A. Call, E.P. Hamilton, G. Colon-Otero, J.R. Diamond, B. O’Neil, A. Kalyan, Guru P. Sonpavde, I. Moreno, A.A. Awan, E. Fontana, P. Xu, F. Zhang, N. Nazarenko, A. Patnaik. First-in-human study of SGN-B7H4V, a B7-H4-directed vedotin ADC, in patients with advanced solid tumors: Preliminary results of a phase I study (SGNB7H4V-001). 660MO (mini-oral presentation).

A 62-year-old man with colon cancer was enrolled in a phase 1 clinical trial of a novel TGF-beta inhibitor combined with a PD1 inhibitor and has now enjoyed a deep response to this therapy for >2 years.

While clinical trials offer enormous benefits to society by bringing new treatments to patients, we are highlighting a 62-year-old man with colon cancer to illustrate the benefit to an individual patient. Mr. Patel was diagnosed with stage 3 colon cancer, for which he underwent surgery. Unfortunately, his cancer returned after approximately three years with lung metastases. Then, he suffered rapid progression within a year after two different types and lines of chemotherapy and targeted treatment. Mr. Patel was referred to the CRU for a phase I clinical trial. He was enrolled in a phase 1 first-in-human clinical trial of a novel TGF-beta inhibitor combined with a PD1 inhibitor. He has now enjoyed a deep response to this therapy for more than two years.



From left to right: Guru Sonpavde, MD and Mr. Patel

Digestive Health

Overview

The AdventHealth Digestive Health Institute (DHI) is a national destination and leader for exceptional digestive health and specialty surgical care. The DHI is at the forefront of advanced care for complex diseases, houses the largest interventional endoscopy center in the United States and holds multiple accreditations for subspecialty programs. The Institute seeks to advance its reputation nationally as a top performer in quality and patient experience while building and expanding comprehensive research and educational programs.

The National Accreditation Program for Rectal Cancer (NAPRC) recognizes the DHI as a Center of Excellence. U.S. News & World Report also recognizes AdventHealth Orlando as one of America's best hospitals for gastroenterology, gastrointestinal surgery and colon cancer surgery. Our research directly impacts the improvement and efficiency of future, surgical care options.

Areas of Focus

- Bariatrics
- Colorectal surgery
- Ear, nose and throat
- Fatty liver disease
- Gastroenterology
- General surgery
- Inflammatory bowel disease (IBD)
- Urology



“The AdventHealth Digestive Health Institute cultivates an environment ripe for breakthroughs by fostering innovative project designs through partnerships with world-leading experts within our institute – leveraging their vast relationships with industry and academia. AdventHealth’s expansive network supports this innovation ecosystem, which includes conducting novel pedagogical research at the Nicholson Center and emphasizing simulation-based training and research. Such collaboration and resource sharing empowers our team to pioneer advancements in digestive health care and education, driving transformative outcomes for the communities we serve.

Investing in talent and research, the DHI capitalizes on the synergy of collaboration among globally renowned specialists, cutting-edge technological resources and a comprehensive support system provided by the AdventHealth network. By nurturing these connections and fostering a culture of continuous learning and innovation, we are dedicated to developing new therapeutic strategies and improving clinical practices. This dedication enhances the quality of patient care and solidifies our commitment to making meaningful breakthroughs that positively impact the health and well-being of our communities.”

— Mark Soliman, MD

Featured Research and Researchers

Center for Interventional Endoscopy (CIE)



Muhammad Khalid Hasan, MD

Muhammad Khalid Hasan, MD, Medical Director of the Center for Interventional Endoscopy, is a clinical gastroenterologist specializing in advanced endoscopic procedures, including endoscopic retrograde cholangiopancreatography (ERCP), endoscopic ultrasound (EUS), advanced polyp resection techniques (endoscopic mucosal resection, EMR/endoscopic submucosal dissection, ESD) and more. Dr. Hasan

completed his Internal Medicine residency and Gastroenterology fellowship training at the University of Oklahoma and advanced endoscopy trainings at Mayo Clinic in Jacksonville, FL and the Medical University of South Carolina, Charleston. He has been a staff physician at AdventHealth, Orlando since 2010 and helped establish the Center for Interventional Endoscopy (CIE) at Florida Hospital in 2013, which is now a premier endoscopy center serving the needs of over 6000 patients annually. His interests include clinical research, trainee and professional education and innovation in endoscopic techniques. His research focuses on clinical outcomes associated with endoscopic procedures and clinical disease states. He has initiated many research projects independently and has participated in multiple multi-center projects as a co-investigator, resulting in over 70 original publications, including premier journals such as Gut, Gastroenterology, Endoscopy and Gastrointestinal Endoscopy. In 2013, Dr. Hasan established the Advanced Endoscopy Fellowship (AEF) at CIE and serves as the program director. During this time, he trained 13 advanced endoscopy fellows from the USA and abroad while mentoring medical students and residents. He also has visited several underserved areas outside of the USA to help with endoscopic training while also engaging in professional societies and committees, including the American College of Gastroenterology, Royal College of Physicians and Surgeons Glasgow and the Annual Scientific Program Committee for American Society for Gastrointestinal Endoscopy and Digestive Diseases Week (DDW).



Mustafa Arain MD

Mustafa Arain, MD, is board-certified in gastroenterology and internal medicine. Dr. Arain received his medical degree from Guy's, King's St. Thomas' School of Medicine. He went on to complete a residency in medicine at the University of Minnesota, followed by a gastroenterology fellowship and advanced endoscopy fellowship in gastroenterology, both also at the University of Minnesota. Dr. Arain's

clinical and research interests include pancreatico-biliary diseases and advanced endoscopic procedures emphasizing endoscopic ultrasound, endoscopic retrograde cholangiopancreatography, small bowel enterostomy and large polyp resection. Dr. Arain sees patients in the CIE clinic setting to provide comprehensive medical care for pancreatico-biliary diseases. He serves as the Medical Director of the Pancreas Center at CIE and AdventHealth, Orlando.

In 2023, Dr. Arain served as the principal investigator on a Panc Encephalopathy study testing the safety and efficacy of understanding how acute pancreatitis affects people's thinking and mental functioning.

Panc Encephalopathy - A Prospective Cohort Study Evaluating for Acute Encephalopathy in Patients with Acute Pancreatitis



Dennis Yang, MD

Dennis Yang, MD, is the Director of Third Space Endoscopy at the Center for Interventional Endoscopy at AdventHealth Orlando and Professor of Medicine at Loma Linda University Health. Dr. Yang received his medical degree at the Ponce School of Medicine and completed his internal medicine training at Mayo Clinic, Rochester MN. He subsequently completed his Gastroenterology Fellowship at the University of Florida

followed by additional training in Advanced Endoscopy at Mount Sinai, New York. Dr Yang's main clinical and research interest is focused on minimally invasive interventional endoscopic procedures for treating motility disorders (POEM, G-POEM) to advanced resection techniques (EMR, ESD) for treating early gastrointestinal cancers.

In 2023, Dr. Yang served as the principal investigator on the SHORT ESD-RCT study. This study aims to compare procedural time, safety and efficacy between two methods of endoscopic resection of large colorectal polyps: hybrid Endoscopic submucosal dissection (ESD) and non-hybrid ESD.

SHORT ESD-RCT-Hybrid versus Non-Hybrid Endoscopic Submucosal Dissection for Colorectal Polyps: A Randomized Trial



Kambiz Kadkhodayan, MD

Kambiz Kadkhodayan, MD, is the Advanced Endoscopy Fellowship Program Director at the Center for Interventional Endoscopy. He is board-certified in gastroenterology and internal medicine. Dr. Kadkhodayan completed his internal medicine residency and a gastroenterology fellowship at the Albert Einstein College of Medicine, Maimonides Medical Center in New York City. He subsequently completed an advanced endoscopy fellowship at the Center for Interventional Endoscopy at AdventHealth Orlando. Dr. Kadkhodayan received additional training in advanced resection at the National Cancer Center and Tokyo Metropolitan Geriatric Hospital in Japan. Before joining AdventHealth, he served as director of endoscopy and taught faculty for the gastroenterology fellowship at Creighton University in Arizona. His clinical and research interests include comprehensive and interdisciplinary management of patients with obesity, complex pancreaticobiliary disease and gastrointestinal cancer. He is proficient in endoscopic bariatric procedures, including endoscopic balloon therapy (EBT), endoscopic sleeve gastropasty (ESG), endoscopic revision of gastric bypass (TORe, SIS, etc.), endoscopic management of post-operative complications (EUS-guided drainage, dilatation of strictures, endoscopic closure of fistulas, etc.), endoscopic treatment of reflux (TIF, ARMS, etc.), interventional EUS (including EUS-guided pancreatic tumor ablation), ERCP, endoscopic resection of large polyps and early cancers (ESD, EFTR). Dr. Kadkhodayan is fluent in multiple languages, including Farsi, Hindi, Gujarati, Marathi, Russian and Urdu.

In 2023, Dr. Kadkhodayan served as the principal investigator on RESTORE. This study compares surgical vs. endoscopic gastrojejunostomy outcomes for patients diagnosed with malignant gastric outlet obstruction by evaluating procedure-related complications. For this trial, qualified patients are randomized into the surgical or endoscopic arm and followed pre- and post-procedure. Relevant data is collected electronically for analysis.

RESTORE - A Randomized Trial Comparing Endoscopic UltraSound-guided GasTrojejunostomy (EUS-GJ) and Surgical GastrojejunOstomy (S-GJ) for the management of malignant gastRic outlEt obstruction. (**RESTORE**-TRIAL)

Surgical Health Outcomes Consortium (SHOC)



Mark K. Soliman, MD

Mark K. Soliman, MD, is the Chief of Colorectal Surgery, the Program Medical Director of the AdventHealth Digestive Health and Surgery Institute and the Colorectal Surgery Department Chair. Dr. Soliman is board-certified in colorectal and general surgery and an internationally recognized expert in advanced, minimally invasive and complex, robotic colorectal surgery for treating benign and malignant diseases. Dr. Soliman is one of the most recognized colorectal surgeons nationwide in robotic, colorectal surgical operations and has written nearly 50 book chapters, scientific abstracts and manuscripts on this and its related fields. His research focuses on pedagogical methodologies to teach surgeons how to navigate learning curves in adopting robotic surgery and outcomes-based studies in novel, robotic, colorectal surgical operations.

Dr. Soliman was awarded a grant from the American Society of Colon and Rectal Surgeons (ASCRS) Research Foundation to examine “Automated Performance Metrics to Assess Surgeon Performance in Colorectal Surgery.” In this study, Dr. Soliman and his team collect objective kinematic data generated by operating on robotic surgical consoles to assess key differences between expert and novice surgeons. This study is the first in a larger series to inform operative instructional design to refine surgeon training.

In 2023, Dr. Soliman served as the principal investigator on the dV Logger study, an introductory pilot study in which the aim will be to identify specific operative segments of a colon resection (i.e. right hemicolectomy), where collected data points are analyzed for patterns common to experienced robotic surgeons compared to novice robotic surgeons.

dV Logger - Analysis of objective performance metrics during robotic-assisted colorectal surgery



Matthew Ross Albert, MD

Matthew Ross Albert, MD, is a member of the elite colon and rectal surgery team at AdventHealth Medical Group, which he joined in July 2004. A fellow of both the American Society of Colon & Rectal Surgeons and the American College of Surgeons, Dr. Ross specializes in laparoscopic and robotic surgery of the colon and rectum, screening and therapeutic colonoscopy, surgery for colon and rectal cancers, inflammatory

bowel disease, pelvic floor disorders, the treatment of anorectal disease, and stomas and hernia issues. Dr. Albert's wide range of colon and rectal surgical services includes the revolutionary technique known as TAMIS (transanal minimally invasive surgery), which he helped invent. He also is credited with spearheading the development of an ACGME-accredited subspecialty training program for colon and rectal surgeons. Dr. Albert specializes in sphincter-preserving surgeries for cancers of the lowest part of the rectum, avoiding the need for permanent colostomy. He has the most experience with TAMIS procedures in the world. He has performed more than 3,000 minimally invasive colorectal operations.

In 2023, Dr. Albert served as the principal investigator on the ASP5354_CL-031 study. This study aims to confirm whether the study medicine ASP5354 is safe. This medicine helps surgeons to visually identify the ureters during surgery, greatly reducing the risk of unintentional injury during minimally invasive and open abdominal/pelvic surgeries.

ASP5354_CL-031 - A Phase 3, Multicenter, Prospective, Randomized, Open-label Study for Intraoperative Ureter(s) Visualization When Using ASP5354 with Near-infrared Fluorescence (NIR-F) Imaging in Participants Undergoing Minimally Invasive and Open Abdominopelvic Surgeries

Urology



Michael McDonald, MD

Michael McDonald, MD, is a board-certified urologist and the Medical Director of the Minimally Invasive Endo-Urologic program at Celebration. Dr. McDonald has advanced training in state-of-the-art, da Vinci robotic surgery and other minimally invasive techniques. He specializes in treating patients with kidney disorders, including kidney stones, obstructions and cancers, and has performed hundreds of laparoscopic and robotic surgeries to address these

conditions. Other specialties include treatments for enlarged prostate (BPH), urinary incontinence, erectile dysfunction, prostate cancer and bladder cancer. Dr. McDonald has nearly 20 years of experience in his field and is known as one of Central Florida's finest urologists. He earned his medical degree and completed his residency training at the University of Ottawa in Canada, followed by an advanced fellowship in endourology at the University of California in San Francisco. In 2023, Dr. McDonald served as the principal investigator on the HOPE4KIDNEY study. HistoSonics' image-guided sonic-beam therapy system uses advanced imaging and proprietary sensing technology to deliver non-invasive, personalized treatments with precision and control. The science of histotripsy uses focused sound energy to produce controlled acoustic cavitation that mechanically destroys and liquifies targeted tissue at sub-cellular levels.

HOPE4KIDNEY - The HistoSonics Edison™ System for the treatment of primary solid renal tumors using histotripsy

Genomics and Personalized Health

Overview

December 8, 2023, will likely be considered an inflection point for genomics and precision medicine. The FDA approved two new gene therapies for sickle cell disease that day. One was the first medicine ever approved to utilize the ground-breaking CRISPR method for gene editing. These approvals represent the next gene-therapy development breakthrough and herald many additional therapies in the future. With the unprecedented advances in scientific knowledge and the ongoing development of novel therapies, the Genomics and Personalized Health program (GPH) is now bringing potential cures to previously incurable diseases through research-based clinical trials. Urea cycle disorders, lysosomal storage disorders, neurodegenerative diseases and inborn errors of metabolism are a few of these diverse therapeutic areas. As we look forward, the Genomics and Personalized Health program seeks to build on this foundation to become a nationally recognized leader in deploying precision diagnostics and therapeutics.

Since 2020, AdventHealth has partnered with Rady Children's Institute for Genomic Medicine in San Diego to offer rapid whole genome sequencing (rWGS) to identify or rule out genetic disease in critically ill infants. This diagnostic technology empowers clinicians to intervene quickly and precisely to make disease-specific treatment decisions to improve outcomes in extremely ill children. As a part of this work, AdventHealth Orlando secured a \$725,000 grant in the Florida state budget for 2022-2023. This grant enabled AdventHealth to expand its advanced genomics program for critically ill newborns. An important component of this work was collaborating with the Tufts Center for Evaluation of Value + Risk in Health to complete an economic analysis to qualify the clinical and financial outcomes associated with rWGS. Tufts compared the cost-effectiveness of rWGS and standard-of-care (SOC) testing for diagnosing critically ill infants with suspected genetic conditions. The analysis determined that first-line rWGS was the most cost-effective strategy based on various assumptions. In addition, the report noted that the cost-effectiveness and potential savings associated with rWGS may continue to improve as the cost of rWGS decreases. The analysis of rWGS cost-effectiveness had a palpable impact on the adoption of



this ground-breaking technology. In mid-2023, the governor of Florida signed the state budget that included the creation and funding of the Andrew John Anderson Rapid Whole Genome Sequencing program.

Effective January 1, 2024, the Florida Agency for Health Care Administration (AHCA) will reimburse for rWGS provided to Medicaid recipients who are 20 years of age or younger, have a complex or acute illness of unknown etiology, and are receiving inpatient treatment in a hospital ICU of high-acuity pediatric care unit. Our work and the cost-effectiveness report developed by Tufts directly contributed to the approval of this program. For breakthroughs to be adopted clinically, there must ultimately be a pathway to reimbursement. Reimbursement is predicated on the generation of clinical evidence related to benefit. GPH investigates the clinical utility of genomic innovations and generating real-world evidence related to cost-effectiveness and financial outcomes required by legislators and policymakers to fund life-saving new programs.

Population genomics is another important area of our work. We specifically launched a population-level program to identify those at high risk of developing hereditary cancers and intervene in an evidence-based manner. In 2023, we deployed this clinical program in several primary care settings. Once individuals are identified as high-risk, they are navigated to evidence-based surveillance care pathways that can potentially prevent the disease or detect the cancer at an early stage. High-risk individuals are also offered genetic counseling and testing. Our nurse navigators use electronic tools to perform a risk-assessment survey and collect family history to provide monitoring and guidance based on risk-appropriate management guidelines. We will use the lessons learned from the deployment at these practices to inform our subsequent roll-outs to other venues, such as mammography centers and GI clinics. Through this program and its associated services, AdventHealth is leading the way in the early detection and prevention of hereditary cancers.

Priorities and Goals

- Population genomics
- Pediatrics
- Rare disease
- Novel therapeutics
- Women's health
- Genomics and genetics workforce development
- Policy impacts

“Genomics and personalized health create an environment where breakthroughs occur by partnering with national and international leaders in genomic sequencing technology and clinical consortia, which are developing next-generation approaches to prospectively identify genetic diseases as soon as possible after birth and facilitate immediate precision treatment.

By supporting our medical director and research staff, we bring breakthrough, clinical-trial treatment options to families and children with previously devastating diseases via access to world-class expertise and truly transformational therapeutics.”

— Wesley Walker, MD, Director, Genomics & Personalized Health,
Central Florida Division

Featured Researchers and Research



Rebecca Zuvich
Essner, PhD

Rebecca Zuvich Essner, PhD, is a research scientist and the principal investigator of the WholeMe research study. Advances in risk stratification and genomics now enable us to tailor screening recommendations for individual patients in important ways. With the implementation of the Epic electronic health record, AdventHealth can now use these new tools to create a clinical program that proactively identifies those at high risk and navigates those individuals into evidence-based clinical pathways.

A fundamental tenet of whole-person care is engaging with those we serve to promote wellness and preventative care actively. Cancer screening, early detection and prevention are cornerstones of this work. The program uses a screening appointment (such as a primary care wellness visit, a screening/diagnostic colonoscopy, or a woman's annual screening mammography appointment) as the point of entry for introducing an electronic risk-assessment survey. The survey results enable those at high risk to be identified and have additional clinical steps introduced under the guidance of a nurse navigator. Based on evidence-based guidelines, these next steps include additional imaging, genetic counseling, and genetic testing.

Care pathways and algorithms have been developed for each clinical program based on industry-leading organizations' widely accepted evidence-based practice guidelines to personalize care based on cancer risk profiles. The workflows were designed with the clinical teams to ensure clinical pathways are not disrupted and are complemented with a care navigation team to guide patients through these high-risk pathways and ensure no gaps in care.

Like WholeMe, downstream care will be measured and tracked to quantify these programs' comprehensive costs and benefits. By leveraging IT applications and tools, these programs aim to design and refine workflows that could potentially be applied to venues and facilities across AdventHealth's entire national footprint.

By performing personalized cancer risk assessment and prevention clinical programs, AdventHealth uses advances in genomics and risk stratification to tailor cancer screening recommendations for individual patients. Lastly, these genomic initiatives also involve navigating the policy changes and reimbursement opportunities as genomics is further integrated into clinical care across AdventHealth.



Majed Dasouki, MD

Majed Dasouki, MD, is a board-certified clinical and biochemical geneticist and cytogeneticist who serves as Medical Director for AdventHealth's Genetics and Genomics department. Dr. Dasouki studies biochemical genetics, clinical cytogenetics, newborn screening, tandem mass spectrometry, novel therapies, clinical trials for metabolic genetic disorders and gene mapping of single-gene disorders.

In 2023, Dr. Dasouki collaborated with the n-Lorem Foundation to provide investigator-sponsored novel and personalized gene therapies for rare genetic disorders. The development of these novel therapeutics occurs on an individualized basis and includes antisense oligonucleotides (ASOs). Currently, they are progressing in an open-label, single-center, single-patient research study for children of an experimental antisense oligonucleotide treatment for developmental and epileptic encephalopathy 69 (DEE69) caused by a heterozygous CACNA1E gene mutation — which is a very rare genetic disorder. This interventional study will evaluate the safety, tolerability and effect of mutation-specific antisense oligonucleotide treatment in a single patient with CACNA1E gene activating mutation-related developmental encephalopathy or DEE69. Participants will have access to treatment for life as long as Dr. Dasouki deems the treatment beneficial for the participant. Currently, there are three active participants enrolled.

Dr. Dasouki is also currently working on a study to evaluate the effect of venglustat tablets on neuropathic and abdominal pain in male and female participants ≥ 16 years of age with Fabry disease (PERIDOT). This investigation is a 12-month, parallel treatment, phase 3, double-blind, randomized, placebo-controlled study to evaluate the effect of venglustat on neuropathic and abdominal pain symptoms of Fabry disease in participants ≥ 16 years of age with Fabry disease who are treatment-naïve or untreated for at least six months.

Lastly, Dr. Dasouki is involved in a dose-finding study to evaluate mRNA-3210 in participants with phenylketonuria (PKU). The main goal of this study is to assess the safety and tolerability of multiple doses of mRNA-3210 in participants with phenylketonuria. There are no active participants in this study.

A Story That Changed a Patient's Life

Through the work in WholeMe and these clinical programs, we are equipping our patients with more complete, personalized information about themselves and their family's health.

In WholeMe, we were able to help a mother who sought out help with her young daughter's Type 1 diabetes diagnosis and care. She decided to join WholeMe to learn more about her genetic makeup. Through the results from the American College of Medical Genetics and Genomics (ACMG) gene panel known to have actionable genomic results, she discovered a positive variant, which carries a high propensity for an aggressive form of thyroid cancer. With this information, she is working with AdventHealth health care providers to actively monitor her thyroid for any early warning signs of this cancer.

"As soon as something starts developing, they'll know to remove my thyroid while it's still very early and before it ever gets to stage 4," Samantha Arceneaux says. "It was eye-opening to know I have this cancer risk, because there was no family history."

Similarly, we reached a female patient with the hereditary cancer risk-assessment tool through the primary care setting. The results revealed a high-risk indication, but genetic results came back negative. As a family caregiver, her health has often taken a backseat. Supplied with some health information and resources for high-risk patients, she will now have the tools to take a more preventive approach to her health. Additionally, new genomic variants are being discovered every day. Now, with her initial test results, she and her clinical provider will get updates if any of her variants come back positive for breast cancer, which could dramatically change her care plans.

Whether through early cancer detection or patient peace of mind, this program can provide personalized and proactive health to our patients. Identifying and intervening with high-risk patients is essential to diagnose cancer early and often and potentially prevent cancer in the future. Genomics and risk assessment hold the key to this future.



Samantha Arceneaux and her daughter

Heart, Lung and Vascular Institute

Overview

The Heart, Lung and Vascular Institute (HLVI) conducts research to help patients access innovative and promising new treatments and technologies before they become the standard of care. The Institute offers leading-edge, patient-focused research while leveraging extensive clinical and scientific expertise. The HLVI vision is to transform health care through groundbreaking, globally recognized, whole-person research.

The institute treats nearly 80,000 patients yearly, from routine arrhythmia treatments and preventive cardiology to minimally invasive vascular surgery and heart and lung transplants. The institute also pairs hundreds of patients, some facing life-threatening diagnoses, with leading-edge research studies and clinical trials. In addition, HLVI creates a seamless research experience through its broad network of heart specialists and hospitals to simplify the “bench-to-bedside” process and ensure patients receive the most effective care available.

Areas of Focus

- Cardiovascular surgery
- Coronary artery disease
- Heart failure
- Heart rhythm disorder
- Heart-valve disease treatment
- Interventional cardiology
- Pulmonary hypertension

“We are intentional in our focus on futuristic drug and device discovery alliances through clinical and translational research. Through cross pollination across the spectrum of cardiology, vascular, cardiac and thoracic surgery, structural heart and electro-physiology we have created a united but multidisciplinary panel that brings on these breakthroughs.

At HLVI we promote investigator initiated studies, and support clinical trials that are enrolling patients both nationally and internationally. These studies have opened doors to communities including those who do not speak English as a first language. Bringing these promising and many times breakthrough scientific discoveries has given our fellow citizens these options right at home.”

— Rohit Bhatheja, MD



Featured Researchers and Research



Kevin Accola, MD

Kevin D. Accola, MD, is a board-certified thoracic surgeon and served as the principal investigator for the ON-X study. The study opened in 2006 and closed in 2023 at AdventHealth. ON-X was a randomized study comparing the On-X valve on low-dose anticoagulation (target INR 2.0-2.5 test group) to concomitant control groups of On-X valves receiving standard coumadin/ aspirin therapy for mechanical valve prosthesis (INR 2.5-3.5). In 44 sites in North America, 408 subjects were randomized and followed for up to eight years. Twelve subjects were consented at AdventHealth. The primary study endpoints were the rates of occurrence of valve thrombosis, thromboembolism, and all major and minor bleeding events, whether or not related to drug therapy, reoperation, explant and death.

Dr. Accola co-authored the publication “Low-Dose vs. Standard Warfarin After Mechanical Mitral Valve Replacement: A Randomized Trial Study,” which concluded that, compared with standard-dose warfarin, low-dose warfarin did not achieve non-inferiority for the composite primary endpoint.

Michael W. A. Chu, Marc Ruel Allen Graeve, Marc W. Gerdisch, Ralph J. Damiano, Jr., et al..... **Kevin D. Accola**, Francois Dagenais, Alan H. Markowitz, Ian Ye, Michael E. Sekela, Ryan Y. Tsuda, David A. Duncan, Daniel G. Swistel, Lacy E. Harville III, Joseph J. DeRose, Eric J. Lehr, John H. Alexander, John D. Puskas, PROACT Mitral Investigators. Low-Dose vs. Standard Warfarin After Mechanical Mitral Valve Replacement: A Randomized Trial. The Society of Thoracic Surgeons. DOI: <https://doi.org/10.1016/j.athoracsur.2022.12.031>



Rohit Bhatheja MD, MBA, FACC, FSCAI

Rohit Bhatheja, MD, FSCAI, Medical Director, AdventHealth HLVI Services – South, and **Kapil Kapoor, MD, PhD, FAHA**, Research Senior Scientist in the Cardiovascular Department, are the authors of the scientific article entitled “Adenosine-Induced Atrial Fibrillation During Coronary Angiography and Fractional Flow Reserve Procedures.”

Pharmacological testing with agents like isoproterenol and adenosine are routinely used to characterize the electrophysiological properties of pulmonary vein ectopy and as a diagnostic tool to assess the presence of non-decremental accessory pathway conduction before catheter ablation. In interventional cardiology, adenosine is used as a vasodilator during angiography



Kapil Kapoor MD, PhD, FAHA

procedures to help assess fractional flow reserve and the hemodynamic significance of coronary stenosis. Drug-induced atrial fibrillation is more likely associated with risk factors and comorbidities such as advanced age, alcohol consumption, family history, hypertension, sleep apnea, thyroid dysfunction and heart disease. Episodes of adenosine-induced atrial fibrillation have been reported to be short-lived and transient because of its short half-life and clinically inconsequential. However, it can be of significant clinical importance when an accessory pathway is present.

An example is Dr. Bhatheja’s and Dr. Kapoor’s case study, published in 2023 in Cureus. The case reports about a woman in her sixties who presented with a history of progressive shortness of breath, palpitations and feelings of chest heaviness for the last eight months. To rule out obstructive coronary artery disease, an invasive cardiac catheterization was planned. Resting full cycle ratio (RFR) and fractional flow reserve (FFR) values were measured to assess the hemodynamic significance of the lesion. During this procedure, almost immediately after starting an IV adenosine infusion, the patient went into atrial fibrillation, which was reversed by IV aminophylline. Awareness of this uncommon effect of adenosine on the cardiac electrical pathways merits knowledge and justifies a thorough follow-up testing of these patients.

Rohit Bhatheja, Shammass Bajwa, **Kapil Kapoor**. Adenosine-Induced Atrial Fibrillation During Coronary Angiography and Fractional Flow Reserve Procedures. Cureus. DOI: [10.7759/cureus.34328](https://doi.org/10.7759/cureus.34328)



George Monir, MD

George Monir, MD, is an award-winning, board-certified cardiologist specializing in cardiovascular disease, nuclear cardiology, arrhythmia treatment, catheter ablations and cardiac electrophysiology. Dr. Monir is a co-author of the “Very High-Power Short-Duration, Temperature-Controlled Radiofrequency Ablation in Paroxysmal Atrial Fibrillation. The Prospective Multicenter Q-FFICIENCY Trial” article published in

JACC: Clinical Electrophysiology journal. This study aims to evaluate the safety and 12-month effectiveness of the QDM catheter in paroxysmal atrial fibrillation (AF) ablation using the vHPSD mode combined with conventional-power temperature-controlled (CPTC) mode.

In this prospective, multicenter, nonrandomized study, patients with drug-refractory, symptomatic paroxysmal AF underwent pulmonary vein (PV) isolation with QDM catheter with vHPSD as primary ablation mode, with optional use of the CPTC mode (25 to 50 W) for PV touch-up or non-PV ablation. The primary safety endpoint was the incident of primary adverse

events within 7 days of ablation. The primary effectiveness endpoint was freedom from documented atrial tachyarrhythmia recurrence and acute procedural, repeat ablation, and antiarrhythmic drug failure.

Of 191 enrolled participants, 166 had the catheter inserted, received RF ablation, and met eligibility criteria. Median procedural, RF application for ablating PVs, and fluoroscopy times were 132.0, 8.0, and 9.1 minutes, respectively. The primary adverse event rate was 3.6%. Imaging conducted in a subset of participants (n ¼ 40) at 3 months did not show moderate or severe PV stenosis. The Kaplan-Meier estimated 12-month rate for primary effectiveness success was 76.7%; freedom from atrial tachyarrhythmia recurrence was 82.1%; clinical success (freedom from symptomatic recurrence) was 86.0%; and freedom from repeat ablation was 92.1%.

The study findings showed that temperature-controlled paroxysmal AF ablation with the novel QDM catheter in vHPSD mode (90 W, #4 seconds), alone or with CPTC mode (25 to 50 W), is highly efficient and effective without compromising safety.

Jose Osorio, Ayman A. Hussein, M. Craig Delaughter, **George Monir**, Andrea Natale, Srinivas Dukkipati, Saumil Oza, Emile Daoud, Luigi Di Biase, Moussa Mansour, Robert Fishel, Miguel Valderrabano, Kenneth Ellenbogen, on behalf of the Q-FFICIENCY Trial Investigators. Very High-Power, Short-Duration, Temperature-Controlled Radiofrequency Ablation in Paroxysmal Atrial Fibrillation The Prospective Multicenter Q-FFICIENCY Trial. JACC Clinical Electrophysiology. DOI: 10.1016/j.jacep.2022.10.019



Usman Siddiqui, MD

Usman Siddiqui, MD, is a board-certified cardiologist with training in internal medicine, cardiovascular disease, clinical care electrophysiology and nuclear cardiology. In 2023, Dr. Siddiqui was a co-investigator for research into the safety and effectiveness of the first contact force ablation catheter with a flexible tip. The study sought to evaluate the safety and effectiveness of the TactiFlex SE ablation catheter for treating drug refractory (PAF).

Atrial fibrillation (AF) is a leading public health concern, as it is closely associated with heart failure, stroke, cardiovascular mortality, decreased quality of life, and increased health care burden. Atrial flutter (AFL) often accompanies AF, and the prevalence of individuals with AF/AFL is estimated at 37.65 million worldwide. One in 4 middle-aged adults is predicted to develop these arrhythmias in their lifetime. AF management includes treatment with rate-control measures, antiarrhythmic drugs (AADs), and interventional procedures, typically isolating the pulmonary veins (PVs) by ablation. Strides have been made to improve ablation's safety, efficiency, and efficacy, including cardiac imaging, 3-dimensional

mapping systems, open irrigation catheters, and real-time contact force (CF) feedback. Improved procedural efficiency has been associated with improved long-term clinical success.

Catheter ablation is an established therapy for PAF. The TactiFlex Ablation Catheter, Sensor Enabled (TactiFlex SE), is a next-generation radiofrequency ablation catheter incorporating fiber optics-based contact force-sensing technology with a flexible, laser-cut tip. The TactiFlex AF investigational device exemption was a prospective, nonrandomized, multicenter clinical study conducted between June 26, 2020, and June 18, 2021. Subjects with PAF underwent de novo pulmonary vein isolation and, if indicated, ablation for typical atrial flutter. Subjects were followed for 12 months.

Of the 355 subjects enrolled at 37 sites worldwide, 334 underwent ablation with the TactiFlex SE catheter. The Kaplan-Meier estimate of 12-month freedom from AF/atrial flutter (AFL)/atrial tachycardia recurrence was 72.9% (95% confidence interval [CI] 95% CI 67.2%–77.8%), and clinical success was 83.6% (95% CI 95% CI 78.1%–87.2%). As-treated analyses compared subjects treated at high power (left atrium time-averaged power setting 40–50 W; n 5 222) vs. low power (40 W; n 5 97). The Kaplan-Meier estimate of 12-month freedom from AF/AFL/atrial tachycardia recurrence was 76.4% (95% CI 69.3%–82.0%), and clinical success was 83.9% (95% CI 77.5%–88.6%) in the high-power group compared with 66.8% (95% CI 56.1%–75.5%) and 80.7% (95% CI 70.8%–87.5%), respectively, in the low-power group. The primary safety event rate in all treated subjects was 4.3%; 4.1% in the HP group, and 5.2% in the LP group (P 5 .7671). The results suggested that TactiFlex SE is safe and effective for treating drug-refractory PAF and concomitant AFL and enables more efficient procedures than previous-generation catheters.

Devi Nair, Martin Martinek, B Judson Colley, Sri Sundaram, Ramesh Hariharan, Gustavo Morales, Philipp Sommer, Stewart Healy, **Usman Siddiqui**, Douglas Gibson, Kristina Chapman, Anne Sarver, Monica Lo. Safety and effectiveness of the first contact force ablation catheter with a flexible tip. Heart Rhythm 02. DOI: 10.1016/j.hroo.2023.10.006

AdventHealth Redmond

In 2023, AdventHealth Redmond had 4 new research studies in cardiovascular.



Charles F. Jackson, III, MD

Charles F. Jackson, III, MD, is a board-certified interventional cardiologist specializing in coronary artery and valvular disease. Dr. Jackson earned his medical degree at the Medical College of Georgia in Augusta. He completed his internal medicine residency program and cardiology and interventional cardiology fellowships at Emory University in Atlanta.

Dr. Jackson is an active clinical researcher and the principal investigator for the DAPA ACT HF-TIMI 68 study. This investigation is a randomized, double-blind, placebo-controlled trial in patients who have been stabilized during hospitalization for acute heart failure — evaluating the effect of in-hospital initiation of dapagliflozin versus placebo on the clinical outcome of cardiovascular death or worsening heart failure.



Hector R. Picon, MD, FACC

Hector R. Picon, MD, FACC, is a board-certified interventional cardiologist. After earning his medical degree at Harvard Medical School in Boston, Dr. Picon completed his residency at George Washington University Medical Center in Washington, DC and a fellowship at Emory University Hospital in Atlanta, Georgia.

Dr. Picon co-authored “The 1-Versus3-Month DAPT in Older Patients at a High Bleeding Risk Undergoing PCI: Insights from the XIENCE Short DAPT Global Program,” a scientific article that was published in the American Journal of Cardiology.

Dr. Picon focuses on coronary artery disease, the leading cause of death in people over age 65. The number of patients in this age group and those undergoing percutaneous coronary intervention (PCI) is steadily increasing. Dual antiplatelet therapy (DAPT) is the standard of care to reduce the rate of recurrent ischemic events after PCI. Still, it can also increase the risk of bleeding complications associated with considerable morbidity and mortality. Older age is associated with a higher risk of ischemic events after PCI; thus, it is an even stronger predictor of bleeding events. Accordingly, the Academic Research Consortium identified an age of 75 or older as a minor criterion when assessing bleeding risk (HBR). However, the optimal

DAFT duration that would provide the right amount of antithrombotic effect with minimal bleeding-related harm in this subgroup of patients is still unclear.

Dr. Picon’s study investigated this question, and the study and results were presented in the article “The 1-Versus3-Month DAPT in Older Patients at a High Bleeding Risk Undergoing PCI”: Insights from the XIENCE Short DAPT Global Program,” published in the American Journal of Cardiology. The article discusses his research analysis evaluating the effect of 1- versus 3-month dual antiplatelet therapy (DAPT) after percutaneous coronary intervention (PCI) in older patients. Data from 3 prospective, single-arm studies (XIENCE Short DAPT Program), including patients with high bleeding risk successfully treated with an everolimus-eluting stent (XIENCE, Abbott), were analyzed. DAPT was discontinued at 1 or 3 months in patients free from ischemic events and adherent to DAPT. Patients were stratified according to age (≥ 75 and < 75 years).

The primary endpoint was all-cause death or myocardial infarction (MI). The key secondary endpoint was Bleeding Academic Research Consortium type 2 to 5 bleeding. The outcomes were assessed from 1 to 12 months after index PCI. Of 3,364 patients, 2,241 (66.6%) were aged ≥ 75 years. The risk of death or MI was similar with 1- versus 3- month DAPT in patients aged ≥ 75 (8.5% vs. 8.0%, adjusted hazard ratio [HR] 0.95, 95% confidence interval [CI] 0.69 to 1.30) and < 75 years (6.9% vs. 7.8%, adjusted HR 0.97, 95% CI 0.60 to 1.57, interaction $p = 0.478$). Bleeding Academic Research Consortium type 2 to 5 bleeding was consistently lower with 1- than with 3-month DAPT in patients aged ≥ 75 years (7.2% vs. 9.4%, adjusted HR 0.66, 95% CI 0.48 to 0.91) and < 75 years (9.7% vs. 11.9%, adjusted HR 0.86, 95% CI 0.57 to 1.29, interaction $p = 0.737$).

The study concluded that in patients at high bleeding risk who underwent PCI, patients older and younger than 75 years derived a consistent benefit from 1- compared with 3-month DAPT in terms of bleeding reduction, with no increase in all-cause death or MI at 1 year.

Gennaro Sardella, Alessandro Spirito, Samantha Sartori, Dominick J. Angiolillo, Pascal Vranckx, Jose M. De la Torre Hernandez, Mitchell W. Krucoff, ...et.al.... **Hector Picon**, Shigeru Saito, Holger Thiele et.al. 1- Versus 3-Month DAPT in Older Patients at a High Bleeding Risk Undergoing PCI: Insights from the XIENCE Short DAPT Global Program. The American Journal of Cardiology. DOI: 10.1016/j.amjcard.2023.12.049



Neuroscience Institute

Overview

Investigators at the AdventHealth Neuroscience Institute focus on understanding brain health and function across the lifespan and developing approaches for maintaining and improving brain health — even in the face of disease or disorder. We seek breakthroughs that enhance and maximize the healthy brain, prevent neurocognitive decline and establish the most effective treatments for improving function. As a research institute, we are making significant strides toward these goals and disseminating our findings to the scientific and medical communities through presentations, published manuscripts, and our work with industry sponsors.

The Neuroscience Research Institute brings together multidisciplinary experts in neurology, neurosurgery, psychiatry, psychology and other related disciplines. These collaborations foster a comprehensive understanding of how to mitigate neurologic disorders and age-related cognitive decline. Our focus on translational research aims to bridge the gap between basic science discoveries and clinical applications. This approach allows research findings to be rapidly translated into improved patient care and outcomes. In 2023, we completed 27 peer-reviewed manuscripts related to our work in translational neuroscience.

The Institute is equipped with state-of-the-art technology and facilities that allow researchers to conduct advanced imaging studies, analyses, and other cutting-edge research procedures. This technology enables researchers to make breakthrough discoveries and develop novel therapies to treat or prevent cognitive impairment.

Overall, the research conducted at AdventHealth's Neuroscience Research Institute sets us apart from competitors by emphasizing collaboration and innovation and translating research findings into real-world applications. Our commitment to advancing medical knowledge and improving patient care positions us as a leader in neuroscience research.

Areas of Focus

- Alzheimer's and memory disorders
- Cranial surgery
- Epilepsy
- Headache and migraine
- Minimally invasive brain surgery
- Movement disorders
- Multiple sclerosis
- Neuromuscular diseases
- Sleep medicine
- Spine services

Active Clinical Trials Underway

- Alzheimer's
- CDKL5 deficiency disorder
- Chronic inflammatory demyelinating polyneuropathy (CIDP)
- Dementia with Lewy bodies
- Dravet syndrome
- Glioblastoma
- Lennox-Gastaut syndrome
- Spine surgery
- Stroke
- Thrombectomy
- Multiple sclerosis
- Multiple system atrophy (MSA)
- Parkinson's disease
- Spinal muscular atrophy (SMA)

“The Neuroscience Research Institute’s groundbreaking research and successful outcomes would be impossible without our exceptional team of physician investigators, scientists, clinical research manager, and coordinators. By investing in talent and building infrastructure, we bring innovative minds together under one roof to encourage cross-pollination of ideas that lead to the fruits of new knowledge and applications to improve the quality of care in our community and beyond.”

— Anwar Ahmed, MD

Featured Researchers and Research



Audrey M. Collins, PhD

Audrey M. Collins, PhD, is a Postdoctoral Research Scientist in the Neuroscience Department. Dr. Collins received her PhD in Exercise Physiology and began her postdoctoral training at the University of Pittsburgh. She joined the AdventHealth Neuroscience Institute in 2022. Dr. Collins’ research career is coupled with years of experience in health and fitness settings, where she employed evidence-based strategies to promote movement behaviors across many settings and populations. Dr. Collins studies the influence of lifestyle behaviors on the brain across the lifespan, focusing on the role that 24-hour time-use plays in promoting healthy aging. Mentored by Kirk Erickson, PhD, she explores these relationships and contributes to a vast research program through her expertise in actigraphy and other measures. Dr. Collins conducts whole-person research to optimize and maximize brain health by using health-promoting lifestyle behaviors to break through how we think about preventing, attenuating and treating neurocognitive and neurodegenerative conditions across the lifespan.



UWI SODECO Kingston Town Jamaica



UWI SODECO Kingston Town Jamaica

Dr. Collins is a co-principal investigator of the NIH-funded EX-CORE Study, a moderate-intensity aerobic exercise intervention designed to target the long-term debilitating effects in adult survivors of childhood severe acute malnutrition. The project collaborates with the University of the West Indies Solution for Developing Countries in Kingston, Jamaica. Malnutrition has both immediate effects on brain development in early childhood and long-term negative consequences for brain function into adulthood. Thus, it is imperative to establish cost-effective, accessible and translational interventions that effectively rehabilitate the long-term neurocognitive sequelae of malnutrition. In this project, Dr. Collins and her collaborators study a sample of middle-aged adults who survived severe acute malnutrition in early life, such as marasmus and kwashiorkor. Dr. Collins will measure participants' cognitive function at baseline, then randomize them to a 6-month aerobic exercise intervention to learn if exercise can modify cognitive function and other health outcomes in this sample. Dr. Collins says, "Our results could be ground-breaking and potentially alter the neurocognitive trajectory of billions of adults worldwide." In 2023, Dr. Collins traveled to Kingston, Jamaica, to provide training for this project.

Press Release for FLAME



Kirk Erickson, PhD
Director, Translational Research

The AdventHealth Neuroscience Institute will lead first-of-its-kind research on exercise and brain health as part of a national, multi-site effort funded with \$11 million from the National Institutes of Health (NIH), the largest source of medical research funding worldwide.

Dr. Kirk Erickson, a leading researcher on exercise and dementia, is coordinating a major five-year study called **Follow-Up Longitudinal Analysis of Moderate-Intensity Exercise (FLAME)**. This new study aims to answer the questions, "Why is exercise good for your

brain? How much exercise will deter dementias like Alzheimer's disease? Why do some seniors stay the course and others don't?"

This study will re-examine more than 600 older adults in three cities who participated in an earlier clinical trial – the IGNITE study – which explored the effects of exercise on the brain. "We want to know how active they are on many parameters, which will help doctors write the right prescriptions for exercise tailored for individual seniors. We've established that exercise affects the brain," says Dr. Erickson. "Now we want to provide a more definitive statement about the impact of exercise behaviors on reducing age-related cognitive impairments."

In addition to AdventHealth, the University of Pittsburgh, Northeastern University and the University of Kansas Medical Center will also serve as sites for this research.

**"AdventHealth researcher could help doctors prescribe the right exercise to battle dementia" WMFE | By Joe Byrnes
Published November 27, 2023.**

Kirk Erickson – 2023 Interview Highlights

“AdventHealth to lead first-of-its-kind research around Alzheimer’s and exercise” *Dr. Erickson for Orlando Business Journal, Published on November 17th.*

“Dr. Kirk Erickson, Director Translational Neuroscience at AdventHealth Research Institute in Orlando.” *Becker’s Healthcare Podcast. Published on October 10, 2023.*

“Exercise is a key to a healthy brain as we grow older, AdventHealth research shows.” *Interview with Kristi Powers. AdventHealth Newsroom. Published October 10, 2023.*

“Research breakthroughs in health care that will change the world: An interview with AdventHealth investigators.” *Inspiring Wholeness Podcast. Published on September 28, 2023.*

“AdventHealth’s Dr. Steven Smith and Kirk Erickson on research breakthroughs.” *Orlando Business Journal. Published on September 28, 2023.*

“AdventHealth scientists help develop blood test that detects indicator of Parkinson’s Disease.” *AdventHealth Newsroom. Published on September 26, 2023.*

“Staying fit as you age isn’t just about exercise. Experts say to prioritize these 4 habits.” *Interviewed by Kristine Gill. Fortune. Published July 23, 2023.*

“Alzheimer’s Research: Is This the Beginning of the End?” *Interviewed by Susan Jenks. Orlando Magazine. Published March 8, 2023.*

“Exercise mimicking drugs boost brain health.” *Interviewed by Hannah Thomasy, PhD. Drug Discovery News. Published January 5, 2023.*



Anita Fletcher, MD
Medical Director,
Neuroscience
Institute,
AdventHealth

Anita Fletcher, MD, was appointed the Medical Director of AdventHealth Neuroscience Research in 2023. She is an incredibly accomplished physician and researcher, and we are thrilled to be working with her as we build our program.

Dr. Fletcher grew up in Orlando and relocated to Kentucky. She graduated from the University of Kentucky with a degree in Biotechnology where she received the Glenn B. Collins Award for Achievement in Research in Biotechnology. At the University of

Kentucky, she spent 13 years as a Research Analyst and Scientist II in Neuroscience and Neurosurgical laboratories. Dr. Fletcher investigated the neurotrophic environment of the brain in normal, aging and neurodegenerative conditions, optimizing the brain environment for cell replacement therapy and restoration of neurological circuitry and function in models of neurodegeneration.

Dr. Fletcher later received her medical degree from the University of Louisville School of Medicine, receiving Distinction in Research and Outstanding Academic Performance in Clinical Medicine awards. Upon completing her residency, she took a prestigious fellowship in Neuroimmunology and Neuroinfectious Diseases at the National Institutes for Neurological Disorders and Stroke at the NIH. There, she served as an investigator on multiple sclerosis trials, HTLV-1-associated myelopathy and multiple trials for progressive multifocal leukoencephalopathy. She served as Director of the Neuroimmunology and Neurovirology Clinic, as a medically accountable investigator, as well as lead and associate investigator on multiple studies until leaving full-time service at the NIH.

Dr. Fletcher’s contributions to science include neurotrophic factor research, experimentation with functional delivery systems for factors increasing survivability and innervation of grafted neurons, investigation of compacted DNA nanoparticles, evaluation of antibody testing in autoimmune neurology, research into the treatment and imaging of multiple sclerosis, chronic viral infections of the spinal cord and progressive multifocal leukoencephalopathy.

In 2023, Dr. Fletcher returned to her hometown of Orlando to be close to her family and to become the Director of Neuroscience Clinical Research. Additionally, she continues to see patients as a specialist in neuroimmunology. Dr. Fletcher says, “I am excited by the potential for neuroscience research growth, paving the way for groundbreaking advancements in diagnostics and therapeutics, advancing medical science and ultimately enhancing lives.”



Shivangi Jain, PhD

Shivangi Jain, PhD, specializes in cognition and brain sciences research. During her studies at Georgia Institute of Technology, she trained in cognitive interventions in aging, followed by postdoctoral training in neuroscience techniques and exercise science at the Duke University Medical Center and the University of Iowa. She utilizes cognitive tasks in conjunction with structural and functional magnetic resonance imaging and blood-based biomarkers to examine the impact of age on cognitive functions, specifically memory and executive functions, the domains most severely affected by aging and neuropathology.

Dr. Jain is currently investigating the relationship between brain and physical health variables, such as white matter lesions, markers of systemic inflammation, blood-based AD neuropathology measures, body composition measures and their impact on cognition in aging. She uses advanced statistical methods, such as mediation and moderation models, to examine these variables’ impact on each other and cognition in aging. Dr. Jain also explores the protective role of physical exercise on these brain and health variables and cognition. She has presented her research at international conferences and published in peer-reviewed journals. Building upon her previous work, Dr. Jain recently submitted a grant proposal to examine Alzheimer’s disease-related blood biomarkers in physical exercise intervention and the socio-demographic moderators of this relation.



Cristina Molina-Hidalgo, PhD

Cristina Molina-Hidalgo, PhD, is a Postdoctoral Research Scientist in the Neuroscience Department. Dr. Molina-Hidalgo received her PhD with honors in Psychology and Neuroscience from the University of Granada (Spain), followed by postdoctoral training in neurosciences techniques and exercise interventions at the University of Pittsburgh. She has participated in

many national and international studies throughout her career, focusing on the effects of physical activity and exercise interventions on cognitive and brain health across various settings and populations.

Dr. Molina-Hidalgo is an early career scientist who uses functional magnetic resonance imaging to investigate the effect of aging and lifestyle behaviors on brain health. She focuses on memory and executive functions, the domains most affected by aging and neuropathology. She is investigating how uniquely objective and subjective stress markers can predict brain health, such as hippocampal volume and dysfunction, and memory performance. Under the guidance of Kirk Erickson, PhD, Dr. Molina-Hidalgo is leading and exploring these relationships in multiple NIH-granted projects led by Dr. Erickson, such as FLAME. FLAME is a 5-year follow-up of a multi-site Phase III randomized clinical trial examining the impact of exercise on neurocognitive function in late adulthood. She also plans to investigate the impact of lifestyle behaviors on promoting healthy brain aging, specifically on minority groups under social risk conditions. Her goal is to develop a panel of social protective factors that may guide future interventions while also personalizing the type of population.

New Investigators



Ryan Mizell, MD

Ryan Mizell, MD, is a board-certified neurologist who primarily treats patients with complex multiple sclerosis (MS) and neuroimmunology issues. After earning bachelor’s degrees in exercise and sport science and biomedical sciences at the University of Florida (UF) and the University of South Florida, respectively, he completed a master’s degree in biobehavioral science specializing in biomechanics at UF. Dr. Mizell earned his medical degree at the University of Central Florida and completed his internship and residency in adult neurology at the University of Louisville. He completed a multiple sclerosis/neuroimmunology fellowship at the MS Center of Excellence at the Baltimore VA and University of Maryland Medical Center.

Dr. Mizell joined the staff at AdventHealth Medical Group in 2020 as a multiple sclerosis and neuroimmunology subspecialist. He is now the Director of AdventHealth Neuroimmunology. Dr. Mizell says, “I wanted to join AdventHealth’s Neuroscience Institute because of its unified goal to bring together top clinicians and researchers to increase patient access to top-tier research and care.”

In 2023, Dr. Mizell opened enrollment on a Novartis-sponsored clinical trial called A Randomized, Double-blind, Double-dummy, Parallel-group Study, Comparing the Efficacy and Safety of Remibrutinib Versus Teriflunomide in Participants with Relapsing Multiple Sclerosis, Followed by Extended Treatment with Open-label Remibrutinib, also known as the REMODEL-2 study. Dr. Mizell says, “This study is exciting because it investigates the effectiveness of Bruton tyrosine kinase (BTK) inhibitors, a novel therapeutic mechanism in treating Multiple Sclerosis. BTK inhibitors may prevent adaptive and innate inflammation to prevent relapses and gradual loss of function that can affect patients with Multiple Sclerosis.”

Dr. Mizell also published an article based on his investigator-initiated work in 2023 in the International Journal of MS Care, titled “The Impact of Insurance Restrictions in Newly Diagnosed Individuals with Multiple Sclerosis.” This study investigated how insurance restrictions impact patients with multiple sclerosis. Patients with multiple sclerosis and other diseases are often denied access to FDA-approved therapies by their insurance companies. From this work, Dr. Mizell found that an initial denial from insurance was more likely to occur if an oral or infusion medication was prescribed or the patient had Medicaid. If a patient received an initial denial, the likelihood of disease activity, such as relapse or new lesion on imaging, was higher when compared to an initial approval. This publication was the first to show an association between insurance restrictions and an increase in disease activity in patients with multiple sclerosis.



Lauren Oberlin, PhD

Lauren Oberlin, PhD, is a licensed clinical psychologist focusing on geriatric neuropsychology. Dr. Oberlin received dual PhDs in Clinical Psychology and Biological and Health Psychology from the University of Pittsburgh. She completed her clinical internship at New York University and her postdoctoral fellowship at the Weill Cornell Medicine Institute for Geriatric Psychiatry. Dr. Oberlin then worked as an assistant professor at the Cornell Geriatric Institute for several years before starting work at AdventHealth, where she is now an associate investigator at the AdventHealth Neuroscience Institute.

Dr. Oberlin’s clinical work and research focus on maximizing brain health and well-being in older adulthood. Her published works have examined predictors of cognitive decline and neurodegeneration and how this data can be used to guide treatment development. She also explores behavioral interventions that promote neuroplasticity in late life, including physical activity and digital cognitive training, and strategies to optimize the potency and efficacy of these promising treatments. She was recently awarded NIH funding to conduct a clinical trial examining the impact of a technology-assisted cognitive intervention on brain health, mood, and cognition in geriatric depression. Her work has been recognized in numerous awards, including the International Neuropsychological Society’s Excellence in Research Award and the Cornell Distinguished Award in Psychiatry Medicine.



Nursing, Whole-Person and Academic Research

Overview

Our theme, "Caring for Our Caregivers," continues to guide our activities, including adapting existing well-being interventions like the RISE program for health care worker populations that have not often been studied, such as chaplains and unit-based nurse leaders. Originally developed for direct care nurses, RISE was adapted uniquely for unit-based nurse and assistant nurse managers. A randomized controlled trial showed the program effectively reduced stress and burnout and improved well-being in this population. We also completed a validation study of the Moral Injury Outcomes Scale (MIOS) in nurses to assess and address the levels of moral injury through testable interventions. We examined the sufficiency of AdventHealth's pastoral staff to identify its future capacity. Also, we adopted Trauma-Informed Peer-to-Peer Surveillance (TIPPS) as a novel way for trained individuals to provide on-the-unit confidential support to colleagues experiencing personal or work-related distress.

The Center for Academic Research Excellence (CARE) creates a learning ecosystem through Graduate Medical Education (GME) training to enhance the research conducted by our clinical learning and research community. CARE supports researchers and investigators with individual project design, protocol mentoring, regulatory documentation, study startup directions, modifications, study renewal, and closure assistance. In 2023, we implemented online, on-demand modules to help educate our growing learner community, including Loma Linda medical students and Rothman orthopedic researchers. Breakthroughs include our first two GME grant submissions and more podium presentations, posters, and manuscripts from our 16 residency and 11 accredited fellowship programs.

Our next goal is to decrease the time between research publication and the operational launch of programs. In addition to supporting GME, the CARE team offers a full spectrum of services to AdventHealth research units, leaders, and clinicians conducting clinical and scholarly research. Our five biostatisticians provide study design, sample size calculations, randomization options, and statistical analysis plans. Our team also analyzes data after completing the collection.

Breakthroughs in 2023 include four presentations at Digestive Disease Week, two presentations on metabolism and diabetes and 108 projects supported from across the AdventHealth Research Institute. Our biostatisticians were authors or coauthors on 19 publications in 2023.

Areas of Focus

- Workforce Well-Being and Recovery
- Transformative Whole-Person Health Care Delivery
- Mentor the next generation of Physician Leaders on clinical research
- Scientific Foundation of Wholeness in Mind, Body, Spirit and Social

“When I hear research as a care option, it describes my whole career as a nurse. I remember studying a new instrument called a ‘bladder scanner,’ and now we are giving a common transplant drug to my pediatric patients, which was once new in research. Research as a treatment means getting state-of-the-art mental, physical and spiritual care to our frontline caregivers. Leading a team that is creates solutions for the future of our clinicians is a true privilege. Healthier clinicians is our promise to our doctors, nurses and the patients they care for.”

— Patricia Robinson, PhD, APRN

“Academic research mentors create an environment of online, group, and one-to-one education to encourage and develop research skills in the next generation of doctors and nurses entering our workforce.”

— Julie Pepe, PhD

Featured Researchers and Research

A radiology team led by **Connor Woodward, MD** (fifth-year radiology resident) and **Jennifer Williams, MD** (pediatrics radiology), conducted a study to assess the impact of intervention delays on the outcomes of pediatric patients with ileocolic intussusception. This emergency condition occurs when a portion of the intestine invaginates into an adjacent portion of the intestine, causing obstruction and significant morbidity, including ischemia and bowel perforation, if not treated. Treatment delays more than 24 hours are associated with poor outcomes. Shorter delays, including those caused by patient transfer from a community to a children’s hospital for more specialized care, repeat treatment attempts after an initial failure, or delays in allowing adequate staff and patient preparation, occur commonly and may even benefit the patient. However, there is limited knowledge about the impact of these shorter delays on patients’ outcomes.

The research team found that delays of up to 8 hours between imaging diagnosis and treatment made no difference in the treatment efficacy and complication rates of patients with intussusception. The study was awarded first place for podium presentations at the 2023 AdventHealth GME Research Day and publication in the *Emergency Radiology Journal*. The published results sparked the interest of the radiology community, leading to a multi-institutional collaboration, including AdventHealth and 42 additional institutions across the United States, organized to reproduce the findings. If successful, these results may lead to a change in practice that will allow more efficient health care delivery and improved patient outcomes.



From left to right: Joseph Portoghese, MD, FACS, Chief Academic Officer, Connor Woodward, MD



Jennifer Williams, MD

RISE for Nurse Leaders



Amanda Sawyer, PhD



Amanda Sawyer, PhD, is the principal investigator of the RISE for Nurse Leaders study. Unit-based nurse leaders can influence workplace culture, foster a healthy work environment, and provide psychosocial support to nurses while managing their own stress and exhaustion during the pandemic and beyond. However, much of the relevant research on individual-level interventions to address stress and burnout has included nurses and physicians. In contrast, the population of unit-based nurse leaders has been overlooked in the literature. During the COVID-19 pandemic, the original RISE program was adapted to meet the unique needs of nursing leadership by integrating conceptual underpinnings of authentic leadership principles and post-traumatic growth.

This randomized controlled trial examined the effects of RISE for Nurse Leaders among 77 unit-based nurse leaders, specifically nurse managers and assistant nurse managers. This 9-week psychoeducational group intervention was developed around the themes of resilience, insight, self-compassion, and empowerment to fight burnout and enhance purposeful adaptive coping to reduce distress and improve mental well-being. Given the enduring effects of the pandemic, post-traumatic growth was added as a conceptual underpinning during adaptation. Compared to the waitlist control group, the intervention group showed significant improvement in post-traumatic growth between baseline and all follow-up time points. Among the intervention group, there were significant improvements in self-reflection and insight, self-compassion, psychological empowerment, and compassion satisfaction, as well as significant reductions in perceived stress, burnout, and secondary traumatic stress.

Translating Research to Clinical Settings

In 2023, RISE was operationalized in CFD and is now offered as a service to nurses and unit-based nurse leaders. This rapid implementation of RISE at AdventHealth is leading the field in caring for hospital caregivers due largely to collaborative partnerships between the AdventHealth Research Institute (AHRI), executive and clinical nurse leadership, nursing education and the skilled team of Mental Health Consultants. This trained and



Mental Health Consultants, Rise Facilitator Training, 2023

licensed professional team provides monthly RISE groups in concert with AHRI to ensure fidelity to the evidence-based program and continuous program improvement.

To further improve health care outcomes, our team partnered with the University of Southern Florida's Mental Health and Law Department to provide qualified patients at AdventHealth Kissimmee Hospital with an opportunity to participate in a comparative effectiveness clinical trial. We believe that our unified goal of reducing readmission rates for some of our most vulnerable patients aligns with the goals of the PCORI CTI Study, which was designed for racial/ethnic minority older adults age 60+ living with chronic illness. The study assesses how Care Transition Intervention (CTI) and CTI and Peer Support (PS) compare to usual care on unplanned hospital readmissions for these qualified patients. AdventHealth Whole-Person Research enrolled more than 100 patients in 2023 with the overall goal of staying engaged through study completion and results dissemination.

“Examination of The Evidence-Based Care Transitions Intervention Enhanced with Peer Support to Reduce Racial Disparities in Hospital Readmissions and Negative Outcomes Post Hospitalization (PCORI CTI)”

— Patricia Robinson, PhD, APRN

Care Delivery Model for the Nursing Workforce



Jeanette Green, PhD, APRN, CPNP-PC, PMHS

Jeanette Green, PhD, APRN, CPNP-PC, PMHS, leads the Care Delivery Model for the Nursing Workforce project. Fundamental aspects of safe, high-quality health care delivery involve nurse leader (NL) strategies to optimize nurses' practice environment and patient and family satisfaction outcomes while carefully aligning financial resources.

Workforce optimization and financial stewardship require NLs' data-driven decision-making regarding emerging models of care. Pandemic-related disruptions in nursing workforce retention often require NLs' quick and innovative actions to ensure safe, quality, and enduring care delivery. Thus, NLs have been faced with implementing care delivery models that align with the health system's vision and mission while considering the human and material resources available.

Competitive nurse travel and agency contracts, early retirements, workload intensity and burnout substantially disrupted medical-surgical and progressive care unit staffing. Care delivery models that integrated a Virtual Nurse (VN) and/or Licensed Practical Nurse (LPN) were employed to continue meeting patient care needs. Analyzing the impact of each staffing strategy and care delivery model is integral to understanding the impact on the nurse practice environment, nurse retention, patient and family satisfaction and financial stewardship. Therefore, the overall objective of this study was to ascertain the differences in nurse practice environment, nurse retention and patient and family satisfaction outcomes between each nurse staffing strategy to ascertain best practice units and inform NL and nurse executives' decision-making. VN and LPN staffing models were launched in 12 non-intensive care unit settings throughout a large non-academic health system between January 2021 and October 2022. Comparisons were made to determine differences between the total number of falls, total patient falls per patient day, catheter-associated urinary tract infection (CAUTI) and hospital-acquired pressure injuries (HAPI). Units that integrated VNs had statistically significant differences in nurse-sensitive indicators, with a substantially lower number of falls with injury, total falls per patient day, CAUTI and HAPI than units that integrated LPNs. While adding VNs showed improvement in all nurse-sensitive indicators, the greatest improvement was seen with falls with injury and total patient falls. Direct VN observation of high-risk patients allows real-time safety interventions to prevent falls.

Moral Injury Outcomes Scale

Moral injury (MI) has recently gained attention from health care providers, especially front-line nurses, principally due to the unprecedented impact of the COVID-19 pandemic. However, most measures of moral injury have been developed and validated in samples of military veterans. The Moral Injury Outcomes Scale (MIOS) was originally developed for and validated by active-duty service members, veterans and mental health clinicians. While other surveys measure the symptoms of moral injury, the MIOS takes this a step further to measure the outcomes, such as the impact on relationships and daily functioning.

Patricia Robinson, PhD, APRN, and **Hong Tao, PhD, RN**, principal investigator, launched this MIOS validation study in collaboration with Duke, Vanderbilt, and the VA researchers to examine the outcomes of moral injury in the nursing population among a sample of 309 acute care nurses, a representative and diverse sample of the nursing workforce.

The results demonstrate that MIOS is reliable and valid and can be a useful measure of potential moral injury in this population. This study examined the relationship between demographic variables and moral injury, and several significant associations emerged. Nurses over 40 years old and non-white nurses tended to report lower overall moral injury, specifically on the trust-violation subscale. Additionally, nurses who were married or partnered exhibited lower functional impairment related to moral injury. These findings are consistent with previous research that found lower moral injury among older individuals and those with social support.

The findings contribute to the growing literature on moral injury among health care workers and emphasize the need for tailored interventions. By accurately identifying and assessing moral injury, health care organizations can work to develop targeted strategies to reduce the potential for moral injury in health care workers, support their psychosocial-spiritual well-being, and promote their retention in direct care roles.



Patricia Robinson, PhD, APRN
*Scientific Director,
Nursing, Whole-
Person and Academic
Research*



Hong Tao, PhD, RN



Well Nurse



Andrea Brennan, PhD

Andrea Brennan, PhD, is the principal investigator of the Well Nurse study, a randomized, wait-list control pilot study to analyze the impact of an on-site, 12-week exercise training intervention on post-traumatic growth and whole-person well-being (mental health, physical health, spiritual well-being, perceived social support, and occupational health) among inactive, shift-working acute care nurses within AdventHealth. Well Nurse is a collaboration between the Department of Nursing, Whole-Person and Academic Research and the Translational Research Institute. This study is novel in delivering supervised, prescriptive exercise training from credentialed professionals to shift-working nurses. It measures a range of holistic health outcomes that cover the mental and physical health spectrum. Nurses' health and well-being are integral to providing safe, quality patient care, positive patient-health care provider relationships, high-functioning health care teams, and an engaged and effective workforce. We must identify strategies that optimize health and well-being to retain nurses and provide an environment in which they flourish.



Fanchao Yi

Fanchao Yi, Sr. Data Scientist Biostatitian, used a linear mixed model approach on a project with Steven R. Smith, MD and Karen Corbin, PhD titled, "Microbiome: Integrating Quantitative Energetics Determines the Microbiome's Contribution to Energy Balance." This project was funded by the NIH with results published in Nature Communications.
DOI: 10.1038/s41467-023-38778-x

Trauma-Informed Peer to Peer Surveillance (TIPPS)



Mandi Bailey, MA, LMHC

Mandi Bailey, MA, LMHC, is the project lead of a trauma-informed peer support program developed by external consultants and evaluated by AHRI team members. This workplace intervention program is being piloted on four AdventHealth East units. Individuals trained in trauma-informed care principles provide on-the-unit confidential support to colleagues experiencing personal or work-related distress. TIPPS is a breakthrough program in its novel use of a trauma-informed approach that is employee-facing and manualized to support workforce mental health. In a health care setting, those best positioned to help someone in distress are those with existing relationships. Early intervention is crucial to mitigate the risk of acute mental health crises and adverse outcomes. Therefore, the TIPPS program aims to equip individuals who naturally support peers with specialized training by mental health professionals. This collaboration also makes it easy for all team members to access mental health resources.

Employee volunteers from various specialties and levels of care are screened to become peer supporters and attend training and ongoing mentorship. Ms. Bailey is running a QI/QA project to evaluate the program in three main areas: training, implementation, and impact. TIPPS was developed, launched, and evaluated by a dedicated team from AHRI, nursing education, communications, human resources, employee health and well-being, behavioral health, nursing executive leadership, and campus leadership. Representatives from these departments sat on the Strategic Planning Committee and attended the TIPPS Train the Trainer.



From left to right: Diane Scott, DBH, LCSW, MSW, and Billie Ratliff, DBH, LCSW, MSW (Synergy Behavioral Health Solutions, LLC)

TIPPS Peer Supporter Training Feedback

“[This training] really helps recognize triggers that could impact you in the role.”

“This was a lovely and informative course. I am so happy this program is being piloted here.”

“My purpose to serve is validated.”

“[This training] helped me to be a better listener and be able to direct people to the proper channels.”

“Being able to learn how to ask questions about suicide appropriately”

“Enriching” and “Insightful and eye opening”



Orthopedic Institute

Overview

Rothman Orthopaedics Florida partners with top-notch surgeons and academicians, setting AHRI apart from its competitors by harnessing clinical expertise, research acumen, knowledge, and capabilities. This collaboration ensures that research is at the forefront of medical advancements and is directly informed by real-world clinical experiences. Furthermore, the Rothman partnership allows AHRI to tap into a vast network of resources, patient data, and clinical insights, which is uniquely advantageous in developing and implementing innovative therapeutic approaches. This extensive network also facilitates the translation of research findings into practical clinical applications, which differentiates AHRI from its competitors. Overall, the collaborative efforts with renowned orthopedic specialists and academic experts enhance the quality and relevance of AHRI research and position the organization as a leader in driving advancements in orthopedic care and therapeutic solutions.

Our orthopedic milestones and achievements include groundbreaking discoveries, innovative treatments, and a commitment to translational research that benefits patients directly. The Rothman Orthopaedics and AHRI leverage their collective expertise to establish new standards of excellence in orthopedic care and drive the development of cutting-edge therapies that can lead to improved patient outcomes.

Areas of Focus

- Foot and Ankle
- General Orthopedics
- Hand and Wrist
- Joint Replacement
- Non-operative Primary Care Sports Medicine
- Operative Sports Medicine
- Orthopedic Trauma/ Fracture Care
- Physiatry/Pain Management and Rehabilitation (PM&R)
- Physical and Occupational Therapy
- Shoulder and Elbow
- Spine

Featured Research and Researchers



G. Russell Huffman, MD, MPH

G. Russell Huffman, MD, MPH, is board-certified in orthopedic surgery and sports medicine. He is a nationally and internationally recognized expert in Shoulder and Elbow surgery. Dr. Huffman is the principal investigator for the “SMR Stemless Reverse:” A Randomized, Multi-Center, Prospective, Safety and Efficacy Study comparing the outcome of total reverse shoulder arthroplasty (RSA) with SMR Stemless Reverse vs SMR Reverse Shoulder System study. This study aims to evaluate the safety and effectiveness of SMR Stemless Reverse compared to the control device in total reverse shoulder arthroplasty. NCT04697004



Amir Kachooei, MD, PhD

Amir Kachooei, MD, PhD, is the director of research at Rothman Orthopaedics Florida at AdventHealth and an orthopedic hand and elbow surgeon. Dr. Kachooei’s research led to nine patents, more than 115 peer-reviewed articles on elbow and hand surgery, two books and two book chapters, and more than 100 oral and poster presentations nationally and internationally. Furthermore, he supervised more than 20 theses and

served as a mentor to many researchers. Dr. Kachooei was awarded research grant funding from the AANA, AOFAS, and Opioid Foundation. In addition to directing Rothman’s research program at AdventHealth, he is the editor-in-chief of SurgiColl Journal and the deputy editor-in-chief of SurgiColl Journal and Deputy Editor-in-Chief of the Archives of Bone and Joint Surgery Journal.

Dr. Kachooei is the principal investigator for the “CTR After CSI:” Impact of Prior Corticosteroid Injections on Post-Operative Outcomes after Carpal Tunnel Release (CTR) Surgery study to compare the score improvement after CTR between patients with no history of CSI versus patients with prior history of CSI for CTS. Additionally, Dr. Kachooei is the principal investigator for the “NIRS:” Optimization of the leg elevation height after ankle fracture fixation using Near Infra-Red Spectroscopy (NIRS) and physiological parameters study, which aims to assess muscle oxygenation (SmO₂) as the surrogate of optimum perfusion using NIRS at different levels of leg elevation and dependency after ankle fracture surgery compared to the non-operated side as the healthy control.

“Our institute fosters an environment that promotes research and clinical care by prioritizing teamwork, innovation, evidence-based practice, and continuous learning. We encourage interdisciplinary collaboration between researchers, clinicians, and other health care professionals. We support and invest in innovative technologies, methodologies, and practices that have the potential to transform health care. Our institute is designed to be a science factory to achieve breakthroughs and improve patient outcomes.

We invest in talent and research to create breakthroughs for the communities it serves through several initiatives: 1) Research Fellowships: The institute offers several fellowships to educate and train talented individuals in orthopedics. 2) Global engagement: The international research fellowship is an opportunity to attract and invest in talented individuals worldwide who are committed to advancing orthopedic research and innovation. 3) Mentorship: Fellows have the opportunity to collaborate with multidisciplinary teams and receive guidance from experts in the field of orthopedics. 4) Research Grants: By funding cutting-edge research, the institute fosters breakthroughs in treatments, surgical techniques, and rehabilitation protocols that directly benefit the community. 5) Collaborative Partnerships: The institute collaborates with other academic institutions, industry partners, and research organizations to leverage expertise and resources.”

— Amir Reza Kachooei, MD



Luke Oh, MD

In 2023, **Luke Oh, MD**, was the co-investigator on a study titled Quantitative and Qualitative In Vitro Evaluation of Emerging Bioengineered Scaffolds for Rotator Cuff Repair. The study investigated the effect of each scaffold on tendon cell attachment and proliferation in vitro in a bioreactor. Dr. Oh also co-authored the article Adult Prg4+ Progenitors Repair Long-Term Articular Cartilage Wounds In Vivo, published in JCI Insight in September 2023. The study aimed to help elucidate the identity and origin of the stem/progenitor cells for adult joint cartilage repair, which are unknown and impede therapeutic development. The investigators used inducible mouse models with a full-thickness injury model, which provides bone marrow stromal cells (BMSCs) open access to the cartilage wounds and simulates human microfracture surgery.

Dr. Oh also co-authored Plant-Based Diets and Sports Performance — A Clinical Review, published in Sports Science for Health in 2023. The review examined randomized trials and prospective and retrospective studies to determine whether increasingly popular plant-based diets impact sports performance. While many studies have examined plant-based benefits on physiologic health, there is little data on how such diets relate to sports performance. Dr. Oh and his colleagues’ review found no significant differences in athletic performance between participants eating a plant-based diet compared to those consuming omnivorous diets specifically related to strength, power, and endurance. They concluded that micro and macronutrient intake, disease propensities, and oxygen consumption may vary between plant-based and mixed omnivorous eaters, but this does not translate into different physical performance. Maintaining a nutritionally sufficient diet is the most important recommendation to support strength, power, and endurance.



Daryl Osbahr, MD

In 2023, **Daryl Osbahr, MD**, co-authored the publication Analysis of Orthopaedic In-training Examination (OITE) Trauma Questions: 2017-2021 in the Journal of the AAOS Global Research & Reviews. This retrospective study analyzed the 2017-2021 OITE trauma questions to aid orthopaedic students in preparing for the exam. Two independent reviewers analyzed each question’s topic, references, and images. The finding showed that trauma represented 16.6% of the questions, a notable portion of the OITE and an increase over the past ten years.

Dr. Osbahr and his colleagues also published a case report, Little League Shoulder and Subsequent Proximal Humeral Fracture in the Setting of Human Growth Hormone Use, in the JBJS CASE CONNECTOR. This case featured a 16-year-old right-hand dominant male baseball player presenting with little league shoulder in the setting of recombinant growth hormone utilization for growth hormone deficiency. After a prolonged treatment course, including physical therapy and throwing programs, the patient returned to baseball but suffered an ipsilateral proximal humerus fracture around the growth plate. The surgeons concluded that the occurrence of such an injury in the context of human growth hormone treatment merits consideration in youth athletes undergoing similar treatment regimens. They recommended screening pediatric patients with sports-related epiphysiolysis for current or previous growth hormone use because of the possible prognostic implications of such treatment.



Ibrahim Zeini, PhD

In April 2023, **Ibrahim Zeini, PhD**, presented the abstract Perceived Preparedness of Sports Medicine Fellows for Practice at the American Medical Society for Sports Medicine (AMSSM). This survey-based study aimed to determine whether graduating fellows in Primary Care Sports Medicine (PCSM) believe they are prepared for subspecialty practice based on their fellowship training.

The study also sought to qualify perceived preparedness in specific areas of PCSM practice. The survey showed that graduating PCSM fellows feel at least moderately well prepared for subspecialty practice overall. Although this includes nonclinical practice as a whole, they were underprepared for non-sports-specific and non-academic-specific aspects. Dr. Zeini’s academic ecosystem development focus is not limited to fellows. He also published two book chapters and mentored one senior research fellow, six residents and fifteen medical students.

New Investigators



Kassem Ghayyad, MD

Kassem Ghayyad, MD, is an international medical graduate from Lebanon and a research enthusiast in orthopedic surgery. His medical school journey has taken him across borders and continents, shaping his understanding of health care and igniting a passion for research and patient care. He embraced orthopedic surgery rotations in diverse settings, from Egypt’s

bustling hospitals to Prague's historic streets and the USA's leading-edge facilities. These experiences enriched his clinical skills and instilled a deep appreciation for health care's global landscape. Desiring to effect change on a broader scale, he assumed leadership positions such as vice-president of external affairs and supervising the Lebanese Medical Students' International Committee Council. In these roles, he collaborated with diverse stakeholders to advocate for health care policies prioritizing patient well-being and access to quality care.

Dr. Ghayyad is the Senior Research Fellow at Rothman Orthopedics Florida at AdventHealth, where he is immersed in groundbreaking research that seeks to advance orthopedic care and improve patient outcomes. He oversees a comprehensive portfolio of 80+ orthopedic research projects, collaborating closely with a multidisciplinary team. He orchestrates facets of each project while mentoring two other full-time research fellows, six medical student research interns, and ten part-time research volunteers. Emphasizing innovation, he works alongside esteemed mentors who provide invaluable insight, expertise, and support to translate the best ideas into tangible outcomes through competitive grant applications.



George Richard, MD

George Richard, MD, a Central Florida native, graduated from the University of Florida with a Bachelor of Science and earned his medical doctorate at the University of South Florida College of Medicine, where he was inducted into the Alpha Omega Alpha honor society. He completed an Orthopaedic Surgery residency at the University of Florida and an Orthopaedic Surgery Sports Medicine Fellowship at the prestigious American Sports Medicine Institute (ASMI) in Birmingham, Alabama, training with E. Lyle Cain MD, Jeffery R. Dugas MD, Benton A. Emblom MD, and James R. Andrews MD. He was the team Physician for Tuskegee University, Vestavia Hills High School, the SEC baseball tournament, and the Birmingham Barons during his fellowship. He also provided care to the Birmingham Stallions and Alabama Ballet. Dr. Richard is heavily invested in education and sports medicine research. He has published peer-reviewed journal articles and written book chapters and won awards for his education of residents and research into ulnar collateral ligament injuries. He is a reviewer for the American Journal of Sports Medicine and the Orthopaedic Journal of Sports Medicine and an active member of the American Orthopaedic Society for Sports Medicine.

Dr. Richard appreciates the value of physical therapy, rehabilitation, and teamwork in communicating with other medical providers and physical therapists to ensure his patients get comprehensive orthopedic treatment.



Ram Yakkanti, MD

Ram Yakkanti, MD, is a fellowship-trained Orthopedic Surgeon specializing in primary and revision hip and knee replacement. He is an expert in outpatient total joint and partial knee replacements, using advanced technologies to achieve optimal patient outcomes. Dr. Yakkanti earned his medical degree from the University of Louisville School of Medicine and received the O.J. Hurt Orthopedic Excellence Award bestowed on the top graduating Orthopedic student. He completed his Orthopedic surgery residency at the University of Miami/Jackson Memorial Hospital Residency Program, where he earned numerous national and regional awards for his clinical excellence and research, including the H. Clayton Thomas Research Award, McCollister Everts Leadership Nomination, SAMA Research Award, the 2022 Outstanding Senior Resident Award, and the University of Miami Award of Research Excellence. Dr. Yakkanti completed a Hip and Knee Replacement fellowship training with world leaders at the prestigious Rothman Orthopaedic Institute in Philadelphia, where he participated in over 600 surgeries, including complex primary and revision surgeries.

He frequently presents at premier orthopedic conferences, including the American Academy of Orthopedic Surgeons and the American Association of Hip and Knee Surgeons. In addition, Dr. Yakkanti has been invited to present his work at international conferences and appear on international panels. His research has contributed to over 40 peer-reviewed publications and multiple grants, including the esteemed OREF Total Joint Replacement Grant, and over 60 oral and poster presentations. He continues pursuing patient-centric research by serving as the Associate Director of Orthopedic Research at the Rothman Institute/Advent Health Orlando and as a reviewer for the Journal of Arthroplasty.

Dr. Yakkanti is dedicated to the highest standards in patient care and furthering the field of joint replacement through his research efforts. His top priority is providing empathetic and personalized care to his patients while utilizing modern techniques and technology to present them with the most evidence-based and leading-edge treatment options.

Pharmacy Investigational Drug Services (IDS)

Overview

The Investigational Drugs Service (IDS) supports medication-related clinical trials while continuously innovating and leveraging technology to improve efficiency and patient safety. Many patient-care software programs are not designed to accommodate the information required for capturing accurate data outcomes with investigational drugs. The IDS's priorities and goals aim to maximize information related to investigational drugs in the electronic health record and intravenous compounding safety software to ensure accuracy and patient safety.

The department works with vendors and local pharmacy informatics to improve the quality of information and ensure the electronic health record and intravenous compounding safety software capture data that accurately reflects the investigational product. In addition, the intravenous compounding safety data captures real-time photographs of each step along the compounding process, which are viewable to a validating pharmacist located outside the cleanroom. This feature improves efficiency and reduces bioburden within cleanrooms.

“Our experience and efforts with intravenous compounding safety software will be shared with other research pharmacies across the globe.”

— Rebecca Prevost, Sr. Manager, Investigational Drug Services





Pharmacy Technician utilizing intravenous compounding safety software in the cleanroom



Photographs of intravenous investigational medication preparation validation viewable by the pharmacist external to the cleanroom

Translational Research Institute (TRI)

Overview

The Translational Research Institute (TRI) remains at the forefront of medical research, transforming our methods of conducting studies and clinical trials. Its “bench-to-bedside” approach in translational research is a two-way process. First, basic scientists provide clinical researchers with tools and model systems to employ in human studies. Then, clinical researchers make novel observations and conduct clinical trials to understand the nature and progression of the disease. This multidisciplinary, translational approach improves lives through innovation, leading to discoveries and, ultimately, cures.

The TRI’s vision is to develop and conduct world-class translational research addressing diabetes, obesity, the metabolic origins of cardiovascular disease, and aging with diligent respect to AdventHealth’s mission and values. TRI scientists, clinicians, and partners are committed to early-phase clinical studies to understand metabolic disease’s molecular underpinnings. The Institute specializes in proof-of-concept and proof-of-mechanism research studies supported through National Institutes of Health (NIH), Foundations, Biotech, and Pharma-funded projects to enroll and execute scientifically rigorous and high-quality research studies.

Areas of Focus

- Aging and Muscle Wasting
- Exercise and Bioenergetics
- Metabolism and Obesity
- Type 1 Diabetes
- Type 2 Diabetes and Prediabetes

“Through the collaboration among scientists, clinicians and other professionals, the TRI conducts cutting-edge bedside to bench to bioinformatics research into some of most complex diseases and conditions such as aging, obesity, and diabetes. Investment in translational research is an investment into disease prevention, groundbreaking treatment options and eventually cures for our patients and communities.”

— Bret Goodpaster, PhD



Featured Research and Researchers



Karen Corbin, PhD, RD

Karen Corbin, PhD, RD, is an Associate Investigator focusing on how nutrition, energy metabolism and the gut microbiome impacts diseases such as obesity, diabetes and metabolic dysfunction-associated steatotic liver disease (MASLD). Along with a team of scientists from TRI and Arizona State University, Dr. Corbin is the lead author of “*Host-diet-gut microbiome interactions influence human energy*

balance: A randomized clinical trial scientific paper.” In 2023, this study was published in Nature Communications journal and picked up as a story by the Washington Post.



Gut-Microbiome Video

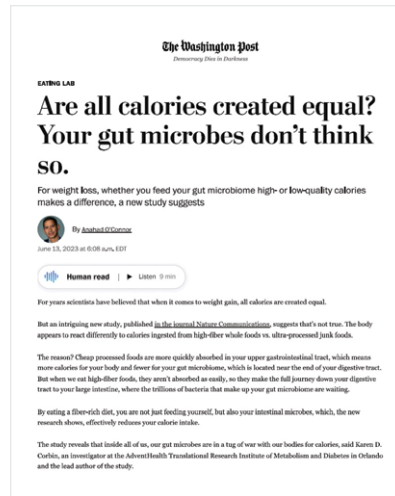


English video



Spanish video

The team discovered that contrary to past scientific beliefs, all calories are not created equal when it comes to weight gain. Why? Foods that are highly processed and lack fiber more quickly “starve” the gut microbes, which means more calories for your body. However, high-fiber whole foods make the full journey down the tract to your large intestine, where trillions of bacteria are waiting. The new research shows that a fiber-rich diet feeds your intestinal microbes, effectively reducing your calorie intake.



Highlights: Host-diet-gut microbiome interactions influence human energy balance: a randomized clinical trial

- The Nature Communications journal listed the article as one of the Top 25 Health Sciences articles of 2023! The Top 25 Health Sciences Articles of 2023 (nature.com)

Scored by Altmetric

- Top 1% of all papers tracked
- Top 2% of papers in Nature Communications journal

2023 Stories

‘Gut Health’ Has a Fatal Flaw — The Atlantic

A Microbiome-friendly Diet Results in Less Calorie Absorption and Could Make it Easier to Achieve and Maintain a Healthy Weight | AdventHealthMD

Can a Healthy Gut Help Solve the Obesity Epidemic? — Medscape.com

2023 Events

• Radio Interview:

- Medical Researcher Dr Karen Corbin on All Calories Are Not Created Equal | KOA 850 AM & 94.1 FM | Ross Kaminsky (iheart.com)

• Podcast Interviews:

- How Diet Can Affect the Gut Microbiome Medical Education on ReachMD (Diabetes Discourse Podcast)
- Diabetes — Optimize Gut Microbiome Through Diet (youtube.com) (Yumlish Podcast)



James DeLany, PhD

AdventHealth Translational Research Institute Senior Investigator **James DeLany, PhD**, is the co-author of the scientific article *Resting and total energy expenditure of patients with long-chain fatty acid oxidation disorders (LC-FAODs)*. The article focuses on medical nutrition therapy for patients with LC-FAODs, which is based on providing adequate energy to maintain anabolism and prevent catabolism. The team measured resting energy expenditure, total energy expenditure and body composition in 31 subjects with LC-FAODs ranging in age from 7 to 64 years. Results suggest that patients with an LC-FAOD exhibit a lower REE and, therefore, have a slightly lower TEE than estimated. The article won the 2023 Emmanuel Shapira Award, established in 2003 to recognize the best paper in the field of biochemical genetics and metabolism published in *Molecular Genetics and Metabolism (MGM)* by a Society for Inherited Metabolic Disorders member or their trainee.

DeLany JP, Horgan A, Gregor A, Vockley J, Harding CO, Gillingham MB. Resting and total energy expenditure of patients with long-chain fatty acid oxidation disorders (LC-FAODs). *Mol Genet Metab.* Mar 2023;138(3):107519. doi:10.1016/j.ymgme.2023.107519 PMC9992335



Richard E. Pratley, MD

Richard E. Pratley, MD, is the Medical Director at the AdventHealth Diabetes Institute and the Diabetes Program Lead of the Translational Research Institute. He is a board-certified internal medicine physician and a nationally recognized diabetes expert with advanced training in gerontology, geriatrics, clinical physiology, and metabolism. Dr. Pratley is the author of the *Cardiorenal outcomes, kidney function, and other safety outcomes with ertugliflozin in older adults with Type 2 diabetes (VERTIS CV)*: secondary analyses from a randomized, double-blind trial article published in *The Lancet, Health Longevity journal*. The VERTIS CV trial evaluated ertugliflozin in adults with Type 2 diabetes and atherosclerotic cardiovascular disease. The analysis reported here aimed to assess cardiorenal outcomes, kidney function, and other safety outcomes. VERTIS CV was done at 567 centers in 34 countries on people with Type 2 diabetes and atherosclerotic cardiovascular disease. The study looked at cardiovascular events, hospitalization for heart failure or cardiovascular death, cardiovascular death, kidney function, and safety. 8246 adults with Type 2 diabetes and atherosclerotic cardiovascular disease were recruited to the study and randomly assigned to receive ertugliflozin 5 mg, ertugliflozin 15 mg, or placebo. Cardiovascular outcomes were more common in older than

younger age subgroups. Ertugliflozin did not increase the risk of major adverse cardiovascular events, cardiovascular death or hospitalization for heart failure, cardiovascular death alone, or the kidney composite outcome. The effects of ertugliflozin on cardiorenal outcomes, kidney function, and safety outcomes were generally similar across age subgroups. These results can potentially help clinical decision-making by providing a longer-term evaluation of the cardiorenal safety and overall tolerability of ertugliflozin in a large population of older adults. The study is registered with ClinicalTrials.gov, NCT01986881.

Pratley RE, Cannon CP, Cherney DZI, Cosentino F, McGuire DK, Essex MN, Lawrence D, Jones PLS, Liu J, Adamsons I, Dagogo-Jack S. Cardiorenal outcomes, kidney function, and other safety outcomes with ertugliflozin in older adults with type 2 diabetes (VERTIS CV): secondary analyses from a randomised, double-blind trial. *Lancet Healthy Longevity.* Doi:10.1016/S2666-7568(23)00032-6

Bret Goodpaster, MD, 2023 Highlights

- Ranked #64 in the 300 Top Scientific Contributors to Gerontology as referenced in the Journals of Gerontology Series A:

Disciplinary Roots of 300 Top-Ranked Scientific Contributors to Gerontology: From Legacy to Enriching Our Discovery. DOI: 10.1093/gerona/glac129

- Ranked #51 in the 100 Most Cited Publications in Aging Research as referenced in the electronic Journal of General Medicine:

Haroon, Yu-Xin Li, Chen-Xu Ye, Tauseef Ahmad, Muhammad Khan, Imranullah Shah, Xiao-Hong Su, Lian-Xi Xing. The 100 Most Cited Publications in Aging Research: A Bibliometric Analysis. *Electronic Journal of General Medicine.* DOI: 10.29333/ejgm/11413

Bret H Goodpaster, Seok Won Park, Tamara B Harris, Steven B Kritchevsky, Michael Nevitt, Ann V Schwartz, Eleanor M Simonsick, Frances A Tylavsky, Marjolein Visser, Anne B Newman. The loss of skeletal muscle strength, mass, and quality in older adults: the health, aging and body composition study. *The Journals of Gerontology. Series A Biological Sciences and Medical Sciences.* DOI: 10.1093/gerona/61.10.1059



Bret Goodpaster, PhD



Transplant Institute

Overview

The AdventHealth Transplant Institute comprises a nationally recognized health care team dedicated to advancing treatment for organ failure and transplantation care for patients in Central Florida and nationwide. We strive to be the destination of choice for complex organ disease and transplantation by delivering clinically superior, innovative and individualized care to improve the quality of our patients' lives. The institute's researchers strategically select protocols that offer new or improved treatments that would not otherwise be available to patients.

The AdventHealth Transplant Institute is home to Orlando's only Transplant Program.

Since 1973, the institute has performed more than 6,000 organ transplants thanks to the many donors who gave the gift of life to our patients. With one of the nation's oldest and largest kidney transplant programs, we offer the only Living Donor Program in Central Florida.

Areas of Focus

- Advanced Heart Failure
- Advanced Liver Failure
- Advanced Lung Failure
- Heart Transplant
- Liver Transplant
- Lung Transplant
- Mechanical Circulatory Support (MCS)

"We have the latest technology in heart transplant and left ventricular assist device space and offer state-of-the-art care for our patients."

— Ahmad Zeeshan, MD

Featured Researchers and Research



Martin Zemora, MD
*Lung Transplant
Medical Director*

Martin Zemora, MD, is a Board-certified Transplant Pulmonologist with a distinguished 40+ year medical career. He earned his medical degree at the University of Colorado Medical School in Aurora, Colorado. He completed an internship and residency in internal medicine at the University of Colorado Health Sciences Center, followed by clinical and research fellowships in pulmonary and critical care medicine. Named one of The Best Doctors in America almost every year since 1996, Dr. Zamora also served as the medical director of the University of Colorado's Lung Transplant program. He has a special clinical interest in connective tissue diseases of the lung, pulmonary hypertension, viral infections, and ischemia-reperfusion injury post-lung transplant. He received numerous research grants and holds four patents.



Shady Guirguis, MD

Shady Guirguis, MD, is trained in the care of patients with liver disease and those in need of liver transplantation. His clinical specialties include advanced hepatology, liver transplantation and endoscopy. Dr. Guirguis completed his internal medicine residency at Lincoln Medical Center in New York. He went on to complete a fellowship in advanced hepatology and liver transplantation at Thomas Jefferson University Hospital in Philadelphia where his training also included upper and lower full-luminal endoscopy methods. Dr. Guirguis sees patients both pre and post-transplant to ensure proper healing is taking place. He is a member of the American College of Gastroenterology, the American College of Physicians and the American Association for Study of Liver Diseases.



Onix Cantres-Fonseca, MD

Onix Cantres-Fonseca, MD, is a Board-certified advanced lung disease and lung transplant physician. Dr. Cantres-Fonseca completed fellowship training in advanced lung disease and lung transplantation at Inova Vascular Institute in Fairfax, Virginia and a pulmonary and critical care fellowship at the VA Caribbean Healthcare System in San Juan, Puerto Rico. He received his medical degree in internal medicine at the University of Puerto Rico School of Medicine, Medical Sciences Campus, Rio Piedras, Puerto Rico, where he graduated Magna Cum Laude. With over ten years of experience as chief of staff at the Department of Veteran Affairs in San Juan, Puerto Rico, he was named the Faculty of the Year in 2019 and 2021.

Cantres' research centers on advanced lung disease and transplant and pulmonary hypertension and will greatly contribute to the Transplant Institute's broad research and clinical capabilities.

AHRI in the Great Lakes Region

Overview

The University of Chicago Medicine and AdventHealth have closed on a transaction to form a joint venture called UChicago Medicine AdventHealth. The new organization will provide academic medicine in the western suburbs of Chicago. Under the new joint venture, UChicago Medicine gains a controlling interest in AdventHealth’s Great Lakes Region. AdventHealth retains the remaining ownership and will continue to manage the daily operations of all facilities.

The University of Chicago Medical Center and AdventHealth Great Lakes partnership builds on the two organizations’ complementary strengths with UChicago Medicine’s national reputation as an academic health system and AdventHealth’s focus on delivering outstanding medical care in community settings. “The biggest benefit of this partnership is to patients,” said Tom Jackiewicz, president of the University of Chicago Medical Center, the hub of the UChicago Medicine health system. This collaboration will allow seamless access to specialty and subspecialty care and the latest clinical trials to patients in the greater Chicagoland area.”

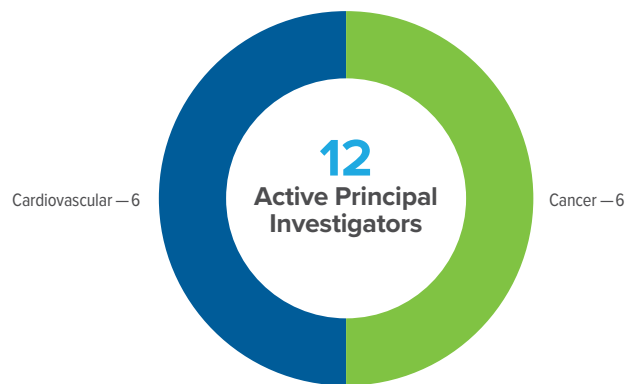
Sandra Valaitis, MD, has been appointed UChicago Medicine’s Chief Physician for the affiliation and will work closely with Bela Nand, MD, Chief Medical Officer at UChicago Medicine AdventHealth Hinsdale and La Grange. “With the launch of this affiliation, we are blessed to continue to build on the rich legacy of whole-person care and further our mission and commitment to making these communities healthier for years to come,” said Terry Shaw, president and CEO of AdventHealth.

Areas of Focus

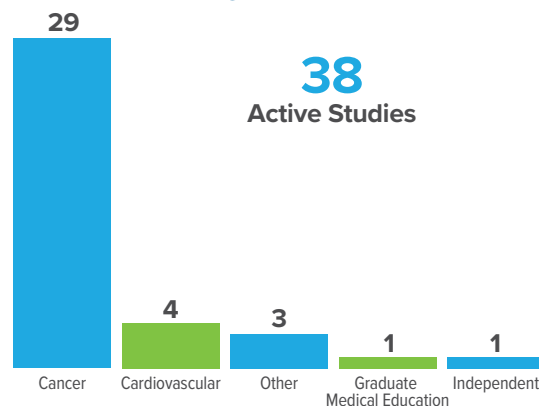
- Cardiovascular
- Oncology

By the Numbers

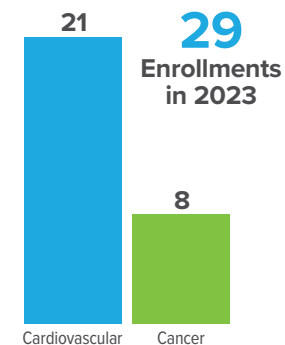
Active Principal Investigators in the Great Lakes Region



Active Studies in the Great Lakes Region



2023 New Enrollments in the Great Lakes Region



“AdventHealth Oncology carries a tradition of excellence in cancer care, not just for the current standard of care treatment but also for pushing the standard with well-conducted clinical trials to improve outcomes for tomorrow’s patients. The collaboration with UChicago Medicine, a Comprehensive Cancer Network member, will further expand that mission in the Great Lakes region.

I look forward to our integration to give the patients in our region access to some of the top clinical research trials in the world, right here in their community.”

— Jay Dalal, MD

Featured Researchers and Research

After more than 100 cycles on the “MAGNIFY” Trial, Ray celebrates this big milestone with our PI, **Jay Dalal, MD**, and his clinical staff enjoying cupcakes decorated with a sparkling “100” topper.

Ray’s journey initially began while being treated for follicular lymphoma long before he was enrolled in a Clinical Trial. “Eighteen months after Dr. Jay Dalal’s initial declaration that I was in remission, my follicular lymphoma returned. This early recurrence was disappointing,” Ray said.

Ray expresses, “Dr. Dalal outlined an initial treatment plan but encouraged me to seek a second opinion, which was easy to do with five teaching hospitals in Greater Chicago. The second opinion offered to me was an overly aggressive treatment plan. In the meantime, Dr. Dalal researched other options. He learned about a drug being trialed for follicular lymphoma called lenalidomide, which held promise. I was enrolled in a clinical trial through Dr. Dalal’s advocacy and have been in complete remission for over eight years. Because of the drug’s success with patients like me, lenalidomide is now fully approved by the FDA for use in follicular lymphoma in combination with rituximab.”

A Phase 3b Randomized Study of Lenalidomide (CC-5013) Plus Rituximab Maintenance Therapy Followed By Lenalidomide Single Agent Maintenance Versus Rituximab Maintenance In Subjects With Relapsed/Refractory Follicular, Marginal Zone or Mantle Cell Lymphoma — The Magnify trial has only a handful of patients worldwide who continue to follow up on the study.



From left to right: Patient Ray & Jay Dalal, MD

Ray happens to be one of them. We are pleased to continue caring for Ray and appreciate his years of commitment to contributing to Oncology Research.

“I am forever grateful for Dr. Dalal’s intellectual curiosity. He has always treated me as an individual first and understands that cancer treatment is not ‘one-size-fits-all.’” I firmly believe that because of Dr. Dalal’s individualized care plan and the availability of a clinical trial, I have no evidence of disease and have a great quality of life today.”



Meechai Tessalee, MD, FACC, FSCAI

Meechai Tessalee, MD, FACC, FSCAI, is an interventional cardiologist focused on providing clinical patient care, serving hospital committees, and overseeing family medicine resident learning. Since 2017, Dr. Tessalee served as the principal investigator on the MINT: Myocardial Ischemia and Transfusion. Patients with acute coronary syndrome (ACS) and a hemoglobin of less than 10 g/dL randomized to one of two transfusion thresholds: 8 g/dL or 10 g/dL study, which closed in 2023. The MINT trial, funded by National Heart Lung Blood Institute, aimed to determine the appropriate blood transfusion strategy in patients with acute myocardial infarction and anemia. We enrolled 3500 patients with acute myocardial infarction with a hemoglobin concentration of less than 10 g/dL to be randomized to either a Liberal (10 g/dL) or Restrictive Transfusion (8 g/dL) Strategy. Patients assigned to the Liberal Strategy received enough blood to maintain a hemoglobin level above 10 g/dL. Except for transfusion decisions, routine clinical care was not affected by the trial. The primary outcome will be all-cause mortality or recurrent myocardial infarction at 30 days post-randomization. Dr. Tessalee co-authored the MINT results article published in the New England Journal of Medicine in November 2023.

Carson JL, Brooks MM, Hébert PC, Goodman SG, Bertolet M, Glynn SA, Chaitman BR, Simon T, Lopes RD, Goldsweig AM, DeFilippis AP, Abbott JD, Potter BJ, Carrier FM, Rao SV, Cooper HA, Ghafghazi S, Fergusson DA, Kostis WJ, Noveck H, Kim S, **Tessalee M**, et.al.; MINT Investigators. Restrictive or Liberal Transfusion Strategy in Myocardial Infarction and Anemia. New England Journal of Medicine. DOI: 10.1056/NEJMoa2307983

AdventHealth Great Lakes Cardiovascular Research Site | MINT Study Highlights

- #3 in enrollment in the United States with 181 patients enrolled
- The study results were presented at the American Heart Association (AHA)

AHRI in the West Florida Division

Overview

AdventHealth’s West Florida Division supports some of the nation’s brightest medical minds, collaborating with surgical pioneers, scientists and researchers to spark lifesaving breakthroughs. Using leading technology and innovation to deliver our standard of whole-person care, the research network of care includes AdventHealth Tampa and AdventHealth Ocala. Getting care at AdventHealth means getting access to the latest research studies, procedures and technologies available, including access to medical, surgical and device-related clinical trials. The Digestive Health Institute is one example of AdventHealth’s efforts to advance patient care through leading-edge, patient-focused research. The goal is to understand study interests and expand the portfolio. **Finding tomorrow’s medical breakthroughs starts with today’s research.**

Areas of Focus

- Cardiology
- Digestive Health

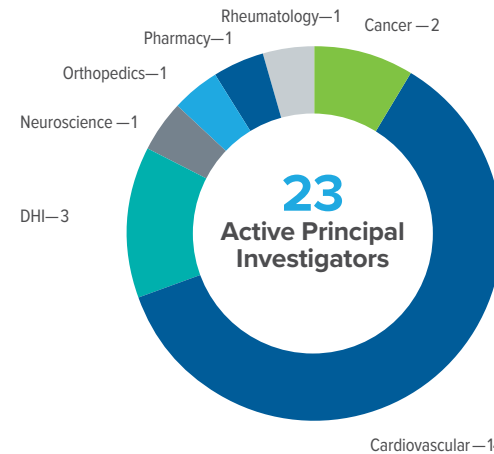
“Our institute fosters research and innovation by encouraging young people to get involved in our clinical research through the summer programs, which gives them opportunities to co-author and present their work at academic meetings. Our research also enhances improved clinical outcomes in robotic Hepatopancreatobiliary surgery (HPB).

We invest in talent by training our fellows and residents in robotic complex hepatobiliary surgery that other institutions across the U.S. do not generally offer. This is to elevate the clinical outcome research associated with this work and increase the number of HPB surgeons available to care for patients nationwide.”

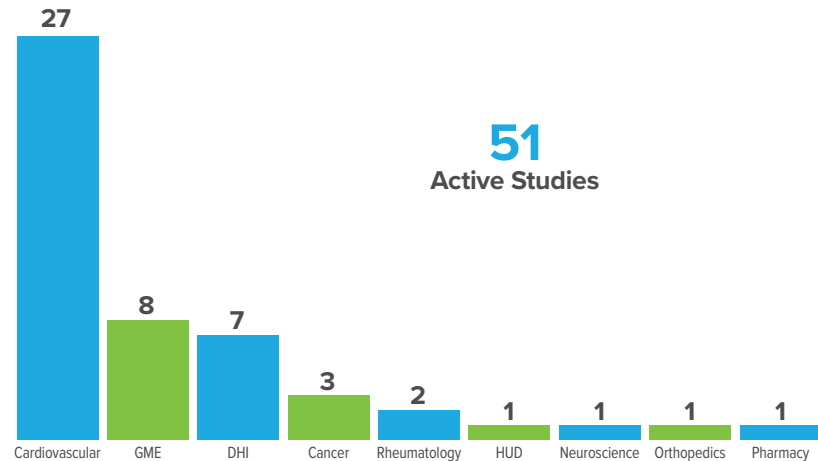
— Iswanto Sucandy, MD

By the Numbers

Active Principal Investigators in the West Florida Division



Active Studies in the West Florida Division



Featured Researchers and Research



Charles R. Lambert, Jr., MD, PhD,

Charles R. Lambert, Jr., MD, PhD, is the Medical Director of the Cardiovascular Institute and the Scientific Director for the Research Institute at West Florida. He is board certified in internal medicine, cardiovascular disease and interventional cardiology and certified by the American Association for Physician Leadership. Dr. Lambert also serves as a fellow in several well-known medical associations, like the American College of Cardiology and the American Heart Association. His research interests have included basic myocardial energetics, cellular electrophysiology, coronary disease pathophysiology, cardiovascular disease pharmacotherapy and interventional cardiology device development. Dr. Lambert has received research support from the National Institutes of Health, Department of Defense, the American Heart Association and many industry and private sponsors. Dr. Lambert have been instrumental in the relaunch of clinical research at West Florida.”



Oliver Abela, MD

Oliver Abela, MD, is a board-certified cardiologist who is dual sub-specialized in Interventional Cardiology and Advanced Heart Failure. He has a special interest in the mechanism of plaque rupture involving cholesterol crystals, streamlining care in acute myocardial infarction, Percutaneous Coronary intervention (PCI), high-risk PCI, chronic total occlusion PCI, cardiogenic shock, mechanical circulatory support, right ventricular dysfunction and structural heart disease. Dr. Abela currently has STEMI DTU open to enrollment and hopes to bring more clinical research trials to AdventHealth Tampa. This study is groundbreaking in evaluating whether using the Impella CP® System or the Impella CP® with SmartAssist® System (a temporary circulatory assist device) before the catheterization procedure has the potential to reduce the damage to your heart caused by a heart attack compared to the current standard of care. “We have added five sub investigators to the trial and I expect enrollments to increase,” said Dr. Abela.



Sharona Ross, MD



Iswanto Sucandy, MD

Board-certified advanced Foregut and HPB surgeon **Sharona Ross, MD,** is a highly experienced board-certified surgeon with dual fellowship training in Hepatobiliary and Pancreatic Surgery and Advanced Gastrointestinal Minimally Invasive Surgery. Dr. Ross and **Iswanto Sucandy, MD,** are the co-authors of “A Decade of Experience with Minimally Invasive Anti-Reflux Operations: Robot vs. LESS.” This study compares the efficacy of robotic and Laparo-Endoscopic Single-Site (LESS) approaches in anti-reflux operations over a decade. It includes data from 228 robotic and 518 LESS fundoplication patients, examining perioperative metrics like age, BMI, previous surgeries, and operation times. Despite the robotic approach involving older patients with more complex conditions, such as type IV or recurrent hiatal hernias, and longer operative times and length of stay, LESS significantly improved patient outcomes, especially in managing more challenging cases. The LESS approach, meanwhile, showed better cosmesis and shorter procedure times, suggesting its suitability for less complex surgeries. The study concludes both methods are effective but should be chosen based on the specific clinical scenario.

Sharona B Ross, Iswanto Sucandy, Michael Trotto, Maria Christodoulou, Tara M Pattilachan, Jenna Jattan, Alexander S Rosemurgy. A Decade of Experience with Minimally Invasive Anti-Reflux Operations: Robot vs. LESS. Surgical Endoscopy. DOI: 10.1007/s00464-024-10771-5

New Investigators

Electrophysiology



Paul Gerczuk, MD

Paul Gerczuk, MD, has extensive experience caring for patients experiencing a wide range of conditions, including atrial fibrillation and heart palpitations. Specializing in medical and procedural treatments, Dr. Gerczuk provides each patient with a comprehensive treatment plan tailored to their specific needs.

Dr. Gerczuk is fellowship-trained in general cardiology, cardiac electrophysiology, and cardiovascular research. His particular area of interest is diagnosing and managing heart rhythm disorders. Dr. Gerczuk can identify abnormalities and determine the most effective treatment methods by studying the heart's electrical activity. Dr. Gerczuk's research focuses on pacemakers, defibrillators, atrial fibrillation ablation, and watchman implants.



Giancarlo Speziani, MD

Giancarlo Speziani, MD, is a board-certified cardiologist who earned his medical degree and then completed his initial residency training in internal medicine at the University of South Florida. Dr. Speziani says, "I chose to do research to enhance my expertise in managing and ablating cardiac arrhythmias, such as atrial fibrillation, ventricular tachycardia, and supraventricular arrhythmias, and managing and

implanting all types of cardiac devices, including the newest and smallest line of pacemakers. AdventHealth has a great research program that will help facilitate sponsorships. Coming to AdventHealth Tampa has been amazing following my incredible research experiences at AdventHealth Orlando. I hope to grow the electrophysiology aspect here with the research team and hospital leaders."



Kenneth Yamamura, MD, FACC

Kenneth Yamamura, MD, FACC, is a board-certified cardiologist specializing in cardiology and clinical cardiac electrophysiology. Dr. Yamamura completed his undergraduate studies at Emory University in Atlanta, Georgia, before attending the University of Miami's School of Medicine, where he was elected to the Alpha Omega Alpha National Honor Society. Dr. Yamamura continued post-graduate studies at Jackson Memorial Hospital in Miami, Florida. While there, he completed his internship, residency, and Cardiology fellowship before completing a specialized fellowship in Clinical Cardiac Electrophysiology. Dr. Yamamura is the Director of Electrophysiology at Advent Health Tampa and a Fellow of the American College of Cardiology and Heart Rhythm Society.

Dr. Yamamura has over 20 years of clinical experience and practices all areas of cardiac electrophysiology, including device implantation and ablation of cardiac arrhythmias (atrial fibrillation, atrial flutter, SVT, PVCs, and ventricular tachycardia). His research focuses on treating atrial fibrillation with ablation for both paroxysmal and persistent forms of the disease, including the implantation of the WATCHMAN device, device therapy for congestive heart failure with cardiac resynchronization therapy, and physiologic pacemaker implantation utilizing HIS Bundle and Left Bundle area pacing.

Interventional Cardiology



Hadi Mahmaljy, MD, RPVI

Hadi Mahmaljy, MD, RPVI, completed internal medicine training at the Southern University of Illinois in Springfield, Illinois, and a cardiovascular fellowship at Geisinger Commonwealth in Danville, Pennsylvania. Then, he completed interventional and peripheral vascular training at the University of Connecticut at Hartford Hospital. Dr. Mahmaljy conducts research in complex coronary artery disease and peripheral vascular disease. He is board-certified in internal medicine, cardiovascular disease, interventional cardiology, echocardiography, nuclear cardiology, and vascular imaging.



Alejandro Michel, MD

Alejandro Michel, MD, is a specialist with 45 years of experience in Cardiology and Cardiovascular Disease and a staff physician at Tampa Community Hospital. Dr. Michel completed his medical school training at Universidad De Buenos Aires. He completed his internship and residency at Mercy Hospital. Dr. Michel completed his fellowship at Albany Medical College. His specialties include Cardiovascular Disease, Internal Medicine, and Interventional Cardiology. Dr. Michel's research focuses on treating heart failure, coronary artery disease, and chronic high blood pressure.



Tariq Salman, MD

Tariq Salman, MD, is a board-certified cardiologist with nearly 20 years of medical experience. He received his medical degree from Wayne State University School of Medicine. Dr. Salman is an expert in treating heart valve surgery, coronary artery disease, and chronic high blood pressure, among other conditions. He conducts research in Conduction Disorders, Aortic Valvular Disease, Mitral Valvular Disease, and Acute Myocardial Infarction (AMI)



Mohammadreza Tabesh, MD

Mohammadreza Tabesh, MD, is a cardiologist with over 21 years of experience in Cardiovascular Disease, Internal Medicine, and Interventional Cardiology. He graduated from Johns Hopkins School of Medicine in 2002. Dr. Tabesh's research includes Heart Failure, Aortic Regurgitation, Acute Myocardial Infarction (AMI), Paroxysmal Supraventricular Tachycardia (PSVT), and ischemic heart disease.

Vascular Cardiology



Diego Ayo, MD, RPVI,

Diego Ayo, MD, RPVI, is a board-certified vascular surgeon specializing in minimally invasive complex tertiary care vascular disease options. He also has an outpatient office-based vein practice where he performs the latest varicose veins and chronic venous disease treatments. Dr. Ayo's research includes minimally invasive options for complex tertiary care vascular disease and the latest varicose veins and chronic venous disease treatments.



Octavio Cosme-Montalvo, MD

Octavio Cosme-Montalvo, MD, is an interventional cardiology specialist with more than 34 years of experience in the medical field and a wealth of experience and expertise in interventional cardiac procedures and heart conditions. Dr. Cosme graduated from the San Juan Bautista School of Medicine in 1988. "I am fascinated to participate in research and contribute my knowledge in structural heart, cardiology, and pulmonary emboli clinical research. I hope to bring my passion for clinical research and more opportunities for patent participation to AdventHealth Tampa."



The Office of the Vice President of Research

Through our centralized services and research operations, the AdventHealth Research Institute (AHRI) orchestrates a vibrant research enterprise of thought leaders, clinical program experts and infrastructure to integrate scientific discoveries into clinical workstreams and enhance health care delivery to patients and the community. The Research Institute supports more than 850 active clinical studies, placing AdventHealth at the forefront of novel treatment options for current and future patients. This capability opens the door to accelerate destination programs and develop nationally leading centers of excellence across all major treatment areas and institutes.

The visibility and strength of a fully functioning and productive research program and infrastructure are vital to recruiting clinical leadership from nationally prominent academic medical centers. Most of these experts require a robust clinical environment and an opportunity to test their innovative ideas in a research milieu and how we contribute to the Center of Excellence and accreditations.

Our research leaders are engaged in a transformational journey to exceed standards that will achieve industry-leading results through world-class clinical research. Through this work, a better treatment option will be available at every stage of disease, growth and discovery will be enabled for clinical investigators and teams, and there will be a reduction in cycle time for discovery.

The Office of the Vice President encompasses Research Administration, Research Services, Research Operations, Research Data Services Core and the Center for Academic Research Excellence (CARE). Each department fulfills a different yet critical function in our research infrastructure, aligning with our commitment to achieving better outcomes within our organization and beyond through our commitment to diversity, equity and inclusion, including our workforce, study methods and data.



Participates in more than 770 clinical studies annually



Supports 180 active principal investigators



Won 17 grant awards in 2023

US News & World Report
Best children's hospital for newborn care in Florida

Level 1 Children's Surgery Center by American College of Surgeons

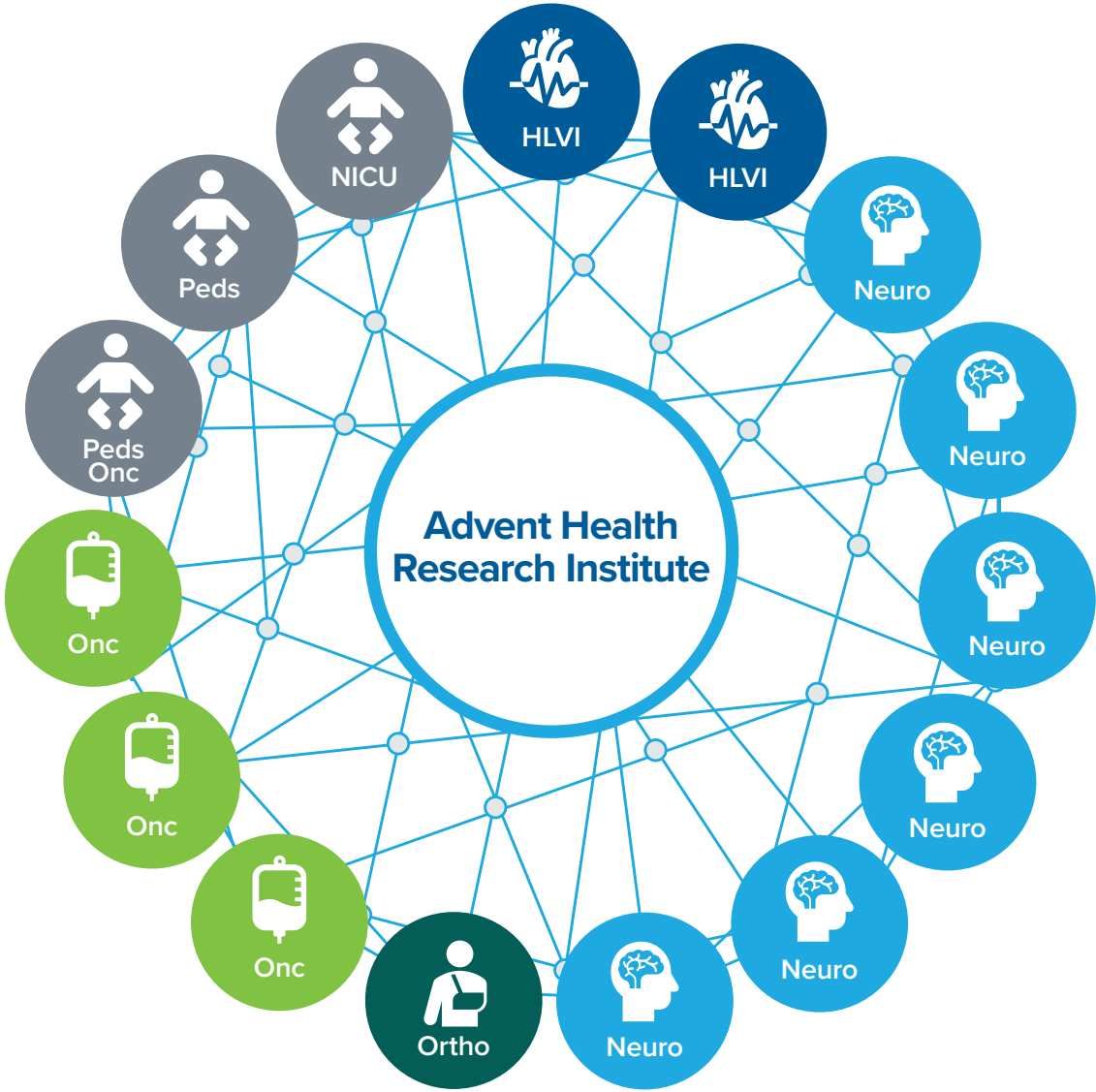
Children's Oncology Group

Lymphedema COE**

National Accreditation Program for Breast Centers

American Society of Clinical Oncology

Orthopedic Surgery Residency Program



GME Cardiovascular Disease Fellowship Program

PH Center of Comprehensive Care

DNV Comprehensive Stroke Center

Huntington's Disease Society of America

Hereditary Neuropathy Foundation (HNF)

State-Designated Memory Disorder Clinic

Muscular Dystrophy Association (MDA)

Commission on Accreditation of Rehabilitation Facilities

System Support

Research Administration

The Research Administration team provides a standardized infrastructure to support the research enterprise across the organization, through embedded administrative team members to support operational activities and a centralized team focused on building a positive culture for our work environment. Research Administration implements engagement activities such as research-wide townhall meetings, Clinical Trials Awareness day celebration and various internal communications to ensure our team feels connected to the research vision, no matter where they are located. Research Administration collaborates with AHRI leaders to coordinate onboarding activities for all research team members, including non-employed partners, consultants, and research Learners.

Business Development

Business Development initiates, establishes, and supports relationships with research sponsors and partners to access innovative therapies and medical devices that benefit AdventHealth patients. The department develops growth strategies designed for long-term profitability. It builds external relationships with stakeholders, while partnering with companies, manufacturers, and medical professionals to transform health care by implementing highly specialized clinical trials.

AdventHealth Research Institute Oncology Pipeline Series

AHRI's Business Development department hosted the 10th Annual AdventHealth Research Institute — Oncology Pipeline Series. The event allowed pharmaceutical partners to engage with physicians and research leadership to present their latest clinical trials and early pipeline assets.

The Business Development team led tours of the Clinical Research Unit (CRU) and the Nicholson Center in Celebration, Florida, and the AdventHealth main campus,



From left to right: Guru Sonpavde, MD, Mark Socinski, MD, Carlos Alemany, MD, Julien Nogues, MBA

Innovation Tower, and the Translational Research Institute (TRI) in Orlando. More than 20 pharmaceutical companies participated in tours and attended the pipeline networking event, connecting with physician investigators, scientists, research leadership, business development, and study intake operations teams.

Research Services

Research Services comprises the Office of Research Integrity and Compliance, Office of Sponsored Programs, and Office of Intellectual Property Development, which support our clinical operations teams and investigators in research, from early pre-clinical to grants and clinical trials. Research Services is central to ensuring regulatory compliance and securing financial and contractual support.

Office of Research Integrity and Compliance (ORIC)

- Ensures all researchers and team members comply with regulatory requirements governing research, including study conduct and billing
- Collaborates across the institution to foster communication, align policies and procedures, train investigators and staff and build an integrated and robust compliance system
- Facilitates the AdventHealth Institutional Review Board (IRB), which reviews and evaluates ethical standards, scientific merit, regulatory compliance, human subjects research rights and welfare protections

Office of Sponsored Programs (OSP)

- Offers research-related agreements, budget and system support and compliant grant processing to help researchers manage funding, data and biospecimens for their studies
- Determines appropriate payors and applicable compliance guidelines, policies and regulations for items and services provided to participating study subjects

Research Operations

The Research Operations department is grouped into various research teams and orchestrates the operational structure to evaluate and execute AHRI clinical trials and research studies. Built with subject-matter expertise in our therapeutic areas, Research Operations collaborates with other investigators and AdventHealth departments to select financially and operationally feasible opportunities and develop trial and study portfolios targeted to address the barriers to health and wholeness in the communities we serve. Our experienced, physician-led research teams interrogate breakthrough compounds, trial lifesaving surgical techniques, and develop whole-person care treatment methods to improve quality of life for the entire lifespan, from NICU babies to mature adults. Participant safety and clinical advancement receive the highest priority.

Our equipment and facilities include:

- Central Processing laboratory containing advanced research instrumentation, systems, and resources to conduct advanced trials and studies
- Molecular Biology Analysis instruments for cancer biomarker analysis and tumor tissue processing and review
- Biorepository
- Research Laboratory
- Metabolomics Core
- Clinical Research Unit
- Nutrition Core
- Energy, Metabolism, and Calorimetry Core
- Exercise and Bioenergetic Laboratory

Research Data Services Core

The Research Data Services Core (RDSC) supports the data needs of AdventHealth's research partnerships. The RDSC works closely with our investigators and clinical operations teams, delivering a portfolio of data products and capabilities that support research initiatives. The team is shaping AHRI's Real-World Evidence strategy (RWE) to drive the best possible health care outcomes. By leveraging Real-World Data (RWD), researchers can access large sample sizes that enable an analysis of subpopulations and less common effects, which can be difficult in traditional randomized controlled trials.

The Research Data Services Core:

- Strengthens clinical trial accrual through EHR data extracts and reporting
- Serves as the Honest Broker, delivering analysis-ready data sets
- Enables decision-grade Real-World Evidence
- Informs study intake with data-driven feasibility analysis
- Manages electronic data capture systems and activities
- Facilitates secure data transfers between partner organizations

Investigator Support

Center for Academic Research Excellence (CARE)

The Center for Academic Research Excellence (CARE) consists of a team of scientists, mentors, biostatisticians, and research professionals engaged in research to meet some of the biggest challenges in health care.

Projects focus on changing patient care, enriching patient interactions, and improving clinical outcomes. In addition, CARE provides statistical support services and consultations on study design for all AdventHealth-aligned research departments. Through our partnership with faculty, fellows, residents, medical students, and nursing doctoral candidates, CARE also impacts our community of clinical learners by enhancing the quality of their research projects. The CARE team supports graduate medical education (GME) learners, AHU students and faculty.

The CARE Team:

- Addresses evolving needs of health care research
- Conducts data-driven research to meet challenges
- Collaborates with fellow data scientists
- Partners with industry for mutually beneficial projects
- Supports faculty and student academic research
- Brings together statisticians to form a stronger core



Philanthropy

Donations Accelerate Research

Philanthropic contributions empower us to help more people live their best, most vibrant lives. Donations from generous community members advance research capabilities across our vast network, making AdventHealth an ideal platform to increase access to clinical trials and support translational studies that lead to cures.

As one of Florida's largest health care providers nationwide, AdventHealth's commitment to excellence is evident in our clinical outcomes and relentless pursuit of innovation and more personalized care. Donors have a unique opportunity to revolutionize care delivery and impact the health and well-being of this and future generations by supporting AdventHealth Research Institute.

There are many ways to offer support, such as an annual contribution, a multi-year pledge, event sponsorship, or a legacy gift. Some of our most dedicated supporters consider making gifts through their will or trust. Other popular giving options include gift annuities, stock or real estate gifts, and IRA rollover contributions. One of the most impactful ways to advance research is by establishing endowed chair positions for promising investigators. An endowed chair enables AdventHealth to attract and retain the best clinicians and researchers by providing a permanent, stable funding source. They can be named to honor the donor or a loved one and exist in perpetuity while recognizing a family's legacy of generosity.

Generosity Heals

Join us today in Extending the Healing Ministry of Christ by advancing scientific discovery that will help more people experience a life of whole health. Contact AdventHealth Foundation Central Florida at 407-303-2784 or ResearchGive@AdventHealth.com to learn more.

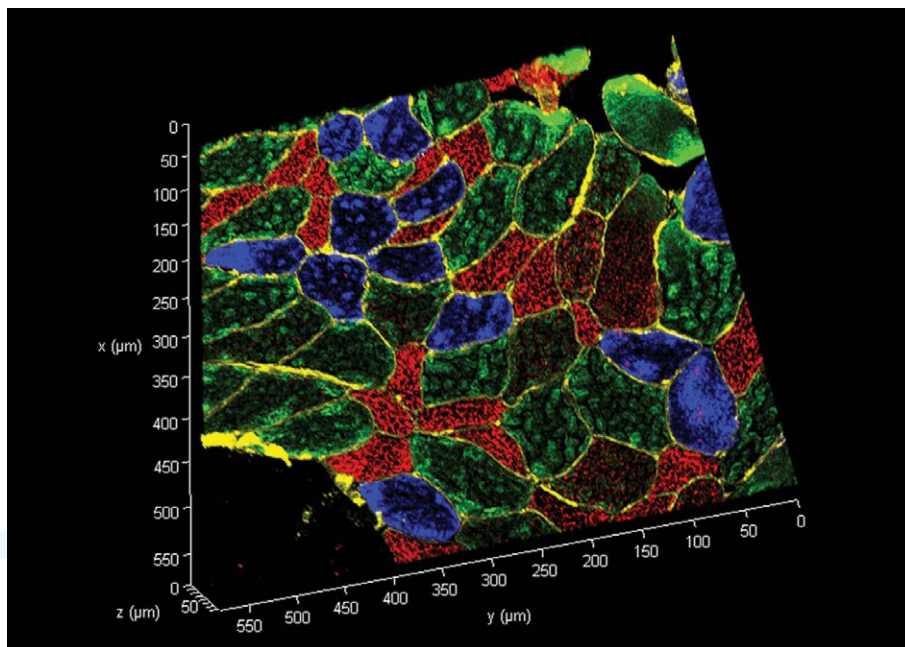


Scan to Give

Expanding Capabilities through Donor Support

Confocal Microscopy Technology

Thanks to the generosity of many, we continue to advance research capabilities at the AdventHealth Translational Research Institute with a newly acquired, state-of-the-art Confocal Microscope. A collective of donors contributed more than \$800,000 to make this philanthropic achievement possible. This technology will allow scientists to observe intricate cellular details quickly through high-speed resonant scanning, elevating research in cancer biology, diabetes, and metabolism.



Leica Stellaris Confocal image of human Vastus lateralis (skeletal) muscle fibers. A Wheat Germ Agglutinin stain is used to identify the border between fibers (yellow). The other colors indicate the type of muscle fiber based on protein expression; Blue being Type I (characterized by a slow contraction rate with high resistance to fatigue), Red being Type IIx (characterized by a very high contraction rate with low fatigue resistance) and Green are Type IIa (characterized by a fast contraction rate with an intermediate fatigue resistance). Hybrid fibers also exist that may be a mixture of Type I, IIa and IIx (a blend of red, green and blue colors).



From left to right: Grant Jester, MD, Mary Broda



From left to right: Sebastian De La Fuente, MD, Mary Broda

Mary's Fight for Her Life

Mary woke up from an endoscopic ultrasound to find Dr. Yang holding her hand, not realizing she was about to receive the most devastating news of her life. The results confirmed that the abnormalities found in her bloodwork were stage 4 pancreatic cancer.

She was placed under the care of board-certified oncologist Dr. Grant Jester, who encouraged her, "I need you to fight, and we will fight with you." Mary fought for the next 21 days in the hospital, three of those days in the ICU, without knowing if she was going to live or die. When her 15-year-old daughter asked, "Mom, are you dying?" Jolted by the enormity of the situation, she assured her daughter, "No, I'm fighting."

In August, Mary began rigorous chemotherapy at AdventHealth Celebration under Dr. Jester's care. "He was there for me whenever I needed him," Mary reflected. "For the doctors to show that kind of care and concern speaks hugely about AdventHealth as a whole."

By January, Mary had endured 12 rounds of chemotherapy, nine hospital emergencies, and more than 59 days in the hospital. On her 50th birthday, Mary was admitted to the hospital, where Dr. Jester gave her a big hug and delivered the good news that she was now a candidate for a pancreaticoduodenectomy (also known as a Whipple procedure) to remove the tumor, "You deserve this," he said.

Dr. Sebastian De la Fuente led her surgery on February 24 and declared that all her margins were clear. “Go and celebrate. You’re good.” Dr. Jester monitors Mary as she is scanned quarterly for any potential re-occurrence. To this day, she has no evidence of disease.

Thanks to the advances achieved through cancer research and the complex Whipple procedure, Mary’s treatments thus far have helped her return to whole health.

Grateful cancer survivor Mary Broda joined the Race for Cancer Research on May 30 to cheer on athletes and local celebrities leading teams of physicians, cancer patients, and professional gamers with Magic Gaming in an epic game of Mario Kart, which raised more than \$8,000 for cancer research.



[Scan to Watch Mary's Story](#)



Research Participant Recruitment

AHRI's dedicated recruitment team enthusiastically initiates each participant's research journey by facilitating study opportunities, scheduling appointments, maintaining key study participant information databases, and fueling research through marketing, in partnership with community and provider outreach efforts. The AHRI Recruitment Team brings awareness and access to clinical trials and research studies to all.

TRI Internal Contact Center

The Recruitment Core occupies approximately 300 sq. ft. of office space with telephones, facsimile, computers, etc. The four full-time recruiters prescreen study participants and work closely with the clinical research coordinators to schedule screening visit appointments, and communicate with participants via phone, text, email, and mail.

After-Hours Contact Support

Third-party vendors are also contracted for specific studies to aid recruitment efforts. Currently, the Recruitment Core is supported by an additional team of after-hours and weekend call center team members, to increase contact with potential and current research participants.

Partnerships — Research Data Services Core (RDSC)

The RDSC supports recruitment by facilitating data abstracts from the electronic medical record Epic, the clinical trial management database, the research volunteer campaign database, dashboards, and data warehouses to help determine patient enrollment eligibility for specific studies. Members of the Clinical Research Unit and the study team also perform detailed chart reviews to help assess eligibility.

Partnerships — Marketing

The Recruitment Core collaborates closely with experienced AdventHealth in-house marketing specialists to develop study-specific marketing campaigns to target potentially eligible participants through omni-channel marketing, including direct-to-consumer approaches such as:

- Print: Rack cards, flyers, pop-up banners, table tents
- Traditional: TV, radio, print, direct mail, mailers
- Digital: Web page, social, search, display campaigns, digital radio, email blasts
- Outreach: Bus ads, newsletters, event sponsorship
- Retention: Cards and promotional products

Provider Engagement

The Research Engagement team raises providers' awareness of available clinical trials and studies using the **Practice-Based Research Network** and marketing tools like pop-up banners, physician emails, AdventHealthMD features, presentations at Grand Rounds, and lunch and learn events. The Research Engagement Specialist and Research Support Assistant coordinate with the physician liaison group to connect with AdventHealth Medical Group, AdventHealth Well 65+ Senior Care Program and external providers to actively educate providers about ongoing research studies. Informed providers can then alert their patients about various studies where they may be eligible to participate. The Research Support Assistant is also embedded into the clinical practice workflow to introduce interested patients to research opportunities onsite at the outpatient practice in the Diabetes Institute. This group and other AdventHealth teams work together to utilize tools in Epic, including BestPractice Advisories (BPA) to clinical providers and MyChart messages directly to patients via the AdventHealth mobile application.

Staffing

The team is led by the Senior Manager, Research Participant Recruitment and is comprised of:

- TRI: Recruitment Core: 4 Research Recruitment Assistants and Recruitment Manager
- COE + DEI: Program Manager
- Provider Engagement: Research Engagement Specialist and Research Support Assistant
- NSI: Research Support Assistant

INPRACTICE: A Practice-Based Research Network (PBRN)

The development of PBRN's mission aligns with AdventHealth Research Institute's mission of expediting groundbreaking and globally recognized whole-person health care research that leverages the scale and diversity of our population. PBRN aims to draw on the experience and insight of practicing clinicians to identify and frame research questions whose answers can improve primary care practice.

INPRACTICE Objectives:

- Develop an AdventHealth-wide network of primary care practices for innovative research that addresses the institution's health priorities.
- Promote research that transforms Primary Care.
- Disseminate key research findings and data to primary care providers to improve practice.
- Create collaborations within primary care, clinical, and public health stakeholders.
- Increase patient access to innovative research trials and treatments conducted at AdventHealth.



Community Outreach & DEI

AdventHealth Research Institute's community outreach and engagement initiatives involve our diversity, equity, and inclusion efforts, primarily geared toward community engagement and raising awareness about research. The team aims to advance equity in clinical research access, outcomes, and experiences to empower community members and encourage research participation. They also aim to foster diverse partnerships that will educate the team about the communities we serve and identify research gaps that support them to create and sustain their health.

For 2023, the team focused on the community via strategies surrounding key pillars of Trust, Data, Awareness and Representation. Their main objective is to build genuine relationships and trust within the community, which, in turn, has allowed them to bring awareness to ethnically and racially diverse populations about research opportunities that are available for their participation. The team has also been working toward increasing access to research studies and clinical trials for all community members.

In building these relationships, the Community Outreach & DEI team hosted educational seminars to teach and learn from the community in settings known as Science Cafés. These seminars have stemmed from asking the community members what health topics are most relevant to them and ensuring they are catering to those indicated needs. As a result, the team has provided education about various therapeutic areas, including diabetes, kidney disease, healthy aging and Alzheimer's Disease. To ensure accessibility, they have intentionally met community members where they are and hosted these events at local congregations, family centers, and other community centers. With the support of the community partners, the team has also been able to have a presence at more than 100 community events and provide support to various local community organizations in 2023. Through these efforts, they expanded outreach and increased awareness about the significance of research and the opportunities available. By doing so, the team is building upon the understanding that research can serve as an additional care option for members of the community. They believe that these endeavors are crucial in providing the best possible care for the community members.



Participate in Research

You could be part of the next medical breakthrough that changes everything. Participating in our research studies gives you the exclusive opportunity to access new and cutting-edge therapies. Your participation will also contribute to advancing medical knowledge and benefit future generations. Our experienced and compassionate team will provide you with expert care and support. Additionally, you will receive compensation for your time and travel expenses.



[Scan to Learn More](#)

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