



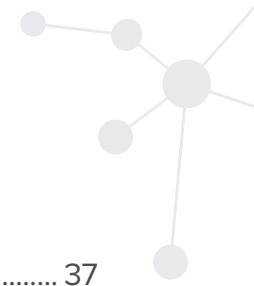
AdventHealth  
**Research Institute**

2022 ANNUAL REPORT

  
**AdventHealth**

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# Welcome

Welcome to the 2022 edition of the AdventHealth Research Institute Annual Report. AdventHealth research continues to develop, and this year's report will bring you up-to-speed on the activities and discoveries that are changing the way we prevent, diagnose and treat various diseases. We are especially grateful for the tireless work of our investigators, staff and, most of all, our research volunteers.

The standard of care for many diseases is well established. Clinical trials are conducted when there may be a better way to diagnose or treat a disease. Therefore, **Clinical Research as a Care Option** is the theme of this year's report and describes the idea that participants are often attracted to clinical trials because they can engage first-hand in studies comparing new treatments or diagnostics to the existing standard of care.

Regardless of their outcomes, research studies provide a baseline for the best-known standard. Research volunteers are essential to drive science forward and ensure that all persons are represented.

This is so important.

In this era of precision medicine, we know that not all diagnostics or therapeutics work effectively for every person. Without representative participation, we, our loved ones, neighbors or community may be left behind.

I was a research participant starting in college and volunteered throughout my undergraduate and graduate studies. As a young investigator, I volunteered for research studies and continue to volunteer as recently as last fall.

Volunteering as a participant helps me, and ultimately, helps the rest of the world. Someday, what others learn from my participation may even help my children and, hopefully, grandchildren.

If you are interested in learning more about how to volunteer and become a research participant, visit [BeTheBreakthrough.com](https://www.adventhealth.com/research) and thank you for advancing the science of optimal health.

Giving back is another way to "Feel Whole!"



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

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



# AdventHealth Research Institute (AHRI) Overview

AdventHealth is 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 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 the community around us is integral to the vision of the Research Institute:

*To expedite groundbreaking and globally recognized whole-person health care research that leverages the scale and diversity of our population to improve the health and wholeness of our communities.*

Our diverse portfolio of clinical trials, involving more than 600 investigators and staff, has strengthened the medical community through various means, like providing better understanding and treatment methods for diabetes. These studies have also led efforts in understanding a COVID-19 vaccine’s safety and efficacy, improving cardiovascular and lung disease intervention and demonstrating scientific principles that underscore our whole-person approach to health. In addition, active clinical trials 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 continues to expand 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, and Great Lakes Region and 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, 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



**Chris Davis, PhD**  
Executive Director  
Research Operations



**Valerie Landrio McDevitt, JD**  
Executive Director  
Research Services



**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

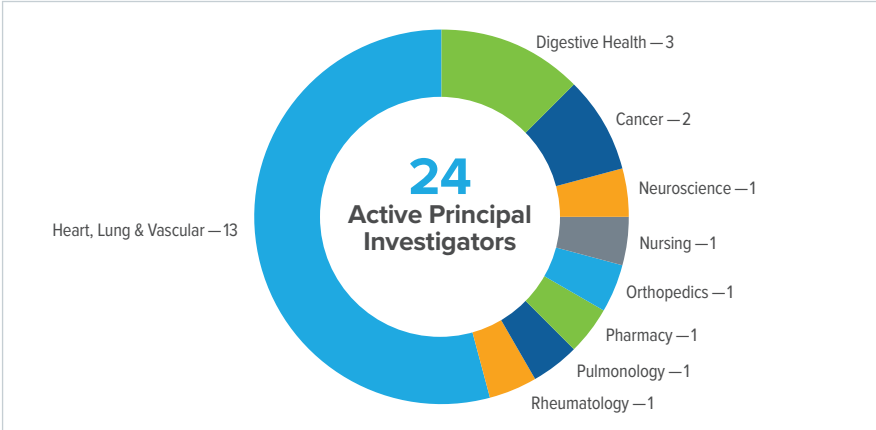


**Christina Jackson**  
Director  
Office of Research Integrity  
and Compliance

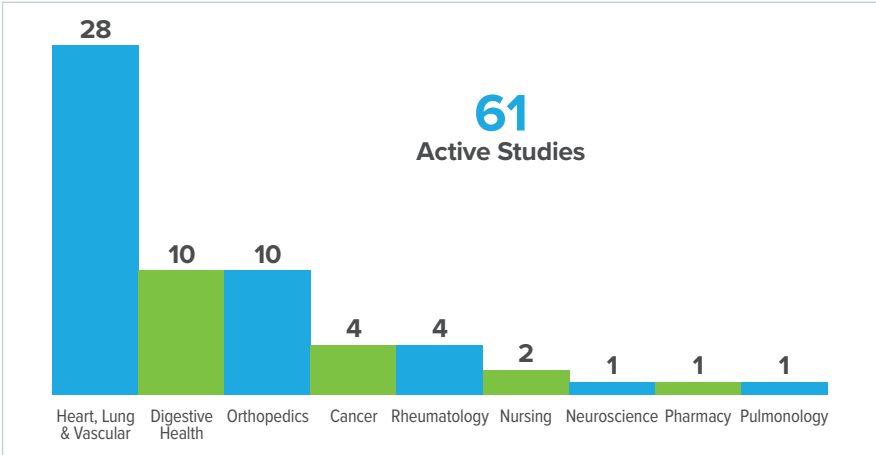
# Introduction to AHRI in West Florida Division

## West Florida Division by the Numbers

### Active Principal Investigators in West Florida Division



### Active Studies in 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 life-saving breakthroughs. Using leading technology and innovation to deliver our standard of whole-person care, the research network of care includes AdventHealth Tampa, AdventHealth Ocala and AdventHealth Sebring.

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. Our Cardiovascular Institute at AdventHealth Tampa, the Dr. Kiran C. Patel Research Institute, is one example of AdventHealth’s efforts to advance patient care through cutting-edge, patient-focused research. **Finding tomorrow’s medical breakthroughs starts with today’s research.**

“The best way to predict the future is to create it.”

—Peter Drucker

## Investigators



**Oliver Abela, MD, FAC**  
 Medical Director of  
 Echocardiography,  
 AdventHealth Medical  
 Group Carrollwood, Tampa

**Oliver Abela, MD, FAC**, is a board-certified cardiologist specializing in interventional cardiology and advanced heart failure. He serves as the Medical Director of Echocardiography for the AdventHealth Medical Group Carrollwood and Tampa clinics and as a diplomat on the National Board of Echocardiography and the Certification Board of Cardiovascular Computed Tomography. He is the first cardiologist to complete a percutaneous axillary artery Impella-supported PCI procedure at AdventHealth Tampa.

Dr. Abela 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. His procedural area of expertise in structural heart disease includes percutaneous TAVR, MitraClip, ASD/PFO closure and left atrial appendage closure/watchman.

Dr. Abela is passionate about research and how it supports patient health and improves medicine. He currently serves as PI for the STEMI DTU clinical study, which tests the hypothesis that unloading the left ventricle for 30 minutes before reperfusion will reduce myocardial damage from a heart attack and lead to a reduction in future heart failure-related events.

**Medical Degree:** Michigan State University

**Residency:** Internal Medicine, Michigan State University College of Human Medicine

**Fellowships:** Cardiovascular Disease, University of Nevada School of Medicine; Interventional Cardiology, University of Arizona College of Medicine; Advanced Heart Failure and Transplant Cardiology, University of Cincinnati School of Medicine



**Ali Alsamarah, MD**

**Ali Alsamarah, MD**, is an interventional cardiologist who specializes in treating complex cardiovascular conditions, and has board certifications in internal medicine, cardiovascular medicine, interventional cardiology and echocardiography.

With nearly a decade of experience, Dr. Alsamarah offers a full spectrum of therapeutic procedures such as complex coronary interventions, peripheral angioplasty of the lower extremities, carotid stenting and endovascular repair (EVAR) of abdominal aortic aneurysm (AAA). In addition, specializes in minimally invasive procedures like transcatheter aortic valve replacement (TAVR), MitraClip, Watchman implantation percutaneous closure of left atrial appendage for patients with atrial fibrillation, percutaneous closure of paravalvular leaks, atrial septal defects and patent foramen ovale.

Dr. Alsamarah believes that to treat patients successfully, he must help them fully understand their diagnosis first. Then, he explains the available options to them in the form of preventive care, diet modifications, medical therapy or therapeutic procedures/interventions.

Dr. Alsamarah, serves as the sub-I for the Comparison of Anticoagulation with Left Atrial Appendage Closure after AF Ablation (OPTION) study.

**Medical Degree:** University of Jordan

**Residency:** Internal Medicine, University of Texas Southwestern Medical Center

**Fellowships:** Cardiovascular Medicine and Interventional Cardiology, Boston University Medical Center; Structural Heart Disease and Peripheral Interventions, Lahey Hospital & Medical Center



**Ravi Chandra, MD**

**Ravi Chandra, MD**, is a specialized surgeon certified in vascular medicine and endovascular medicine for over 15 years. He is currently the only surgeon in Ocala, FL certified by the American Board of Endovascular Medicine and the American Board of Surgery. In 2021, Dr. Chandra also served as a member of the Florida Board of Medicine, an organization that oversees practice standards and certification within the state's medical community.

Dr. Chandra is skilled in performing Transcarotid Artery Revascularization (TCAR) in patients with significant carotid artery disease. He is participating in a post-approval study, "Transcarotid Artery Revascularization in Standard Risk Patients with Significant Carotid Disease," utilizing a Transcarotid Neuroprotection system to temporarily reverse blood flow away from the brain and into a leg vessel. A stent is then implanted, leading to stroke prevention. Carotid artery stenting with proximal embolic protection is an alternative to surgery or transfemoral stenting in treating patients with carotid artery lesions. Participation in this study is currently offered to patients who are at standard risk from carotid endarterectomy surgery or require carotid revascularization and are eligible for treatment using a transcarotid stent.

**Medical Degree:** Gandhi Medical College

**Residencies:** General Surgery, University of Miami; Jackson Memorial Hospital

**Fellowships:** Cleveland Clinic; Miami Children's Hospital

**Training:** Endovascular training, Arizona Heart Institute



**Robert L. Feldman, MD, FACC, FSCAI**  
*Director of the Cardiac Catheterization Laboratory, AdventHealth Ocala*

**Robert Feldman, MD, FACC, FSCAI**, is an interventional cardiologist and the founding Director of the Cardiac Catheterization Laboratory at AdventHealth Ocala since the lab’s inception in 1988. He also served as the head of the Catheterization and Interventional Cardiology program at the University of Florida College of Medicine for nine years.

Dr. Feldman is certified in the Interventional Cardiology subspecialty and Vascular Medicine. He specializes in coronary and peripheral diagnostics, interventions and endovascular

aneurysm repair, with a specific interest in carotid arteries. He is known among his peers as a leader in catheterization technology and focuses his research on new coronary or peripheral technologies.

Dr. Feldman serves as the principal investigator for IMPERIAL study, “A Randomized Trial Comparing the Eluvia Drug-Eluting Stent versus Zilver PTX Stent for Treatment of Superficial Femoral and/or Proximal Popliteal Arteries” as well as for the ECLIPSE, OPTIMIZE, TRANSCEND and OPTION studies.

**Medical Degree:** Rutgers University Medical School

**Internship:** University of Florida College of Medicine

**Residency:** University of Florida College of Medicine

**Fellowship:** University of Florida College of Medicine



**Charles R. Lambert, Jr., MD, PhD**  
*Medical Director, Cardiovascular Institute, West Florida Division*

**Charles R. Lambert, Jr., MD, PhD**, is the Medical Director of the West Florida Division’s Cardiovascular Institute, 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.

Throughout his career, Dr. Lambert has applied clinical research as a care option for patients with cardiovascular disease. Within his interventional cardiology practice, patients have usually exhausted most routine options for care and benefit from translational research as a valuable resource in their treatment journey, often not available at other centers.

Dr. Lambert’s research interests and publications have included basic myocardial energetics, cellular electrophysiology, coronary disease pathophysiology, cardiovascular disease pharmacotherapy and interventional cardiology device development. Most recently, he has studied ischemic heart disease in women and the application of stem cell therapy in cardiac disease. 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 serves as the site principal investigator for the Warrior Trial, which studies women with signs and or symptoms of ischemic heart disease but do not have obstructive coronary disease. These patients have a markedly increased incidence of major adverse cardiovascular events in subsequent years when compared to control populations. Currently, there are no guidelines for treatment of these patients.

The Warrior Trial is the first prospective trial comparing intensive medical therapy versus usual therapy in this patient population.

**Medical Degree:** University of Florida

**Doctoral Degree:** University of Florida

**Residency:** Internal Medicine, University of Florida

**Fellowships:** Post-doctoral Research, University of Florida; Cardiology, University of Florida; Interventional Cardiology, University of Florida



**Sharona Ross, MD**  
Director, Surgical Floor,  
AdventHealth Tampa

**Sharona Ross, MD**, is a board-certified, award-winning advanced foregut and hepatopancreatobiliary surgeon with nearly 20 years of professional experience. Dr. Ross serves as the Director of the surgical floor at AdventHealth Tampa, where she works with nurses and the surgical teams to optimize the quality of surgical patient care. She specializes in robotic and single-incision laparoscopic operations for conditions of the esophagus, stomach, small bowel, pancreas, gallbladder and liver. Dr. Ross serves on several AdventHealth Tampa medical committees, the Society of American Gastrointestinal and Endoscopic Surgeons, and more.

Dr. Ross was one of the first surgeons in the U.S. to offer Laparo-Endoscopic Single-Site (LESS) Surgery. In addition, she is one of few to offer patients robotic complex abdominal operations for the cancers she specializes in. Dr. Ross consistently embraces new surgical technology and innovation that help improve the quality of care for patients.

In 2022, Dr. Ross published more than 15 scientific articles. The following is one of the articles Dr. Ross is the lead author of:

*Shapera E, Ross SB, Chudzinski A, Massarotti H, Syblis CC, Crespo K, Rosemurgy AS, Sucandy I. Simultaneous Resection of Colorectal Carcinoma and Hepatic Metastases is Safe and Effective: Examining the Role of the Robotic Approach. American Surgeon. 2022. DOI: 10.1177/00031348221093533*

**Medical Degree:** George Washington University College of Medicine

**Residency:** General Surgery, University of South Florida College of Medicine

**Fellowships:** HPB/Advanced Gastrointestinal Surgery and Minimally Invasive Surgery, University of South Florida/Tampa General Hospital; Endoscopic Gastroenterology, Department of Medicine, University of South Florida



**Edward Santoian, MD,  
PhD, FACC, FSCAI**

**Edward Santoian, MD, PhD, FACC, FSCAI**, is an interventional cardiologist who joined the staff at AdventHealth Ocala in January 2005. Dr. Santoian is a Diplomate of the National Board of Medical Examiners and the American Board of Internal Medicine. He also serves as a fellow with the American College of Cardiology and Society of Cardiac Angiography and Interventions. He performs all types of coronary, renal and peripheral diagnostic procedures and participates in research on new coronary and peripheral technologies.

Dr. Santoian serves as the sub-I for the Evaluation of Treatment Strategies for Severe Calcific Coronary Arteries: Orbital Atherectomy vs. Conventional Angioplasty Technique Prior to Implantation of Drug Eluting Stents (ECLIPSE). Additionally, along with other studies like OPTIMIZE and TRANSCEND.

**Medical Degree:** Georgetown University School of Medicine

**Doctoral Degree:** Cardiovascular Physiology, Georgetown University School of Medicine

**Residency:** Georgetown University School of Medicine

**Fellowships:** Cardiology, Georgetown University School of Medicine; Interventional Cardiology, Emory University



**Thomas M. Shimshak, MD**

**Thomas M. Shimshak, MD**, is a board-certified cardiologist subspecializing in Interventional Cardiology and Coronary and Peripheral Vascular Disease. He has maintained several professional affiliations and academic appointments while remaining active in clinical practice since 1988.

Dr. Shimshak is a physician trainer and proctor in a broad range of cardiovascular areas and holds membership with associations, including the American Society of Cardiovascular Interventionists, the International Society of Endovascular Specialists and the American Medical Association. He is also a key participant and author in research projects and publications regarding heart disease.

Dr. Shimshak is strongly committed to earning patient trust and pursuing research in the cardiovascular field. He and his experienced team of



physicians and research nurses connect patients to innovative and promising new treatments and technologies to ensure they benefit from the most advanced approaches in cardiac care. Dr. Shimshak serves as the principal investigator for the study STAND: A Clinical Evaluation of the MicroSTent PeripherAl Vascular SteNt in Subjects with Arterial Disease Below the Knee.

**Medical Degree:** Medical College of Wisconsin in Milwaukee

**Residency:** Medical College of Wisconsin in Milwaukee

**Fellowships:** Cardiology, Medical College of Wisconsin in Milwaukee; Advanced Angioplasty, Mid-America Heart Institute



**Iswanto Sucandy, MD**  
*Division Chief for  
Hepatopancreatobiliary  
Surgery,  
AdventHealth Tampa*

**Iswanto Sucandy, MD**, is a pioneer and renowned hepatopancreatobiliary robotic surgeon who has led the Robotic Hepatobiliary Program at AdventHealth Tampa since 2016, serving as Division Chief for Hepatopancreatobiliary Surgery. He has become one of the world's leading experts in his field and is one of eight international experts to write the "United States Procedure Guide for Robotic Liver Surgery."

His research focuses on robotic minimally invasive surgeries for benign and malignant tumors of the liver and bile duct, and for pancreatic and stomach cancer. Since these surgeries are incredibly complex, research and development leads to marked improvement in surgical techniques and the best options for patients' surgical care. Dr. Sucandy's approach is also associated with superior outcomes compared to the traditional "open operation" offered by most surgeons. As an active contributor to surgery literature, Dr. Sucandy has published more than 174 scientific articles, 10 book chapters and numerous surgical technique videos in hepatopancreatobiliary and gastrointestinal surgery.

**Medical Degree:** Airlangga University School of Medicine

**Residency:** General Surgery, Jefferson Health-Abington Hospital

**Fellowships:** Advanced Gastrointestinal/Minimally Invasive Surgery, Yale University; Hepatopancreatobiliary Surgery, University of Pittsburgh Medical Center



**Kenneth Yamamura, MD, FACC**  
*Director of  
Electrophysiology,  
AdventHealth Tampa*

**Kenneth Yamamura, MD, FACC**, is a board-certified cardiologist specializing in cardiology and clinical cardiac electrophysiology and serves as the Director of Electrophysiology at AdventHealth Tampa. Dr. Yamamura has more than 20 years of clinical experience and practices in all areas of cardiac electrophysiology, including device implantation and ablation of cardiac arrhythmias (atrial fibrillation, atrial flutter, SVT, PVCs and ventricular tachycardia).

His special interest is treating atrial fibrillation with ablation for both paroxysmal and persistent forms of the disease. This approach includes 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.

"Finding new techniques and using new catheters to treat this disease is what I strive to do," Dr. Yamamura states. "I hope that bringing new technology to AdventHealth Tampa will result in more efficient patient treatments and greater awareness of the valuable research underway in the West Florida division."

Dr. Yamamura serves as the principal investigator for the Boston Scientific FROZEN-AF IDE clinical trial utilizing the new Boston Scientific cryoballoon for the treatment of patients with paroxysmal atrial fibrillation. That study has been completed and results submitted to the FDA.

**Medical Degree:** University of Miami's School of Medicine

**Residency:** Jackson Memorial Hospital

**Fellowships:** Cardiology, Jackson Memorial Hospital; Clinical Cardiac Electrophysiology, University of Miami, Jackson Memorial Hospital

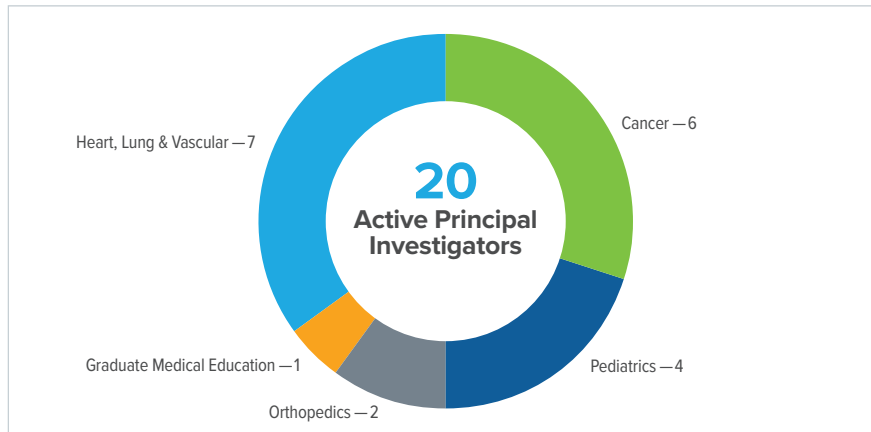
# Introduction to AHRI in Great Lakes Region

## Overview

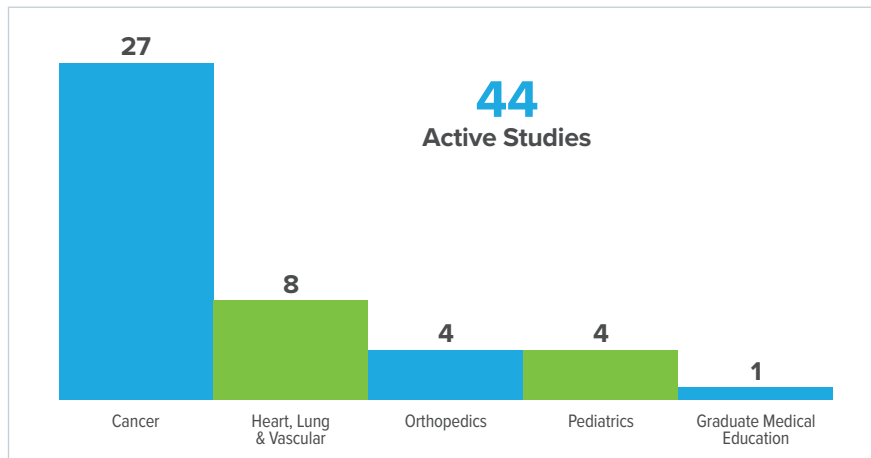
The physicians and staff at AdventHealth Hinsdale Great Lakes Region know you need a special care network to join you on your health journey. Our professionals are here for you for cancer, heart and vascular care, combining research and clinical care that offers a more comprehensive health care plan. Our faith-based values and unwavering commitment to excellence have led to many national certifications and top rankings in the Chicago metropolitan area, Illinois and the nation. Together, we will work to support you, so you and your family can focus on what matters most: Healing.

## Great Lakes Region by the Numbers

### Active Principal Investigators in Great Lakes Region



### Active Studies in Great Lakes Region



## Cardiovascular Investigator



Meechai Tessalee, MD,  
FACC, FSCAI

Meechai Tessalee, MD, FACC, FSCAI, is an interventional cardiologist with AdventHealth since 2001, focused primarily on providing clinical patient care, serving hospital committees and overseeing family medicine resident education.

Dr. Tessalee's research focus involves participation as a principal investigator or sub-PI in two active clinical trials. The first is the NIH-funded, international multicentered MINT Trial, which is investigating a restrictive versus liberal transfusion protocol and how it affects outcomes in acute myocardial infarction (MI) patients. The second active trial, INCEPTION, seeks to determine clinical outcomes of Incliseron, an injectable cholesterol-lowering agent, in post-acute MI patients.

"Medicine is constantly evolving, and treatment options are constantly changing," Dr. Tessalee says, "I always want to provide state-of-the-art medications and treatment options for my patients. This is not always readily available in daily practice, but clinical research is a gateway to providing unique therapies for them. Some say research is a luxury, but I feel it should be a part of our treatment offerings to all our patients."

**Medical Degree:** Rush Medical College

**Fellowship:** Rush University Medical Center

## Oncology Investigators



**Jay S. Dalal, MD**  
Medical Director,  
AdventHealth Cancer  
Institute, Hinsdale; Chair,  
Cancer Committee,  
AdventHealth Hinsdale  
and La Grange

**Jay S. Dalal, MD**, is the Medical Director of the AdventHealth Cancer Institute in Hinsdale, IL, and Chair of the Cancer Committee of AdventHealth Hinsdale and La Grange Hospitals—a long-standing Commission on Cancer (CoC) accredited site. He is also board-certified in Medical Oncology and Hematology, treating a wide range of cancers.

He eagerly stays abreast of the continuous changes in the full spectrum of oncology care and emphasizes providing the best personalized care for each patient. Dr. Dalal focuses his clinical research on all malignancies with a special interest in lung, breast, GI, prostate and lymphomas.

Dr. Dalal sees medical oncology research not just as an option, but as a standard of care. Cancer treatment has advanced enormously over the years, but he believes it is his duty to relentlessly seek advancements that translate into the best patient care. Clinical trials can further improve outcomes, and he hopes to be a driving force in that improvement.

Dr. Dalal is the principal investigator of the clinical study A Single-Center Retrospective Analysis of Reclassified HER-2 Low-Positive Expression in Metastatic Breast Cancer Patients. This study analyzes the status of HER2 low-positive expression, previously considered HER2 negative, in metastatic breast cancer patients at a large community cancer center. This reclassification could potentially offer these patients access to a new therapeutic options.

**Medical Degree:** SUNY Upstate Medical University  
**Residency:** University of Maryland Medical Center  
**Fellowships:** Loyola University Medical Center; Hines VA Medical Center



**Patrick J. Sweeney, MD**  
Medical Director,  
Radiation Oncology,  
Illinois Gamma Knife  
Center, AdventHealth  
Cancer Institute, Hinsdale

**Patrick J. Sweeney, MD**, is the Medical Director of Radiation Oncology at the Illinois Gamma Knife Center in Elk Grove Village and AdventHealth Cancer Institute in Hinsdale, IL. He is board-certified in Radiation Oncology and has been active in private practice with Radiation Oncology Consultants since 1998.

Dr. Sweeney has expertise in brain tumors, sarcomas and prostate cancers using conformal 3-D therapy, intensity-modulated radiation therapy (IMRT), stereotactic radiosurgery using Gamma Knife and high-dose-rate brachytherapy. He is also knowledgeable in breast, lung, head and neck, gastrointestinal and gynecologic malignancies. Dr. Sweeney is active in many professional organizations, has written numerous papers and is a frequently invited local and national lecturer on various cancer topics.

“I find great fulfillment in the care of oncology patients and their families,” Dr. Sweeney states. “I enjoy our ability to integrate cutting-edge technologies into tumor treatment now. These innovations clearly help our patients live longer and with a better quality of life.”

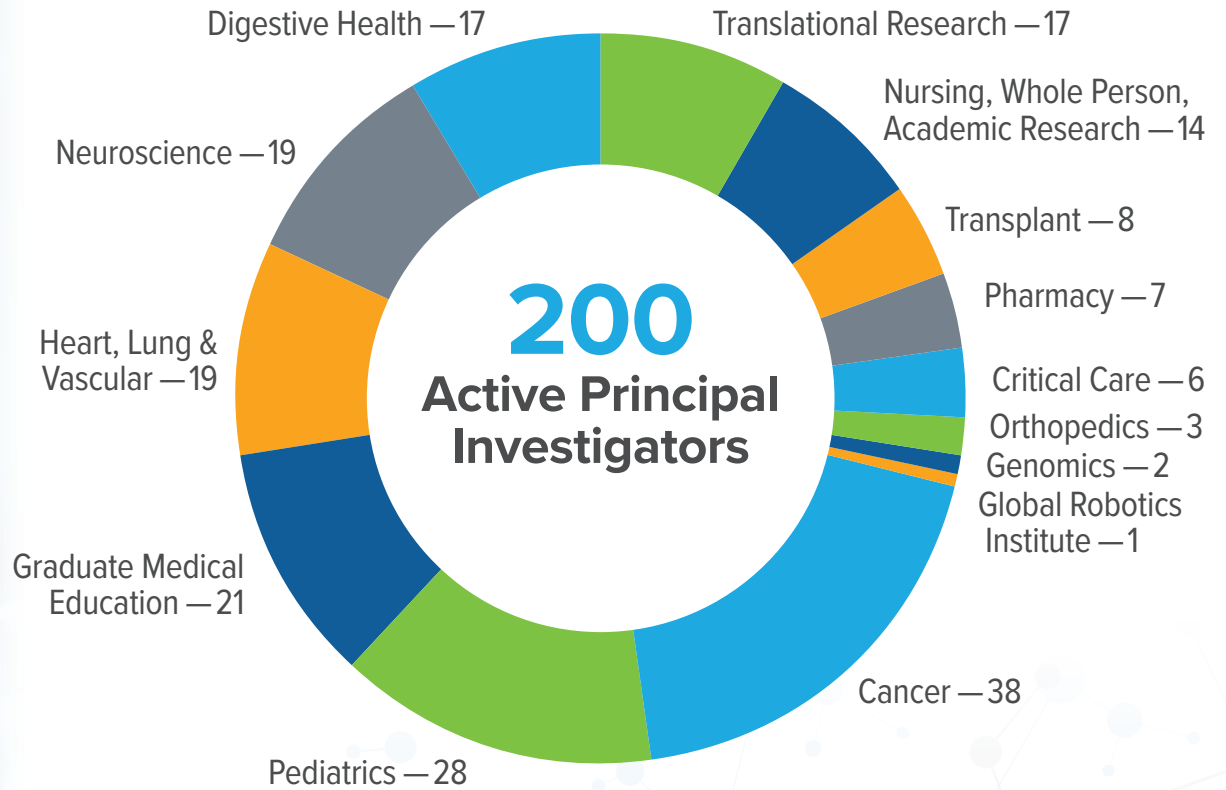
His research focuses on limiting treatment-related side effects, enhancing treatment effectiveness and making participation in clinical trials accessible in a community cancer setting when they are generally available only in the university setting. Dr. Sweeney serves as the principal investigator for the study A Phase 2b/3, multicenter, randomized, double-blind, placebo-controlled study comparing the efficacy and safety of clonidine mucoadhesive buccal tablet to placebo to prevent chemoradiotherapy-induced severe oral mucositis in patients with oropharyngeal cancer.

**Medical Degree:** The Ohio State University  
**Residency:** The Ohio State University  
**Fellowship:** American Cancer Society, University of Chicago

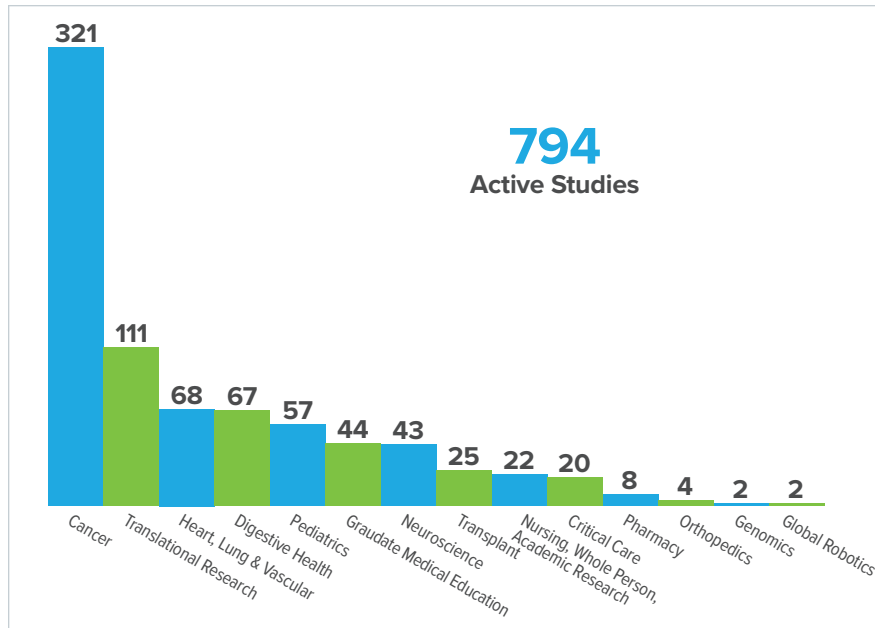
# AHRI in Central Florida Division

## By the Numbers

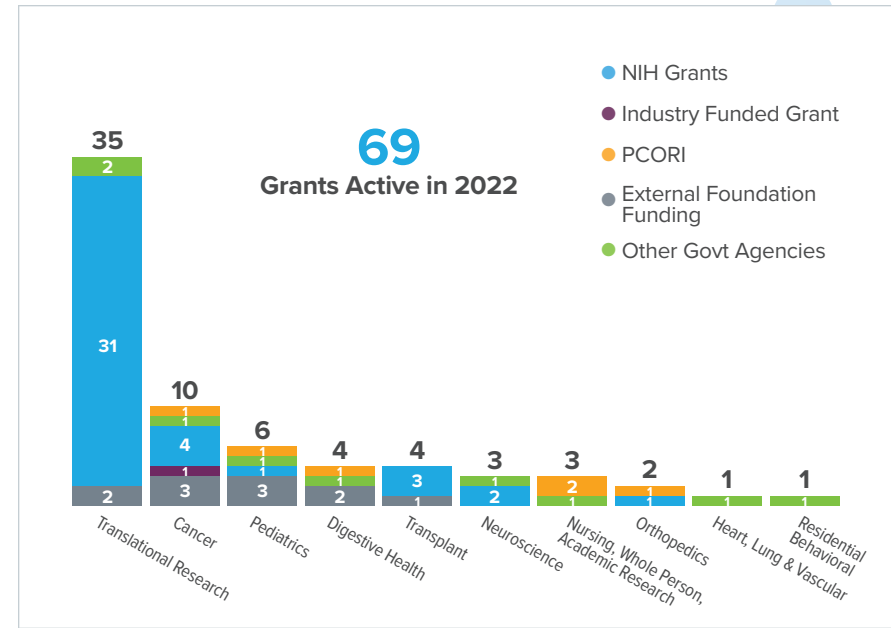
### Active Principal Investigators in Central Florida Division



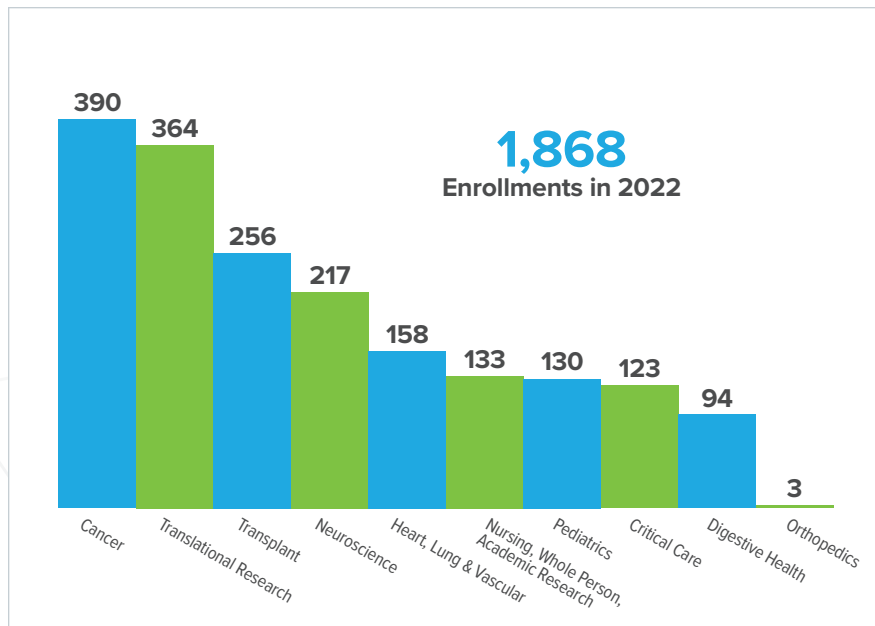
## Active Studies in Central Florida Division



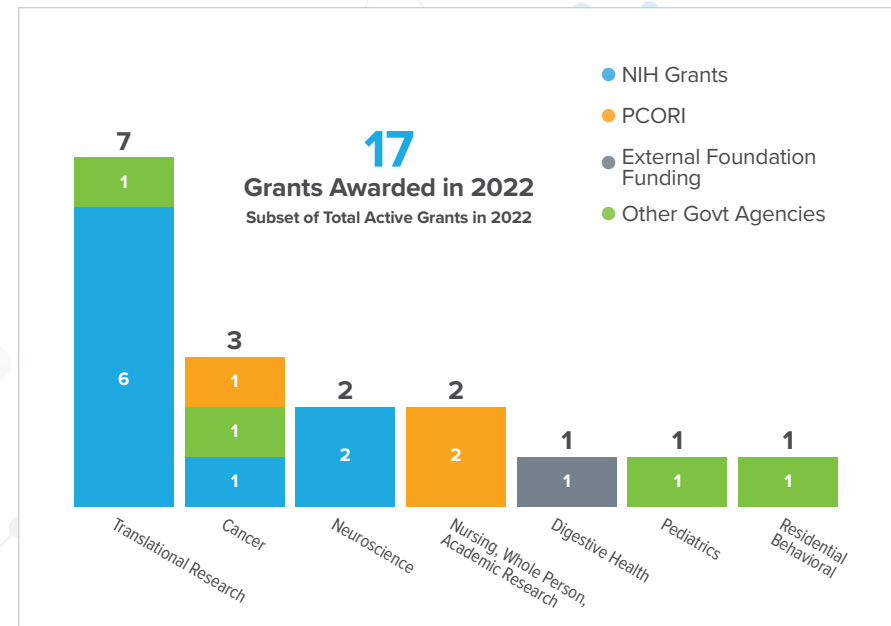
## Grants Active in 2022



## 2022 New Enrollments in Central Florida Division



## Grants Awarded in 2022



# AdventHealth for Children

## Overview

AdventHealth's Center for Pediatric Research is defining the future of pediatric health care through research, data analysis, 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, mental health program, a Level IV Comprehensive Pediatric Epilepsy Center, Level IV Neonatal Intensive Care Unit (NICU), 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
- Hematology
- Hepatology
- Neonatology
- Neurology
- Orthopedics
- Obesity
- Sepsis (Infections)
- Urology
- Vaccines

**“Our pediatric research portfolio helps us bring leading-edge treatments to our pediatric patients. We serve our patients and families by not only providing cutting-edge established therapies and treatments but also by advancing novel treatments for pediatric illnesses through clinical research.”**

— Rajan Wadhawan, MD



## Featured Researchers and Research



Hussnain Mirza, MD

**Hussnain Mirza, MD**, is a board-certified neonatologist at AdventHealth for Children. His several ongoing research projects focus on chronic lung disease of prematurity, neonatal hemodynamics and quality improvement.

Dr. Mirza has teamed up with our pediatric radiology team on a study using ultrasounds to measure an infant's trachea size. The study will determine if chronic ventilation for more than four weeks can lead to an enlarged and dilated trachea compared to infants of similar gestation requiring short-term or no mechanical ventilation. In standard care, endotracheal tube size (breathing tube) is based on the baby's weight. However, infants on chronic ventilation are at risk of airway injury, causing a disproportionately enlarged airway. Therefore, the weight-based size of the breathing tube is inappropriate for these infants. Dr. Mirza believes this new methodology will result in a more accurate, effective gauge to measure the airway size and use the right size of the breathing tube for mechanical ventilation.

In another project, Dr. Mirza has recently completed a study in collaboration with the Florida Institute of Human & Machine Cognition (FIHMC), University of Florida. They used artificial intelligence or machine learning to improve the prediction for bronchopulmonary dysplasia (BPD) or death. Traditionally, the risk of poor clinical outcomes like BPD is statistically calculated by "logistic regression." This new tool will improve the predictability of BPD or death in preterm infants. Dr. Mirza will present an abstract about this new tool later this year at the Pediatric Academic Society meeting in Washington, D.C.

In another project, Dr. Mirza seeks to improve the quality of daily care for extremely preterm infants by measuring their total daily fluid intake more precisely. This project restricts total daily fluid intake by 10 to 30 percent compared to standard clinical practice. This change in clinical practice can help lower the incidence of Patent Ductus Arteriosus (PDA), a heart condition that can be affected by too much fluid intake in the infant's first few days of life.



Brian Tullius, MD

**Brian Tullius, MD**, is a board-certified oncologist specializing in cellular therapies, cancer immunotherapy, innate immunity and stem cell transplantation. Dr. Tullius also holds a U.S. patent on a cellular therapy for treating microbial infections and a patent pending for an innovative website he helped design to improve access to and awareness of clinical trials. Cellular therapy aims to overcome an immunologic barrier in hopes of curing cancer. Dr. Tullius' research focuses specifically on Natural Killer (NK) cells—lymphoid cells of the innate immune system that affect host defense against viruses and cancer immunosurveillance.

Focusing on its role in cancer immunosurveillance, Dr. Tullius and AdventHealth collaborate with researchers at the University of Central Florida (UCF) and the Pediatric Transplant and Cell Therapy Consortium (PTCTC) for two branches of study. Within the project with UCF, they are tasked with taking tumor samples from children with neuroblastoma and growing the tumor as a true-to-life model of their tumor microenvironment. NK cells are then extracted from peripheral blood to determine whether gene editing can remove the cellular "brakes" that neuroblastoma can exploit to hamper its own death through NK cells. They hope this preclinical work can be the foundation for an eventual clinical trial to bring gene-edited NK cells to fight against this life-threatening pediatric malignancy.

The project with PTCTC serves as step two—facilitating the clinical trial arm of our NK cell pursuits. With AdventHealth as a site on their consortium trial, they are administering donor-derived, ex vivo expanded NK cells in three strategically timed infusions to pediatric patients undergoing haploidentical bone marrow transplant for high-risk acute myeloid leukemia (AML) with hopes that the NK cells can reduce their chance of relapse. The current standard of care for children with high-risk AML is a consolidative transplant, where relapse risks remain significant and unable to be improved upon for decades. Dr. Tullius hopes that adding NK cells to a transplant backbone will offer another viable, effective care option—possibly lowering the relapse risk so children and their families can heal with less fear of the unknown.



**Melissa Tyree, MD, FAAP**

**Melissa Tyree, MD, FAAP**, is the AdventHealth Clinical Site Director for the Intermittent Hypoxia and Caffeine in Infants Born Preterm (ICAF) Study. This study is an NIH-funded multicenter randomized placebo-controlled double-blinded first-in-human trial in which convalescent preterm infants receiving routine treatment of caffeine for apnea of prematurity are randomized to continue caffeine treatment or receive a placebo through

43 weeks postmenstrual age (PMA) (gestational age plus chronological age). This approach contrasts standard clinical caffeine discontinuation, which typically occurs at 34 to 36 weeks PMA.

It has been shown that premature infants continue to have intermittent hypoxia episodes throughout the first several months of life, up to 43 weeks PMA. These episodes may cause acute injury through cycles of inflammation and repair from oxidative stress. Extended caffeine use has been associated with enhanced neuroprotection, including improved white matter microstructural development during this critical phase of preterm brain maturation and improved motor, cognitive and language outcomes. The study primarily aims to evaluate the effect of extended caffeine use through 43 weeks PMA on the magnitude of intermittent hypoxia events, associated inflammation-related cytokines, and MRI microstructural and metabolic biomarkers of injury. Researchers can also identify early brain injury mediated by intermittent hypoxia and mitigated by caffeine at appropriate dosing and duration. Such information may help delineate optimum strategies for later definitive neurodevelopmental assessments based on the nature of an acute brain injury. It could also justify future neurodevelopmental outcome studies that will further improve health outcomes of infants born preterm, change clinical practice and significantly benefit public health.

The ICAF study has an inpatient and outpatient component, providing a unique opportunity for preterm infants in the AdventHealth for Children NICU and their families. The study is structured to allow families to take a more active role in care decisions for their young children and regain a sense of control as they prepare for discharge following a long inpatient hospitalization. It also fosters a platform to improve patient access to clinical trials across our diverse patient population. Finally, as an extension of standard therapy, it offers a concrete path to improved health outcomes and patient satisfaction.

## Neonatology Respiratory Studies

AdventHealth for Children is learning revolutionary ways to care for the communities' youngest patients. Within the institute's respiratory team are two studies challenging the current standard of care for better, more efficient strategies providing stronger care outcomes.



**Narendra Dereddy, MD**

**Narendra Dereddy, MD**, is the principal investigator for the AEROFACT study—a partially blinded, randomized, controlled study administering a surfactant to premature babies via aerosol spray while they are on nasal continuous positive airway pressure therapy (nCPAP) or non-invasive motion ventilation (nIMV). The goal is to test the delivery method of the surfactant in decreasing the baby's need to be put on a

ventilator. The surfactant is a chemical that premature babies lack in their lungs, making breathing difficult and possibly leading to lung collapse. In standard practice, this surfactant is administered through a breathing tube, which is invasive, uncomfortable and can lead to complications. However, this study tests surfactant administration non-invasively via aerosol in the baby's nose.

The respiratory team prepares and administers one to four doses of the surfactant as needed and monitors the baby's vitals and oxygen levels throughout the day. This highly detailed process has resulted in invaluable learning and innovation as the team strives to offer a more comfortable, effective, non-invasive way to care for these babies' lungs and promote better health outcomes.





Hussnain Mirza, MD

**Hussnain Mirza, MD**, is also leading a respiratory study using nitric oxide to test its efficacy in extremely preterm infants with pulmonary hypertension to decrease the risk of bronchopulmonary dysplasia (BPD), a long-term lung disorder found in premature babies and ultimately increase health outcomes. The respiratory team administers nitric oxide or a placebo to the selected infants to gather treatment

data. The results are the first in infants younger than 34 weeks—as nitric oxide has not yet been approved for this preterm demographic. The outcomes of this study will directly affect future clinical practice while also attempting to benefit the health outcomes of a small but high-risk group of babies.

“To be in a hospital and organization that lets us participate and possibly broaden what we can do with surfactant or nitric—it’s exciting,” respiratory team member Patricia Johnson said. “We get to be a part of something that could be groundbreaking for our premature babies. It’s all for a bigger cause.”

## New Investigator



Stefany Hernandez Benabe, MD

**Stefany Hernandez Benabe, MD**, is a transplant hepatologist trained in pediatric gastroenterology, hepatology and nutrition at the University of Miami. In addition, she completed a pediatrics residency at the University of Puerto Rico and a pediatric transplant hepatology fellowship at Columbia University Medical Center.

Dr. Hernandez Benabe sees research as an avenue to future advancement, unlocking the best patient care. Her research focuses on ethnic and racial disease variabilities in pediatric autoimmune liver disease. This refers to the specific role or impact of race/ethnicity in disease progression and clinical phenotype variability in diseases like autoimmune hepatitis, primary sclerosing cholangitis and/or overlap syndrome.

# Cancer Institute

## Overview

The AdventHealth Cancer Institute (AHCI), one of Florida's largest cancer care providers, earns worldwide recognition for its comprehensive, state-of-the-art care and reputation as a destination cancer care facility. Patients can access the latest treatments and technology through a multidisciplinary care model with cancer subspecialists. Our vision is to achieve the national recognition that provides patient 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

**“Our state-of-the-art standard of care cancer treatment is largely derived from the results of past clinical trials that have advanced cancer research and offered patients better treatment options. Clinical trial participants benefit from new therapies and help shape where and how new therapies advance the standard of care.”**

— Mark A. Socinski, MD



## Featured Researchers and Research



**Robert W. Holloway, MD**  
Director, Gynecologic  
Oncology Program,  
AdventHealth in Orlando;  
Founder, Global Robotics  
Institute

**Robert W. Holloway, MD**, an internationally recognized pioneer in robotic surgery, is the Medical Director of the Gynecologic Oncology Program at AdventHealth Orlando and the founding member of the Global Robotics Institute. In 2022, Dr. Holloway was named the national principal investigator on the OnPrime study—a sponsored, multicenter, randomized, open-label, phase III trial evaluating the safety and efficacy of Olvi-Vec (olimulogene nanivacirepvec). The FDA-approved study has begun enrolling at AdventHealth, its first site, with 25 other sites nationwide pending further approval.

Olvi-Vec is a genetically modified, attenuated vaccinia virus that selectively infects rapidly dividing cancer cells resulting in oncolysis (cell rupture and death) and the release of many thousands of virus particles that co-infect adjacent cancer cells. Oncolysis also releases foreign “oncoproteins” that activate tumor-specific T-cells (immunologic response). Through various mechanisms, oncolysis also affects the tumor microenvironment in ways that reverse platinum resistance. Given the limited treatment options currently available, the study combining oncolytic vaccinia ‘virotherapy,’ ‘chemotherapy’ and ‘targeted therapy’ (bevacizumab) uses drugs that work by different mechanisms to reduce/reverse resistant mechanisms—like Olvi-Vec. The study may particularly benefit most patients with advanced-stage ovarian cancer, who eventually experience platinum resistance or become platinum-refractory

to the “standard of care treatments.” OnPrime investigates a novel approach to “immuno-chemotherapy” that may enhance survival beyond the current standard of care treatments for some patients with Platinum-Resistant/Refractory Ovarian Cancer (PRROC) [Holloway RW et al. *Int. J. Gynecol. Cancer* 2022; 32 (S2): A1435, Trial-in-Progress].

*Olvi-Vec-022 GOG-3076: A Randomized Phase III Study Assessing the Efficacy and Safety of Olvi-Vec followed by Platinum-doublet Chemotherapy and Bevacizumab Compared with Platinum-doublet Chemotherapy and Bevacizumab in Women with Platinum-Resistant/Refractory Ovarian Cancer (OnPrime Study)*



**Rushang Patel, MD**  
Medical Director,  
Blood and Marrow  
Transplant Center,  
AdventHealth Orlando

**Rushang Patel, MD**, the Medical Director of the Blood and Marrow Transplant Center at AdventHealth Orlando, has been instrumental in creating the Leukemia Service for Central Florida and surrounding areas, which has standardized provider practices and improved patient outcomes.

Dr. Patel has brought innovative therapies, such as CAR-T cell therapy, to his patients. He actively engages in clinical research to explore therapy options that offer patients the best chance of healing. He is involved in the CARTITUDE-5 clinical trial with Janssen launched in 2022, which aims to aid newly diagnosed Multiple Myeloma (MM) patients. The trial brings the first MM CAR-T therapy product to AdventHealth Orlando.



**Mohamedtaki Tejani, MD**  
Medical Director,  
Digestive Tract Cancer,  
AdventHealth Cancer  
Institute

**Mohamedtaki Tejani, MD**, a medical oncologist, is the Medical Director for Digestive Tract Cancer at the AdventHealth Cancer Institute. His research experience and interests include gastrointestinal cancers, biomarkers and therapeutics, patient-provider communication and the culture of medicine.

### **A Phase II, Randomized Study of Magrolimab with Bevacizumab and FOLFIRI in Previously Treated Patients with Advanced Inoperable Metastatic Colorectal Cancer**

In 2022, Dr. Tejani presented a poster at the European Society for Medical Oncology illustrating his ongoing randomized, Phase II study evaluating the safety, tolerability and efficacy of magrolimab with bevacizumab + FOLFIRI in advanced inoperable Metastatic Colorectal Cancer (mCRC) patients. Standard of care doublet or triplet chemotherapy-based regimens are the only available treatment options for patients with mCRC who are ineligible/unable to benefit from novel targeted therapies or immunotherapies.

### **AHCI's Mohamedtaki Tejani, MD, Presents at the 2022 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium**

Dr. Tejani also presented another study at the American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium demonstrating the feasibility of tumor-informed circulating tumor DNA (ctDNA)-based molecular residual disease (MRD) testing in pancreatic adenocarcinoma (PDAC) patients. The study is timely as PDAC is currently the third leading cause of cancer-related death, with a recurrence rate of 85 percent after curative surgery and a five-year survival rate of 10 percent. The study found ctDNA positivity correlated with patient survival outcomes more strongly than CA19-9 in the 93 patients participating. The promising data suggests patients can benefit from personalized and tumor-informed MRD testing as a viable treatment option against this aggressive disease.



**Lindley Mosqueda, APRN**

**Lindley Mosqueda, APRN**, is a research team member at AdventHealth Celebration's Clinical Research Unit (CRU). This state-of-the-art facility houses several Phase I trials of treatments for oncology patients who have exhausted all other treatment options. Mosqueda transitioned to Phase I research in 2021 after working as an AdventHealth nurse practitioner for over 13 years.

The Phase I trials she works on create “the foundation of all drug developments,” transitioning from bench-to-bedside with initial data that helps determine the drug's safety and effectiveness in humans. While the CRU trials are small and concentrated, they serve as a beacon of innovation, possibility and hope.

“This is my second year in research, and I'm enjoying it a lot,” Mosqueda says, “Research chose me—it was meant to be.”

Mosqueda plays an integral role in the CRU's nine open studies, with some studies showing strong treatment responses. This allows them to move toward Phases 2 & 3—serving larger populations.

“We have someone who is a non-small cell lung cancer patient, and her tumor has regressed by 40%—almost half.”

More patients are learning about the resources at the Celebration CRU, which serves Kissimmee, Celebration and the Greater Orlando area. Many of these patients may not have the financial means to access these trials without clinical research units, as the next closest centers are in Tampa or Jacksonville. Mosqueda is happy to “make a difference” in the lives of her patients and to extend and improve their quality of life.

## New Investigators



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

**Guru P. Sonpavde, MD**, is the Medical Director of Genitourinary (GU) Oncology and Executive Medical Director of the CRU for the AdventHealth Cancer Institute. He is also the Christopher K. Glanz Chair for Bladder Cancer Research and a Professor of Medicine at the University of Central Florida.

Dr. Sonpavde earned his Doctor of Medicine and Surgery degree from Christian Medical College in India. He completed two residencies in General and Internal Medicine with Seth G. S. Medical College and Nassau University Medical

Center, respectively, and a Hematology/Oncology fellowship at Indiana University Medical School. In addition, he has held professional and academic titles with Dana-Farber Cancer Institute, Harvard Medical School and the University of Alabama at Birmingham.

Dr. Sonpavde's research focuses on drug development and translational research to cure cancers, especially GU cancers—which have led to more than 500 publications. He has developed trials for all GU cancers, including prostate, bladder and kidney, along with a new drug development Phase I program (CRU). Dr. Sonpavde has brought cutting-edge industry and investigator-initiated trials to patients in Central Florida while helping to initiate several translational research collaborations to discover new therapeutic targets in bladder cancer, including prospective tissue collection research to study cancer biology in more efficient ways.

He is excited about AdventHealth Orlando's highly promising GU and Phase I research program and how it could advance cancer care in Central Florida and beyond.



**Francisco Socola, MD**

**Francisco Socola, MD**, is an acute myeloid leukemia and myelodysplastic syndrome expert, treating his patients with allogeneic stem cell transplants, autologous stem cell transplants, CAR-T cell therapy and non-transplant options based on their different hematologic malignancies. Dr. Socola earned his medical degree from Cayetano Heredia University in Peru and completed a residency in Internal Medicine and

two fellowships in Hematology/Oncology and Stem Cell Transplant/Cellular Therapy, respectively. He is also an assistant professor in the Department of Hematology/Oncology at Tulane University in New Orleans.

Dr. Socola believes clinical research is the best way to improve treatment options and researches acute myeloid leukemia and myelodysplastic syndrome. He seeks new ways to reduce the relapse rate and describe the different types of TP53 mutations and their impact on disease behavior post-treatment. Through his efforts, he hopes to provide the best personalized, updated treatments to the Central Florida community.

# Digestive Health Institute

## Overview

The AdventHealth Digestive Health Institute (DHI) is a national destination and leader for exceptional digestive health and specialty surgical care. DHI is at the forefront of advanced care for complex diseases, houses the largest interventional endoscopy center in the U.S. 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.

DHI is recognized as a Center of Excellence by the National Accreditation Program for Rectal Cancer (NAPRC). In addition, *U.S. News & World Report* recognizes AdventHealth Orlando as one of America's best hospitals for gastroenterology, gastrointestinal surgery and colon cancer surgery—in addition to sharing how the institute is defining the learning curve for new procedures. Our research directly impacts the improvement and efficiency of future surgical care options.

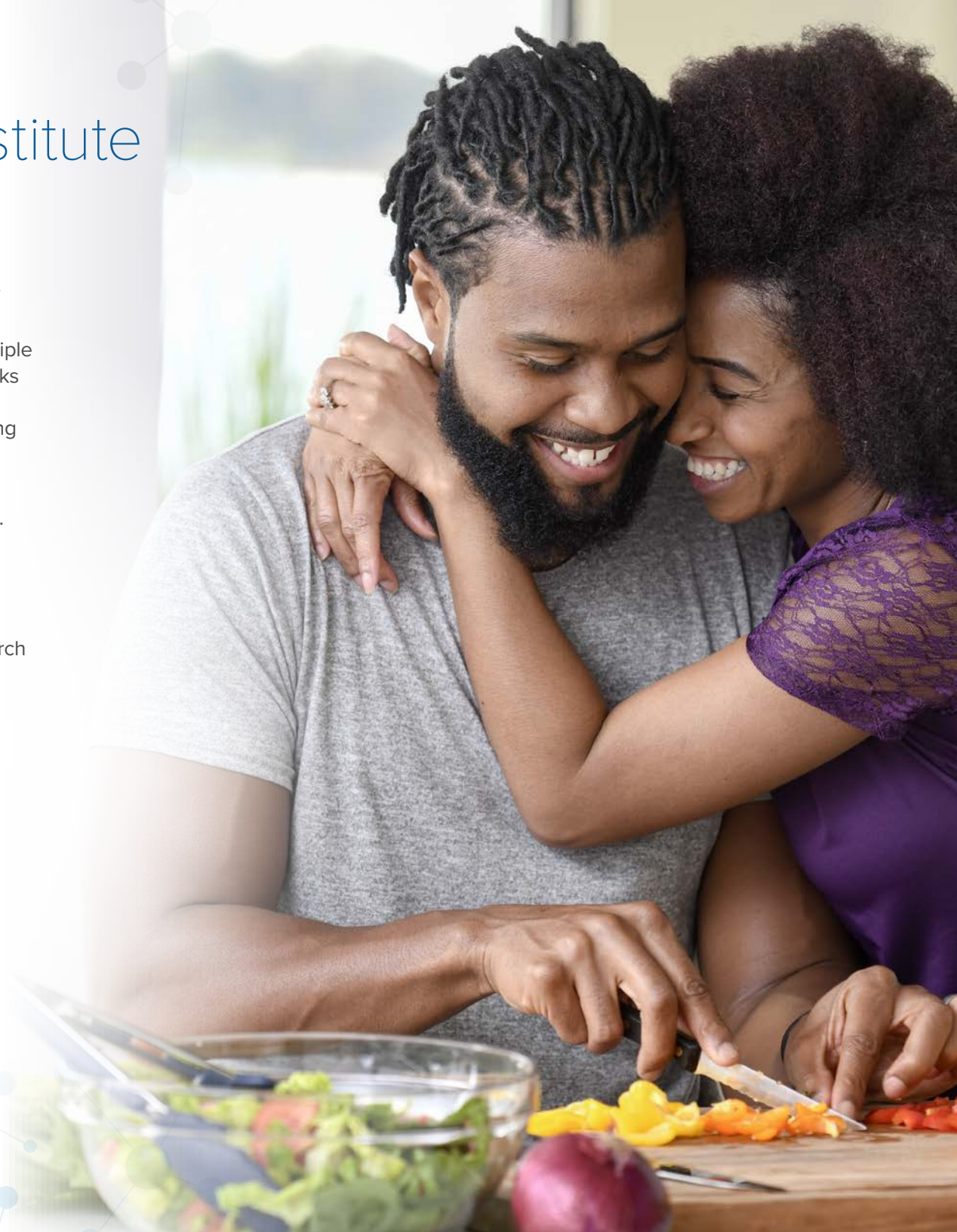
## Areas of Focus

- Bariatrics
- Colorectal Surgery
- Ear, Nose and Throat
- Fatty Liver Disease
- Gastroenterology
- General Surgery
- Inflammatory Bowel Disease (IBD)
- Ophthalmology
- Urology

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**“Research creates knowledge, and knowledge improves outcomes. Patients receiving care in centers with research programs benefit from more and better care options from the outset.”**

— John Monson, MD



## Featured Research and Researchers

### SHOC: Surgical Health Outcomes Consortium Research Team



**John R.T. Monson, MD,  
FRCS, FASCRC, FACS**

**John R.T. Monson, MD, FRCS, FASCRC, FACS**, is a colon and rectal surgeon, fellowship-trained in colorectal surgery and surgical oncology. Dr. Monson is an expert in using minimally invasive technologies in colorectal cancer treatment, including Transanal Endoscopic Microsurgery (TEMS and TAMIS), laparoscopic surgery and robotic surgery.

Dr. Monson is credited with leading the development of laparoscopic colorectal surgery in the United Kingdom and was the Founding Chair of the UK's National Training Program. His research encompasses a broad range of cancer-related areas, including the development of national standards in cancer care and qualitative assessments of decision-making in cancer care.

In 2022, Dr. Monson served as the principal investigator on the TU 100 study, testing the safety and efficacy of a new device (TU-100) as an adjunct to an Enhanced Recovery After Surgery (ERAS) protocol in subjects undergoing colorectal resection.

*TU 100 - A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Trial to Evaluate the Safety and Efficacy of TU-100 as an Adjunct to an Enhanced Recovery After Surgery (ERAS) protocol in Subjects Undergoing Bowel Resection*



**Mark K. Soliman, MD**  
*Chief of Colorectal  
Surgery, and Program  
Medical Director, DHI;  
Department Chairman,  
Colorectal Surgery*

**Mark K. Soliman, MD**, is the Chief of Colorectal Surgery and Program Medical Director of the DHI and the Chairman for the Colorectal Surgery Department. 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.

Dr. Soliman's research focuses on learning methodologies to teach surgeons how to navigate learning curves in adopting robotic surgery and outcomes-based studies in novel robotic colorectal surgical operations.

In 2022, 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, his team collects 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, refine surgeon training and enhance research as a care option.

*ASCRS Performance Metrics: Automated Performance Metrics to Assess Surgeon Performance in Colorectal Surgery*



**Matthew Ross Albert, MD**

**Matthew Ross Albert, MD**, joined the elite colon and rectal surgery team at AdventHealth Medical Group in July 2004. Dr. Albert is a Fellow of the American Society of Colon & Rectal Surgeons and the American College of Surgeons specializing 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-ranging services include 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 (Accreditation Council for Graduate Medical Education)-accredited subspecialty training program for colon and rectal surgeons. Dr. Albert specializes in sphincter-preserving surgeries for cancers of the rectum's lowest part, avoiding the need for a permanent colostomy.

In 2022, Dr. Albert served as the principal investigator on the SEAM study, testing the safety and efficacy of a new sutureless Self-Forming End-to-End Anastomosis device by Magnetic Compression.

*SEAM: Sutureless End-to-End Anastomosis by Magnetic Compression: A Study to Evaluate Safety and Effectiveness of the GI Window's Self-Forming Magnet (SFM) Anastomosis Device: A Historically Controlled Propensity Matched Study*



**Leonardo Alfonso Bustamante-Lopez, MD, PhD**  
Post-doctoral research fellow

**Leonardo Alfonso Bustamante-Lopez, MD, PhD**, is a postdoctoral research fellow and colorectal surgeon. Dr. Bustamante-Lopez says, "I am excited to be part of the Colorectal Medical Group, which covers everything in our specialty." "Working with the best surgeons in the field, we can approach research as a care option and an opportunity to improve patient outcomes in colorectal cancer, robotic surgery, IBD, TAMIS, laparoscopic surgery and pelvic floor diseases."

## New Investigator



**David Habib, MD**  
Clinical research fellow and general surgery resident

**David Habib, MD**, a clinical research fellow and general surgery resident from Pittsburgh, PA, enthusiastically pursues research opportunities at AdventHealth and aspires to become a colorectal surgeon following his training.

*Sub-PI on Study: ASCRS Performance Metrics: Automated Performance Metrics to Assess Surgeon Performance in Colorectal Surgery*

## Center for Interventional Endoscopy (CIE) Research Team



**Muhammad Khalid Hasan, MD**  
Medical Director, Center for Interventional Endoscopy (CIE)

**Muhammad Khalid Hasan, MD**, Medical Director of the Center for Interventional Endoscopy (CIE), is a clinical gastroenterologist specializing in advanced endoscopic procedures, including endoscopic retrograde cholangiopancreatography (ERCP), endoscopic ultrasound (EUS), advanced polyp resection techniques and more. As a staff physician at AdventHealth Orlando since 2010, he helped establish the CIE at Florida Hospital in 2013, which has evolved into a premier endoscopy center serving the needs of over 6,000 patients annually.

Dr. Hasan studies clinical disease states and outcomes associated with endoscopic procedures. He has initiated independent research and participated in multiple multicenter projects as a co-investigator, resulting in over 70 original publications in premier journals, such as *Gut*, *Gastroenterology*, *Endoscopy* and *Gastrointestinal Endoscopy*. In 2013, Dr. Hasan established the Advanced Endoscopy Fellowship (AEF) at CIE and served as the program director.





**Dennis Yang, MD**

**Dennis Yang, MD**, is the Director of CIE’s Third Space Endoscopy and a Professor of Medicine at Loma Linda University Health. Dr. Yang’s main clinical and research focus is on minimally invasive interventional endoscopic procedures for treating motility disorders (POEM, G-POEM) and advanced resection techniques (EMR, ESD) to treat early gastrointestinal cancers.

In 2022, Dr. Yang served as the principal investigator on the Purastat study, testing the safety and efficacy of the self-assembling peptide (SAP) forming gel (Purastat) for the prevention of stricture in the esophagus after an endoscopic resection.

*Purastat: Multicenter Prospective Evaluation of the Safety and Efficacy of a Self-Assembling Matrix-Forming Gel to Prevent Stricture Formation in High-Risk Patients*



**Mustafa Arain, MD**

**Mustafa Arain, MD**, is board-certified in gastroenterology and internal medicine and serves as the Medical Director of the Pancreas Center at CIE and AdventHealth Orlando. His clinical and research interests include pancreaticobiliary diseases and advanced endoscopic procedures, emphasizing endoscopic ultrasound and retrograde cholangiopancreatography, small bowel enterostomy and large polyp resection.

In 2022, Dr. Arain served as the principal investigator on the 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 (Italicize the title of the study)*



**Kambiz Kadkhodayan, MD**

**Kambiz Kadkhodayan, MD**, is the Program Director of the CIE’s Advanced Endoscopy Fellowship and is board-certified in Gastroenterology and Internal Medicine. His clinical and research focus includes the comprehensive and interdisciplinary management of patients with obesity, complex pancreaticobiliary disease and gastrointestinal cancer. In addition, he is proficient in endoscopic bariatric procedures, such as endoscopic balloon therapy (EBT), endoscopic sleeve gastropasty (ESG), endoscopic revision of gastric bypass (TORe, SIS, etc.), endoscopic management of post-operative complications.

In 2022, Dr. Kadkhodayan served as the principal investigator on the ABDE-ERCP vs EDGE study, outlining intra-procedural predictors of failure of BEA-ERCP and to evaluate an ideal time to cross over EDGE in RYGB anatomy.

*ABDE-ERCP - Intraprocedural predictors of balloon enteroscopy-assisted endoscopic retrograde cholangiopancreatography (BEA-ERCP) failure in patients with Roux-en-Y gastric bypass (RYGB) and determination of the optimal time to cross over to endoscopic ultrasound directed trans gastric endoscopic retrograde cholangiopancreatography (EDGE)*



# Genomics and Personalized Health

## Overview

The Genomics and Personalized Health team believes Genomics is revolutionizing medicine by enabling physicians and clinical leaders to provide individualized, whole-person care in ways never thought possible. Personalized medicine is a dynamic field where molecular testing increasingly predicts or determines which medical treatments will work best for each patient. By combining molecular testing results with a person's clinical and environmental data, health care providers can develop tailored prevention, diagnosis and treatment plans for those they serve.

Within this context, the Genomics and Personalized Health Program endeavors to become nationally recognized as a leader in transforming the health system into one that demonstrates the value of individualized care through research and the deployment of precision health technologies.

With the unprecedented advances in scientific knowledge and the ongoing development of novel therapies, Genomics and Personalized Health are 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 but a few of these diverse therapeutic areas.

Our program is expanding its biopharmaceutical partnerships to ensure that our patients have access to the most advanced diagnostic tools and treatments in the world close to home. The program applies precision health strategies across the entire clinical spectrum of wellness, disease prevention, diagnosis and treatment. Our program spans clinical practice, research, testing and therapies, as well as inpatient and ambulatory care. By implementing an industry-leading clinic-genomics platform, Genomics and Personalized Health combines genomic and clinical data in powerful, large-scale databases to develop new insights around disease progression, biomarker identification and novel potential drug targets.

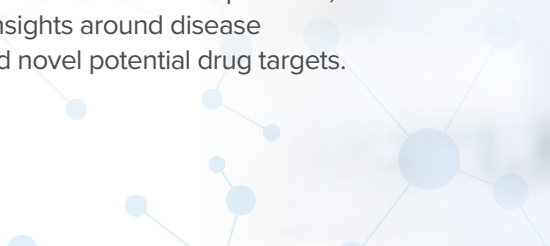
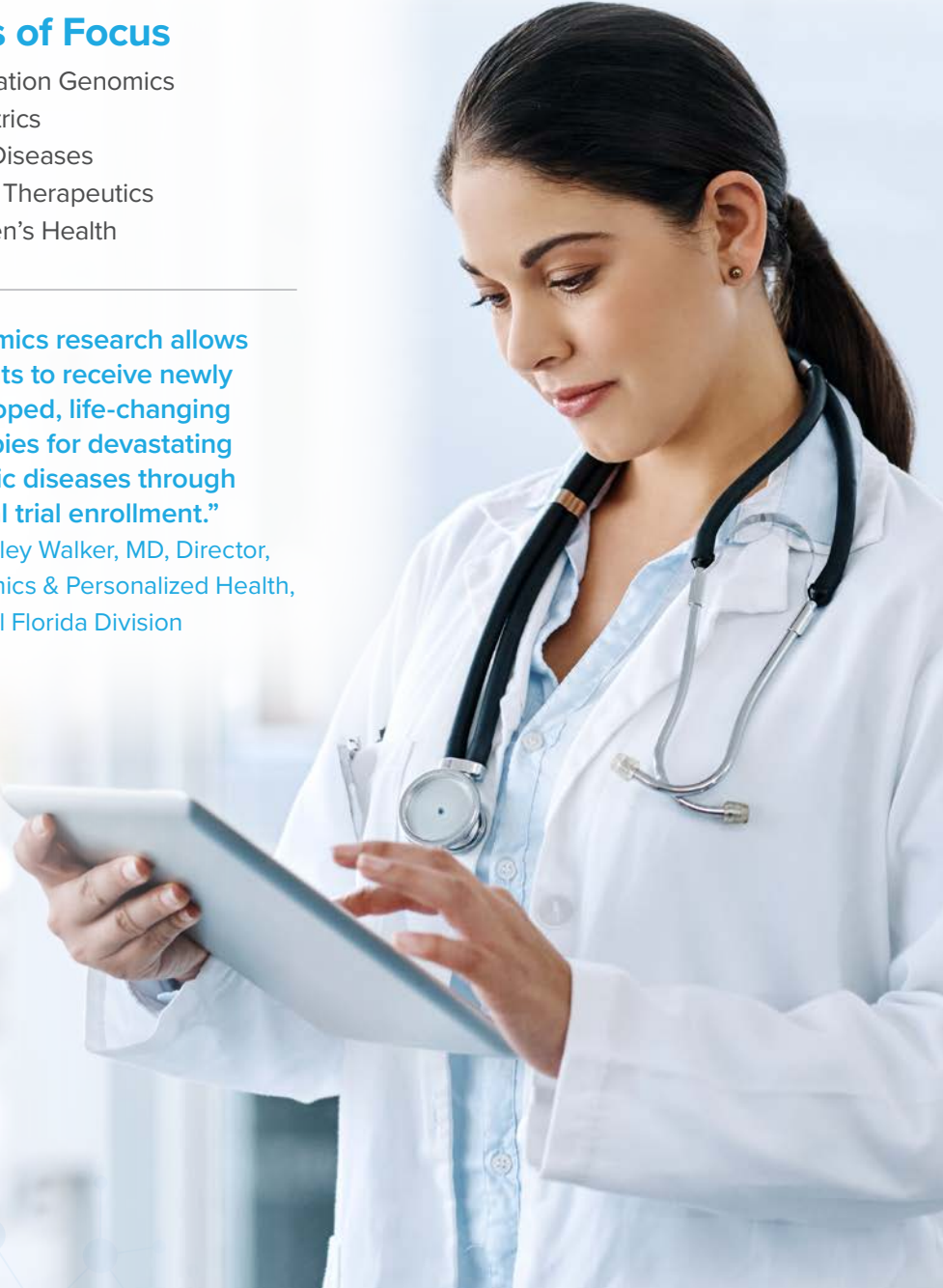
## Areas of Focus

- Population Genomics
- Pediatrics
- Rare Diseases
- Novel Therapeutics
- Women's Health

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**“Genomics research allows patients to receive newly developed, life-changing therapies for devastating genetic diseases through clinical trial enrollment.”**

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



## Featured Research and Researchers



**Rebecca Zuvich  
Essner, PhD**  
*and WholeMe Research*

**Rebecca Zuvich Essner, PhD**, is a statistical geneticist who has been involved with AdventHealth's research for over 10 years and joined Genomics and Personalized Health (GPH) in 2021. In her latest role, Dr. Essner serves as principal investigator for various population genomics studies, including WholeMe Florida, the first-of-its-kind DNA study with 10,000 participants across three different protocols. This study has provided clinically actionable genomic insights and a transition into clinical care for those with pathogenic findings, following their health care decision-making as a result.

Those with positive findings from both phases of the first protocol (420 participants) were provided with step-by-step resources to transition into clinical care. Under the research protocol, this care pathway allowed participants to receive education about their particular genomic condition and guidance on the next steps in their personalized health care journey. In addition, any downstream care sought at AdventHealth for these conditions or related care was also tracked for AdventHealth researchers to better understand the clinical ramifications of population health initiatives, such as WholeMe.

The third phase of the WholeMe, WholeMe Breast Cancer, launched in May 2022. This study sought to juxtapose genetic testing with other preventive screening mechanisms, like mammography. After consenting, participants wishing to enroll would complete a cancer risk assessment to obtain their breast cancer risk profile. Those at moderate risk were then asked to complete genetic testing for an 11-gene breast cancer panel as part of the research protocol. The research team collaborated with various mammography clinics and leadership to ensure the research was not disrupting the clinical workflow. They also enabled those needing a genetic test to fulfill this at the time of their mammography appointment—to “make it easy.” High-risk participants (over 70 percent of participants) were immediately referred to our medical geneticist for clinical and follow-up care.

Using WholeMe learnings, it was decided to pivot away from a research study and use the cancer risk assessment survey in a clinical setting. Beginning in 2023, the GPH team will begin implementing the cancer risk assessment into various clinical settings—focused on breast health, colon health or both. For each clinical program, care pathways and algorithms will be developed based on widely accepted evidence-based practice guidelines from industry-leading organizations to personalize care based on cancer risk profiles. The workflows will be designed with the clinical teams to ensure clinical pathways are not disrupted and will be complemented with a care navigation team to guide patients through these high-risk pathways and ensure no gaps in care.

## WholeMe Research Participant Spotlight—Bettina Thomas



**Bettina Thomas**

Bettina Thomas knows the important role screening plays in the early detection of breast cancer. Her mother is a breast cancer survivor, and her younger sister recently died from the disease. That's why when the former AdventHealth team member saw the poster in a hospital lobby, she did not hesitate to discover more about the WholeMe project, launched in August 2019. Thomas participated in phase 2 of the study, which

included screenings for heart conditions beyond familial hypercholesterolemia—the focus of phase 1. It also screened for hereditary cancers such as breast, ovarian and colon. After two saliva tests, the results confirmed what she had suspected: she was at high-risk for breast cancer. Thomas said she had previously been unsuccessful in her attempts to get genetic screening for mutations in the BRCA (Breast Cancer) genes—the most well-known hereditary breast cancer genes that can indicate increased risk.

Thomas said the process “gave me the insight and information I needed to take care of myself. Having a great doctor, early detection, a support system and a positive outlook are all vital in any journey with cancer.”

She also learned that her time of highest risk is between the ages of 40 and 50. Since turning 40 recently, she has a mammogram every six months, alternating with a breast MRI and an annual ovarian ultrasound and labs. Witnessing cancer in her family was an emotional rollercoaster. That's why, Thomas emphasized, “The whole point is I'm trying to keep from getting cancer and also inform others how important it is to get tested.”



**Majed Dasouki, MD**  
*Medical Director,  
AdventHealth Genetics  
and Genomics*

**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 2022, Dr. Dasouki collaborated with scientists from A\*STAR's Genome Institute of Singapore (GIS) in partnership

with hospitals and institutes across seven countries: India, the U.S., Saudi Arabia, Pakistan, Portugal, Brazil and France. New findings have uncovered how essential the how the essential protein coding gene Focadhesin (FOCAD) is for maintaining a healthy liver, especially in children. Furthermore, scientists have found that children carrying loss-of-function mutations in FOCAD are presented with an early onset, pediatric form of liver cirrhosis that can be life-threatening.

Dr. Dasouki also works 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.

# 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 department offers leading-edge, patient-focused research while leveraging extensive clinical and scientific expertise. Our vision is to transform health care through groundbreaking, innovative, globally recognized whole-person research.

The world-renowned team of scientists and physicians use groundbreaking science to save lives through research studies and clinical trials. 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



**“As patients come into our institution facing health crisis and adversity, they want the best care and, as providers, we want to provide the best care. We are fortunate to have their trust. With that said, the care we are so uniquely skilled to perform is because our colleagues and community contribute their valuable time and consent to participate in research studies. They allow us to deliver the best care possible today. The Heart, Lung, and Vascular Institute (HLVI) does not offer adverse solutions, but rather, we are a futuristic solution to today’s adversities. It is bringing tomorrow to our consumers and physicians today through cutting-edge research and training. If we didn’t have HLVI research, we wouldn’t be able to perform what we do today.”**

— Rohit Bhatheja, MD

## Featured Researchers and Research



**Rohit Bhatheja MD, MBA, FACC, FSCAI**  
Medical Director, HLVI,  
AdventHealth

**Rohit Bhatheja MD, MBA, FACC, FSCAI** is an award-winning cardiologist board-certified in cardiovascular disease, interventional cardiology and internal medicine, who also serves as the HLVI's Physician Leader and Medical Director of the AdventHealth Cardiovascular Services—South & West Markets. As the principal investigator of a 2022 study, Dr. Bhatheja and his team evaluated the safety and efficacy of a new catheter used to fix

artery clots related to acute pulmonary embolism (PE). This disease is highly underdiagnosed and could result in cardiac death shortly after the first symptoms. Unfortunately, doctors have few methods to treat this situation. The most non-invasive option is a heart catheter that administers a tissue plasminogen activator (tPA) to break down the clot inside the artery. With this treatment plan, Dr. Bhatheja says the patient leaves the room “with a band-aid and not a device.”

The Bashir Endovascular Catheter, observed in the study, is the newest catheter technology designed for these kinds of procedures, shortening the time it takes to treat the patient and reducing the need for blood thinners. This “first-in-human” study provided positive results among the 110 participating patients. The Bashir catheter was associated with a significant reduction in the right ventricle/left ventricle diameter ratio, a significant reduction in PA obstruction with low-dose tPA and a very low rate of adverse events or major bleeding in patients with intermediate-risk acute PE. Dr. Bhatheja hopes to collect more registry data to understand further how the catheter's use in treatment might affect hospital discharges and the patient's length of stay without adverse events.



**Kapil Kapoor MD, PhD, FAHA**

**Kapil Kapoor MD, PhD, FAHA**, is a Senior Research Scientist in the Cardiovascular Research department at AdventHealth Orlando with more than 23 years of contributions to Cardiovascular and Neuroscience research fields, including seminal observations in the role of calcitonin gene-related peptide in migraine prevention. As Senior Research Scientist, Dr. Kapoor collaborates with physicians, clinicians and scientific colleagues

to identify, review and develop research opportunities supporting the department's research objectives.

One of his studies, “Impact of Familial Hypercholesterolemia (FH) genetic testing on high-risk cardiovascular disease patient outcomes,” began enrolling in August 2022. This study is important because FH prevalence in the U.S. is around 0.4 percent in the general population and increases more than 10 times in patients with coronary artery disease. FH is severely underdiagnosed, undertreated and rarely diagnosed via genetic testing, even though it is a genetic disorder. In 2018 the international Expert Consensus Panel convened by the FH Foundation recommended that FH genetic testing becomes the standard of care for patients with definite or probable FH and their at-risk relatives. This action will increase the number of diagnoses for FH, leading to more effective cascade testing, risk stratification and therapy initiation at earlier ages to prevent life-threatening cardiovascular diseases.


This clinical research will help evaluate how these newly informed health care needs, as determined by the interpretation of genomic data, can be implemented into and impact clinical care pathways involving the appropriate follow-up testing, education, genetic counseling and cascade screening when appropriate.



**Naushad A. Shaik, MD, FACC, FHRS, CCDS**

**Naushad A. Shaik, MD, FACC, FHRS, CCDS**, is a board-certified cardiologist with training in internal medicine, clinical cardiology and clinical cardiac electrophysiology. He specializes in complex ablation procedures for arrhythmia, including supraventricular arrhythmias, atrial fibrillation, ventricular arrhythmias and implantations.

Dr. Shaik is currently involved in national and international research trials involving catheter ablation and new device therapies and technology. In one study, Dr. Shaik monitors the effectiveness of the Aurora EV-ICD and Epsilon EV lead, a minimally invasive option for specific heart problems. For example, ICDs are highly effective in providing life-saving therapy for patients at risk of sudden cardiac arrest (SCA), an electrical problem with the heart resulting in a dangerously fast heart rate. If not treated immediately, SCA can be fatal. Traditionally, transvenous ICDs are implanted in the chest and attached to leads threaded through veins and into the heart to sense the heart's electrical signals and deliver therapy to terminate a potentially fatal arrhythmia—restoring the heart's normal rhythm. Alternatively, when using



a method that places the lead outside of the heart and veins, like the Epsila EV lead, long-term complications associated with transvenous leads, such as vessel occlusion and blood infections, can be avoided.

In the pivotal global study, the device's effectiveness in delivering defibrillation therapy at implant was 98.7 percent. This finding reflects a greater defibrillation efficacy for the EV-ICD than historical transvenous ICD studies and comparable efficacy to the subcutaneous ICD. Further, in the EV ICD study, the efficacy of anti-tachycardia pacing (ATP)—which paces the heart to interrupt and terminate a dangerous rhythm, potentially avoiding a defibrillation shock—in the EV ICD study was comparable to ATP efficacy in transvenous defibrillators. In total, 33 shocks were avoided by having ATP programmed “on.” In addition, no major intraprocedural or unique complications were observed related to the EV-ICD procedure or system.

“The growing physician and patient awareness about the risks that accompany placing leads in the heart or veins are addressed by the Aurora EV-ICD system,” Dr. Shaik states. “It provides an extravascular solution while maintaining the traditional ICD benefits of pacing and defibrillation therapy.”

Insights into new devices and procedures enable doctors to explore new ways of addressing patient needs, increasing medical knowledge and improving patient care. This study will provide valuable knowledge which can be shared with other doctors for an even greater impact.

### **AdventHealth Among First in the U.S. to Use New MITRIS RESILIA Bioprosthetic Mitral Replacement Valve with Anti-calcification Technology**



Kevin Accola, MD

In March, the U.S. Food and Drug Administration (FDA) granted pre-market approval for Edwards Lifescience's MITRIS RESILIA valve, a tissue-based mitral valve replacement designed to last longer than previous bioprosthetic valves. AdventHealth Orlando Cardiovascular Surgeon **Kevin Accola, MD**, was among the first to use the new MITRIS valve and participated in the COMMENCE pre-market clinical trial evaluating its safety and effectiveness.

The American College of Cardiology estimates that four million people in the U.S. suffer from significant mitral valve disease caused by mitral regurgitation, mitral stenosis and rheumatic valvular disease. Some mitral valves can be repaired, but others must be replaced with an artificial valve.

“Mechanical replacement valves have been around for decades and are still used and appropriate for some patients,” explains Dr. Accola. “These valves require lifelong anticoagulation treatment, which can particularly burden younger patients. Bioprosthetic valves incorporate animal tissue and eliminate the need for anticoagulants. However, they have historically proven less durable, limiting their use to older patients.”

A primary challenge with bioprosthetic replacement has been structural valve deterioration caused by calcium buildup on the valve's tissue over time. The new MITRIS RESILIA, made with bovine pericardial tissue and designed to mimic the native valve, incorporates an anti-calcification, integrity-preservation technology designed to help the valve last longer. This technology also allows the valve to be stored under dry packaging conditions. In addition, the MITRIS valve features a low-profile frame that helps avoid obstruction of the left ventricular overflow tract by stent posts and is visible under fluoroscopy to facilitate potential future transcatheter interventions for patients, including valve-in-valve implantation.

“We continue to explore new approaches to increase the durability of bioprosthetic valves,” shares Dr. Accola. “The technology built into the MITRIS valve should help mitigate the calcium buildup issue and extend longevity, which could benefit younger patients who have historically had to receive mechanical valves instead.”

The COMMENCE trial included 83 patients in its mitral valve replacement arm and 694 in an aortic replacement valve arm using the same tissue technology. Patients were followed for five years, and the findings included clinically stable hemodynamics (blood flow), minimal regurgitation and no evidence of structural valve deterioration. A new arm of the COMMENCE trial will explore 10-year outcomes of the MITRIS RESILIA valve, in which AdventHealth will also participate.

“At the AdventHealth Cardiovascular Institute, we believe in continually improving patient care and outcomes,” says Dr. Accola, “That is why we are committed to staying on the cutting-edge of new valve replacement technologies that will allow our patients to access the most advanced solutions for their particular problems.”

## AdventHealth First in Central Florida to Implant Dual Chamber Leadless Pacemaker as Part of AVEIR DR i2i Clinical Trial



**Usman Siddiqui, MD**

In August 2022, AdventHealth HLVI cardiologist **Usman Siddiqui, MD**, implanted Central Florida's first dual-chamber leadless pacemaker system in the Aveir DR i2i clinical trial. This prospective, multicenter, international, single-arm study is designed to evaluate this new device's clinical safety and efficacy.

While a traditional transvenous pacemaker delivers electrical impulses through thin, insulated wires called cardiac leads that connect to the heart muscle chambers, a leadless pacemaker is a self-contained generator and electrode system implanted directly into the right ventricle through a minimally invasive, catheter-based procedure and requires no subcutaneous generator pocket. This approach decreases the risk of complications like infection, erosion and pocket hematoma. In addition, it allows for a less restrictive recovery period, and aesthetically, the patient does not have to live with device protrusion.

While nearly 80 percent of people who receive a pacemaker need a dual-chamber option to pace both chambers on the right side of the heart, leadless pacemakers have historically been limited to single-chamber devices because synchronization of two leadless pacemakers had been difficult to achieve. However, the new Aveir DR i2i dual-chamber leadless pacemaker's technology was designed to solve this challenge, synchronizing the heart rate between two leadless pacemakers—one placed in the right ventricle and the other positioned in the right atrium. In addition, this new dual-chamber leadless pacemaker provides a real-time mapping capability so physicians can assess therapy delivery and reposition the device before implant during a patient's procedure. It was also designed to be retrievable so the system can be replaced as therapy needs evolve.

**George Monir, MD**, is an award-winning, board-certified cardiologist specializing in cardiovascular disease, nuclear cardiology, arrhythmia treatment, catheter ablations and cardiac electrophysiology. He also serves as the Medical Director of the Arrhythmia and Ablation Center at AdventHealth and has received several awards and recognition for his medical research.



**George Monir, MD**  
*Medical Director,  
Arrhythmia and Ablation  
Center, AdventHealth*

Dr. Monir led the clinical trial AdmIRE to study the safety and long-term effectiveness of the BWI irreversible electroporation (IRE) ablation system consisting of the TRUPULSE™ Generator and VARIPULSE™ Catheter in subjects who have failed at least one antiarrhythmic drug to treat Paroxysmal Atrial Fibrillation (PAF). The BWI IRE Ablation system uses a new type of energy source called "pulse field." Pulse field ablation applies ultra-rapid electrical fields to the heart muscle to cause IRE to treat AF. The results of this trial could benefit future care options and provide effective alternatives to patients with drug-resistant PAF.

## AdventHealth Redmond



**Robert Styperek, MD**

**Robert Styperek, MD**, is a Cardiac Electrophysiologist with over 20 years of expertise in the field. He earned his medical degree and completed his internship and residency at Emory University School of Medicine in Atlanta. He furthered his training with two fellowships in cardiology and electrophysiology at Jackson Memorial Hospital in Miami.

Dr. Styperek has actively engaged in clinical research for more than 13 years. In his current study, the Optimizer Smart PAS is monitored for its ability to evaluate the safety of long-term use of cardiac contractility modulation, also known as CCM therapy, for patients in need of heart failure therapy. Heart failure is typically treated with medications to improve the strength of the heart muscle and reduce the amount of work the heart must perform, but they are not always successful in improving quality of life. Therefore, as part of clinical research, patients in this study can help evaluate the effects of long-term use of CCM therapy on quality of life, heart failure symptoms and its impact on the heart's ability to pump.

"Bringing patient care and research together helps to improve efficiency and outcomes and encourage patient-centered studies that increase the diversity of patients that have access to clinical trials," Dr. Styperek says. "Treating research as a viable care option benefits patients, physicians and the research community and can lead to a higher study participation rate."



# Neuroscience Institute

## Overview

The AdventHealth Neuroscience Institute (NSI) aspires to build a world-class neurology and neurosurgery network recognized among the top one percent of programs in the country and to be known as a neuroscience research destination by 2030. We aim to grow volume, differentiate programs, expand services and research platforms and achieve national recognition among our specialty services.

## Areas of Focus

- Alzheimer's and Dementia
- Cranial Surgery
- Epilepsy
- Headache and Migraine
- Minimally Invasive Brain Surgery
- Movement Disorders
- Multiple Sclerosis
- Neuromuscular Diseases
- Sleep Medicine
- Spine Services
- Stroke

## Active Clinical Trials Underway

- Alzheimer's
- Amyotrophic Lateral Sclerosis (ALS)
- CDKL5 Deficiency Disorder
- Charcot Marie Tooth (CMT)
- Dravet Syndrome
- Glioblastoma
- Lennox-Gastaut Syndrome
- Multiple System Atrophy (MSA)
- Parkinson's
- Spinal Muscular Atrophy (SMA)
- Stroke
- Subdural Hematoma
- Thrombectomy

**“Neuroscience research provides patients with clinical trial opportunities to address their unmet needs in treating devastating, progressive neurological illnesses. Clinical studies offer hope for patients when no approved effective treatment is available to treat symptoms effectively and advance science and knowledge about the disease process. Participating in clinical studies leads to improved motivation and positive attitude towards fighting the disease effectively.”**

— Anwar Ahmed, MD

## Featured Researchers and Research



**Ki Lee, MD**  
Medical Director,  
Children's Pediatric  
Epilepsy Center,  
AdventHealth  
for Children

**Ki Lee, MD**, is a board-certified neurologist and epileptologist with AdventHealth Medical Group and the Medical Director of AdventHealth for Children's Pediatric Epilepsy Center in Orlando. A leading provider of diagnostic and surgical techniques for addressing epilepsy and seizures, Dr. Lee seeks research that advances the state of epilepsy patient care through medical breakthroughs and new technologies.

The epilepsy center is conducting an active clinical trial for Dravet syndrome gene therapy, sponsored by Stoke Therapeutics. Dravet syndrome is caused

by mutations in the SCN1A gene, which codes for a protein critical for the function of neurons in the brain. The mutations in the SCN1A gene produce a defective protein that disrupts the normal functioning of neurons, leading to seizures, developmental delays and other neurological symptoms. Currently, no treatment is available to modify or reverse the disease course with Dravet syndrome.

The Dravet gene therapy trial is designed to address this underlying genetic defect by using a gene therapy approach to increase the production of an SCN1A protein. The gene therapy treatment involves delivering a small piece of RNA, called an antisense oligonucleotide, to the brain to increase the production of SCN1A protein.

The first of this two-part study, a dose-escalation study, is designed to evaluate the safety and tolerability of the gene therapy treatment in a small number of patients with Dravet syndrome. The second part will enroll a larger number of patients and is designed to evaluate the efficacy of gene therapy treatment in improving seizure control and other neurological symptoms.

Preliminary results from the first part of the trial have been promising. According to the sponsor, the gene therapy treatment has been well-tolerated in patients with Dravet syndrome, with no serious adverse events associated with the treatment.



**Ira Goodman, MD**  
Consulting Director,  
Neurology Clinical Trials

**Ira Goodman, MD**, a board-certified adult neurologist specializing in neurodegenerative diseases, is the Consulting Director of Neurology Clinical Trials for the AHRI Neuroscience Institute. He received his medical degree from the Medical College of Pennsylvania and completed a Neurology Residency at the University of Florida in 1983. Dr. Goodman has practiced Neurology in Central Florida for over 35 years and is active in medical education with faculty appointments in the Departments of Medicine and Neurology at the University of Florida, Florida State University and the University of Central Florida. Dr. Goodman also has participated in the AdventHealth Geriatric Fellowship Program.

Dr. Goodman helped develop the state-funded Memory Disorder Center of Central Florida, where he served as the Director until 2011. He also is extensively involved in clinical research in neurodegenerative diseases. He has served as a principal investigator in conducting dozens of Clinical Research Trials over the years, including nearly all ongoing trials involving anti-amyloid vaccines and small molecules benefiting individuals with Alzheimer's Disease. He has authored several publications and presentations while also working with numerous pharmaceutical companies in developing and writing clinical trial protocols.

### AdventHealth Enrolling for Davos Alzheimer's Collaborative (DAC) Clinical Trial Focused on Increasing Early Detection and Accurate Diagnosis



**Valeria Baldivieso, MD,**  
and the DAC study

The AdventHealth Research Institute (AHRI) has joined forces with the international DAVOS Alzheimer's Collaborative study to revolutionize the future of Alzheimer's care. The first of its kind in the U.S., the DAC study goes beyond a memory test and aims to improve early detection and delay cognitive decline in millions of people worldwide. The study aims to create a cost-effective, global clinical pathway to help physicians, especially those working in primary care, to more quickly detect and effectively diagnose Alzheimer's cases. This would speed patient access to

AdventHealth participated in a groundbreaking international research study aiming to aid the early detection and treatment of Alzheimer's disease. With the hope to encourage Hispanics to participate in the research, Dr. Valeria Baldivieso from AdventHealth and one of the investigators in the research study encouraged the Hispanic population in Central Florida to take part in the study during an interview with Univision Orlando.

AdventHealth participó en un innovador estudio de investigación internacional con el objetivo de ayudar a la detección temprana y el tratamiento de la enfermedad de Alzheimer. Con la esperanza de alentar a los hispanos a participar en la investigación, la Dra. Valeria Baldivieso de AdventHealth y una de las investigadoras del estudio de investigación, alentó a la población hispana de Florida Central a participar en el estudio durante una entrevista con Univision Orlando.



emerging treatments and innovations that could slow the onset and progression of the disease and, ultimately, improve patients' quality of life for a longer period. Partnering closely with primary care physicians, they want to build a system where screening for Alzheimer's becomes as easy and commonplace as checking for hypertension.

The new PrecivityAD blood test is utilized to detect Alzheimer's disease-related biomarkers and integrate technology-enabled cognitive assessment tools into clinical practice. Combining these measures

with the patient's age, the test uses a statistical algorithm to calculate an Amyloid Probability Score (APS) to indicate the likelihood of beta-amyloid plaques in the brain, one of the biological hallmarks of Alzheimer's disease.

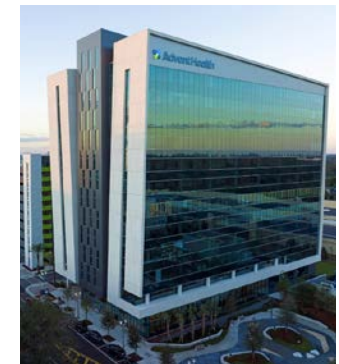
This system could change the future of Alzheimer's care by empowering doctors to have proactive conversations with affected patients and maximize preventative care options for optimum quality of life. Early detection would slow potential cognitive decline, minimize risk factors and connect the patient to stronger support networks and resources. In addition, the results of this research could impact future care integrated into routine health exams, similar to cholesterol tests, putting confidence and knowledge back into the patient's hands.

### Neuroscience and Neurology Research Joins Innovation Tower

On August 22, 2022, the AHRI proudly opened its new 18,000-square-foot Neuroscience Research facility on the 2nd floor of the Innovation Tower housing a research clinic, laboratory, phlebotomy room, medication room, computational data room and administrative offices.

Patient comfort and care are the clinic's top priority in all ten exam rooms, four patient consenting rooms, two infusion rooms, and the nursing station. The computational data room is designed to support specialized neuroimaging data and statistical analysis using top-end computer systems. The neuroscience research team and the neurology clinical teams are united in the same tower, thus offering patients a seamless standard of care and research care options.

A team of sixteen highly skilled Neuroscience professionals support the Brain Health, Neurosurgery and Translational Neuroscience research portfolio including Directors, an Operations Manager, Postdoctoral Fellows, Research Coordinators, Research Support Assistants and Administrative Assistants. The team is instrumental in providing excellent patient care and will continue to grow with the expanding portfolio of groundbreaking research, leveraging our population's scale and diversity.



## New Investigators



**Kirk Erickson, PhD**  
*Director of Translational  
Neuroscience,  
Neuroscience Institute;  
Mardian J. Blair  
Endowed Chair*

**Kirk Erickson, PhD**, is the Director of Translational Neuroscience and the Mardian J. Blair Endowed Chair of Neuroscience at AHRI's Neuroscience Institute. Dr. Erickson received his doctorate at the University of Illinois at Champaign-Urbana and was a postdoctoral scholar at the Beckman Institute for Advanced Science and Technology in Urbana, IL. He was also a Professor of Psychology and Neuroscience at the University of Pittsburgh before joining AdventHealth. Dr. Erickson's vast research program focuses on the effects of physical activity on brain health across the lifespan. This research has resulted in over 260 published articles and 15 book chapters.

"I was incredibly impressed by what I saw at AdventHealth during my initial visits, and I thought that the potential to build a translational neuroscience research community here was unprecedented," Dr. Erickson states. "I came to AdventHealth because of its high-level, high-quality science, the institute's ability to build something amazing, and my potential to contribute to a talented scientific community."

Dr. Erickson's research has been funded by numerous awards and grants from NIH, the Alzheimer's Association and other organizations. He is the principal investigator of a multi-site Phase III randomized clinical trial examining the impact of exercise on neurocognitive function in late adulthood. His research resulted in the prestigious Chancellor's Distinguished Research Award from the University of Pittsburgh. He was named a Fellow of the Academy of Behavioral Medicine Research in 2016 and received a Distinguished Scientist Award from Murdoch University in Australia in 2018. He holds a Visiting Professor appointment at the University of Granada, Spain.

"I view research as a central component of health care. To that end, patients must be aware of the most cutting-edge treatments. As researchers and physicians, we need to be aware of the potential for research to change therapeutic options and the interest from patients to engage in this way."



**Mitesh Lotia, MD**  
*Medical Director,  
Movement Disorders,  
AdventHealth  
Neuroscience Institute*

**Mitesh Lotia, MD**, is a fellowship-trained Movement Disorder Neurologist who joins the AdventHealth Neuroscience Institute as a Medical Director for Movement Disorders, helping patients with Parkinson's, Dystonia, Tourette syndrome and other movement disorders. After completing a two-year Movement Disorders Fellowship at Baylor College of Medicine under the guidance of Dr. Joseph Jankovic, where he also served as a chief fellow, Dr. Lotia joined the University of Arkansas for Medical Sciences (UAMS) as an Assistant Professor. At UAMS, Dr. Lotia served as

the neurology residency Program Director and worked in multiple leadership roles.

Dr. Lotia has been involved in clinical research throughout his career, focusing on Parkinson's disease, neuromodulation and education.

"With AdventHealth, there has been a well-executed effort to synchronize the expert availability to help provide the highest level of care in the Central Florida region and beyond," Dr. Lotia said. "I am privileged to have joined the Neuroscience Institute to develop to develop timely and effective pathways to personalize each patient's care. The whole-person care model has been our care philosophy and is ideal for our patients."

Dr. Lotia is a recipient of the AB Baker Teacher Recognition Award, the founding member of the Functional Neurological Disorder Society (FNDS) and an active member of the American Academy of Neurology (AAN) and Movement Disorders Society (MDS).

"My idea of the highest level of care includes patient access to clinical research—one of the most significant parts of the patient journey, providing hope and optimal therapeutic options. As we strive to improve our patient's life, the goal is always disease modification and a potential cure, especially with neurodegenerative conditions... It is increasingly important to identify therapies that not only help slow down degeneration but potentially reverse conditions. We can only accomplish that by offering more opportunities for research participation."

# Nursing, Whole-Person and Academic Research

## Overview

The AdventHealth Nursing, Whole-Person and Academic Research team leads in recognizing, describing, delivering and measuring the specific, defining behaviors of wholeness and whole-person care as essential elements of excellence in health care delivery. This research translates insights from scientific discovery into application in clinical, operational and academic settings to drive improvements in care delivery, quality of care, consumer experience, health outcomes and population health.

The team is dedicated to creating new knowledge by developing approaches to stabilize the clinical workforce and improve the mental, spiritual, physical and social health of clinical providers while also prioritizing the inclusion and diversity of the populations we study. We are intentional in closing the gaps in our understanding of all of our communities and our experiences.

The staff also offers structured programming to support graduate medical education, graduate nurse education, evidence-based practice residencies, doctoral nursing students and AdventHealth University faculty and students. The team comprises research scientists, biostatisticians, academic advisors and research and administrative coordinators working harmoniously to mentor junior investigators and executives in research methodologies and actionable program evaluations that drive change. In addition, we aim to establish and foster external, high-impact academic collaborations that recognize our health care system as the leader in whole-person care.

## Areas of Focus

- Wellness of Body, Mind, Spirit and Social Support
- Transformative Whole-Person Health Care Delivery
- Scientific Foundation for Wholeness
- Workforce Well-Being and Recovery



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**“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. It is a true privilege to lead a team that is creating solutions for the future of our clinicians. Healthier clinicians is our promise to our doctors, nurses and the patients they care for.”**

— Patricia Robinson, PhD, APRN

## Featured Researchers and Research

### Caring for Caregivers

#### RISE for Nurse Leaders



Amanda Sawyer, PhD



Building on the success of RISE (Resilience, Insight, Self-Compassion, Empowerment) for Nurses, the RISE for Nurse Leaders randomized controlled trial was completed in 2022. The study was originally developed to promote self-care, protect against burnout and improve well-being indicators among nurses. The nine-week virtual program was delivered via Microsoft Teams. It was adapted for leaders with authentic leadership and post-traumatic growth (PTG)—the positive psychological change experienced through adversity, trauma or crisis.

The findings revealed significant differences in the total PTG inventory scores between the intervention and control groups, along with scores monitoring relation to others, new possibilities, personal strength and spiritual change. Significant improvements were also shown in self-reflection and insight, self-compassion, psychological empowerment, compassion, satisfaction and noteworthy reductions in perceived stress, burnout and secondary traumatic stress.

“The difficulties of being a nurse leader are well-known,” said one participant. “However, addressing these difficulties and becoming equipped with the knowledge and skills to navigate them makes me feel hopeful for myself and future leaders. The information, skills and their importance in my mental health are priceless.” RISE is the first intervention designed for nurses to address these outcomes and has been critical to AdventHealth nurses during the COVID-19 pandemic.

### Virtual Nursing



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

The acute care work environment directly impacts employee health due to perceived job stress and work demands that can lead to burnout and voluntary resignation of nurses. Pre-existing job stressors were amplified by the COVID-19 pandemic leading to high turnover among acute care registered nurses (RNs). As a result, hospitals explored innovative approaches to stabilize the workforce and support RNs while reducing their perceived workload intensity. One strategy integrated Virtual Nurses (VNs) and Patient Safety Companions in Medical-Surgical and Emergency Department settings. VNs are expert RNs who engage with patients and their primary RN via technology throughout their hospital stay, record patient histories, reconcile medication, educate patients, monitor vital signs and labs, conduct hand-off reports and provide discharge education. The VN care delivery model has provided staffing solutions, decreased time to discharge and improved patient throughput and safety outcomes. Still, whether the VN approach has impacted nurses’ perceived workload intensity, stress, burnout or intent to stay is unknown. Therefore, it is critically important to compare the VN-RN and the traditional RN-RN nurse care delivery model to determine whether integrating VNs impacted the RNs’ perception of workload intensity, their professional quality of life (i.e., compassion satisfaction, perceived support, burnout, secondary traumatic stress, moral distress) and intent to stay. This study illustrates research to ensure patient care delivery strategies align with caring for nurses and their patients.



## Chaplain Well-Being Study



**Mandi Bailey, MA, LMHC**

The COVID-19 pandemic had extensive mental health ramifications on clinical staff. However, health care team members on the frontlines, particularly in a faith-based organization like AdventHealth, were suffering greatly without recognition or support. Chaplains were engaged in end-of-life care during the pandemic, connecting terminal patients with family members via video chat and ministering to clinical staff in spiritual and psychological crises.



**Stephanie Harris, MLS**

The chaplains asked psychotherapist **Mandi Bailey, MA, LMHC**, to present a well-being workshop series to help cope with the stressors of the pandemic. In collaboration with principal investigator **Stephanie Harris, MLS**, and Scientific Director **Patricia Robinson, PhD, APRN**, Bailey developed a series of six monthly workshops for AdventHealth chaplains that were delivered both in-person and virtually, allowing chaplains from across the system to participate. Topics included enacting healthy boundaries, emotional and spiritual resilience, grief, secondary and vicarious trauma, self-compassion and post-traumatic growth.



**Patricia Robinson,  
PhD, APRN**

*Scientific Director,  
Nursing, Whole-Person  
and Academic Research*

“I did not previously realize how affected I have been by my caring experiences,” a participant stated. “The information in this presentation connected well with my feelings and reactions to the traumas I’ve observed. As a result, I’ve stopped minimizing thoughts that I’m all right and acknowledged the damage done. In addition, it’s helped me ask questions about what and how frequently I am willing to expose myself. Finally, it has motivated me to reach back to session one and implement the boundaries discussed there while also initiating liberation from a survival mentality toward a pursuit of wellness and balance.”

The team used a mixed-methods study design to collect survey data on key constructs and conducted interviews about chaplains’ experiences with job-related stress and the workshops. After the workshops, scores on burnout and secondary traumatic stress decreased, while a measure of self-compassion significantly increased. Qualitative data revealed that chaplains greatly benefited from gaining a new vocabulary to express their experiences and from the social support afforded by the workshop groups.

Caring for caregivers and measuring the impact of interventions on the mental well-being of our workforce drives much of the Whole-Person research we conduct. Chaplains are key multidisciplinary care team members in a faith-based institution and an invaluable source of support to many patients, visitors and staff members. This study contributed to the literature on the organizational support of chaplains and provided psychological and emotional support to AdventHealth’s chaplain staff when it was most needed.

## A Collaboration with Loma Linda University



Hong Tao, PhD, RN

A shared interest in the well-being and caregiving of nurses sparked a collaboration between AdventHealth and Loma Linda University researchers. With **Hong Tao, PhD, RN** as the principal investigator, the Nursing, Whole-Person and Academic Research team was in the pre-launch stages of a study to validate an instrument to measure moral injury in nurses supported by the Wholeness Institute. Concurrently, the nurse

researchers at Loma Linda University were interested in empathy in nursing staff, a key aspect of whole-person caregiving and a characteristic influenced by mental well-being. Patricia Robinson, PhD, developed a strategy to combine the initiatives into one grand data collection effort, thus reducing the survey burden on an already overtaxed nursing staff and streamlining study processes for both institutions.

The Moral Injury Outcome Scale study, led by **Hong Tao, PhD, RN**, exemplifies Nursing, Whole-Person and Academic Research's commitment to diversity, equity and inclusion. By recruiting a sample population representative of nursing workforce diversity, they utilized survey software capable of setting demographic quotas to ensure that all voices had a chance to be heard.

## Mentoring and Academic Research

### Management of Complex, Painful Post-operative Wounds



Daniel Farinas-Lugo, MD

A general surgery collaboration with the AdventHealth Wound Care Team, led by a fourth-year resident, **Daniel Farinas-Lugo, MD**, created a project assessing the benefits of a transforming powder dressing (TPD—Altrazeal®) in the management of painful, complex post-surgical wounds. Dr. Farinas-Lugo presented his results at the 2022 AdventHealth Research Day, where he earned the first-place award for a podium presentation.

Complex post-surgical wounds are often associated with high pain scores and respond poorly to conventional treatment, leading to decreased quality of life and extended hospital length of stay.

TPD is a powder dressing that polymerizes when hydrated, forming a moist, flexible and oxygen-permeable matrix that protects the wound while allowing drainage of exudate. Once applied, the dressing can stay in place for up to 30 days.

The project included 12 patients with various wound types and sizes who reported severe pain scores. Using TPD instead of a conventional dressing resulted in an 80 percent decrease in reported pain and the use of pain medications. This project also resulted in an average length of stay at 2.5 days after the initial application of the dressing, with no adverse events or wound-related complications reported. Nursing efficiency was also enhanced as the need for dressing changes and wound care assessments decreased from three to one time per week. These findings open the door to safer and more effective wound pain treatment options, which may improve clinical outcomes while decreasing costs and increasing patient satisfaction.



## Using a mobile health (mHealth) intervention to promote physical activity in Phase III cardiac rehabilitation clients with AdventHealth University



Chia-Wei Fan, PhD

Cardiac rehabilitation improves patients' functional capacity and quality of life recovering from cardiovascular disease, reducing acute hospital admissions. Cardiac rehabilitation includes four phases, from shortly after the acute cardiovascular event to the maintenance phase when patients independently apply the knowledge and strategies learned in the previous phases to achieve their optimal health.

Although maintaining adequate physical activity is one of the 2030 American Heart Association impact goals for ideal cardiovascular health, achieving this goal becomes challenging to patients in phase 3 of rehabilitation when the resources and support provided during previous phases are not as readily available. Looking for innovative ways to help patients maintain their path toward recovery, **Chia-Wei Fan, PhD**, designed a research study in collaboration with the AHU HOPE clinic, which provides occupational therapy to Central Florida's underserved and uninsured communities. Dr. Fan's study seeks to assess how using a wearable device to track activity, in addition to motivational coaching, influences patients in the later phases of cardiac rehabilitation in meeting their physical activity goals. Dr. Fan and her team are confident that their results will increase cardiac patients' physical activity, ultimately bringing them closer to optimal health by increasing their functional capacity and improving their sleep and overall quality of life. The professionals on the Center for Academic Research Excellence (CARE) team at AHRI were proud to support this work of Dr. Fan and other AHU faculty.

## New Investigator



Andrea Brennan, PhD

**Andrea Brennan, PhD**, is a Biobehavioral Research Scientist in the Whole-Person, Nursing and Academic department. Dr. Brennan earned her doctorate in Clinical Exercise Physiology from Queen's University in Ontario, Canada, before joining AdventHealth as a postdoctoral research fellow with Bret Goodpaster, PhD, in 2019. As a fellow, she studied the role of exercise and nutrition in aging and obesity, focusing on skeletal muscle composition and regional adiposity. She has published several peer-reviewed manuscripts in exercise Randomized Control Trials (RCTs), lifestyle treatment of obesity and response variability. Her current research interests include the interaction between nutrition and movement-based strategies for disease risk in special populations.

Dr. Brennan continues her endeavors at AdventHealth because of its unique research infrastructure, opportunities to engage participants from all walks of life and commitment to translating study findings to the "real world." The notion that research is a care option aligns with Dr. Brennan's commitment to designing and disseminating research studies that have value, relevance and applicability to the end user. She is currently exploring how physical activity strategies can effectively improve whole-person health in shift-working health care workers, a vital population group whose mental, physical and spiritual health needs to be supported and maintained. In line with this aim, she recently completed a cross-sectional study examining current physical activity behaviors and influencing factors among shift-working AdventHealth nurses. She will use these findings to inform future interventions.

# Orthopedic Institute

## Overview

The AdventHealth and Rothman Orthopaedics partnership strategically invests in investigator-initiated studies that advance innovation, clinical quality and improve patient outcomes. These initiatives have elevated our reputation among study sponsors, philanthropy and industry to guide cohesive education and collaborations. As a result, AdventHealth and Rothman are evolving into a comprehensive, connected, highly specialized continuum of musculoskeletal subspecialties, maximizing patients' clinical care and whole care experience. The partnership also is expanding high-quality elective surgery opportunities by pioneering unprecedented access to high-performing training, research, education and innovative programs to attract the best and brightest provider talent and retain discerning consumers. Co-building this Academic Ecosystem expands the current clinical model and is a critical component of physician recruitment, sub-specialization destination program development, novel therapy access and increased whole-person care.

Through validation, their research drives continuous quality improvements through evidenced-based medicine and insight into best practice education and training, resulting in better patient care outcomes and lower costs for value-based care.

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**“The highest quality orthopedic care is achieved by inquisitive physicians always searching for better patient care options. This premise is fundamental to innovation, research, education and clinical care, elements that are paramount to the outstanding orthopedic care we provide for our patients. It is critical that research is at the heart of the pathway leading to high-quality clinical care by promoting innovation and driving education that improves patient outcomes. We are so proud of our amazing orthopedic surgery partnership between Rothman Orthopaedics and AdventHealth and grateful to the outstanding clinical providers who are dedicated to continually driving orthopedic excellence through this pathway to assure that our patients are receiving the highest quality orthopedic care.”**

— Daryl C. Osbahr, MD, Chief, Orthopaedic Surgery and Managing Partner, Rothman Orthopaedics Florida; Executive Medical Director, AdventHealth Orthopedic Institute; Orthopedic Residency Director, AdventHealth



## Featured Research and Researchers



**Daryl Oshbar, MD**  
Chief, Orthopaedic Surgery and Managing Partner, Rothman Orthopaedics Florida; Executive Medical Director, AdventHealth Orthopedic Institute; Orthopedic Residency Director, AdventHealth

### Daryl Oshbar, MD, Donald Youmans, MD and Ibrahim Zeini, PhD Collaborate on Hospital Readmission Study

In 2022, **Drs. Osbahr, Youmans and Zeini** published their findings in a study that evaluated risk factors related to 30-day hospital readmissions after arthroscopic knee surgeries and complications that may arise from surgery. Over 83,000 knee arthroscopic procedures between 2012 and 2017 were obtained from the National Surgical Quality Improvement Program database. The study revealed the hospital readmission rate was 0.87 percent; complication rates were highest for synovectomy and cartilage procedures, 1.6 percent and 1.3 percent, respectively. Most readmissions were related to the procedure (71.1 percent), with wound complications being the primary reason (28.2 percent), followed by pulmonary embolism and deep vein thrombosis, 12.7 percent and 10.6 percent, respectively. Gender and body mass index were not significant, but age over 65 was an independent risk factor. The most prevalent complications were wound infection, deep vein thrombosis and pulmonary embolism.



**Harrison Youmans, MD**



**Ibrahim Zeini, PhD**

The doctors concluded that health care professionals have a unique opportunity to modify treatment plans based on patient risk factors. For example, clinicians should carefully weigh risk factors when considering surgical and non-surgical approaches for patients at higher risk of inferior surgical outcomes.

*White-Williams, C., Bagwell, M.T., DeDeo, M., Deal, M. J., Baker, A., Richey, B., Zeini, I. M., Service, B. C., Youmans, D. H., Osbahr, D. C. (2022). Demographics and surgery-related complications lead to 30-day readmission rates among knee arthroscopic procedures. Knee Surg Sports Traumatol Arthrosc. <https://doi.org/10.1007/s00167-022-06919-2>.*

## New Investigators



**G. Russell Huffman, MD, MPH**

**G. Russell Huffman, MD, MPH**, is a board-certified orthopedic surgeon subspecializing in orthopedic sports medicine. Dr. Huffman received his medical degree from the Duke University School of Medicine, where he was awarded a Howard Hughes Research Fellowship for student research. He also completed a Master's in Public Health from Johns Hopkins University before continuing his orthopedic surgery residency at the University of California, San Francisco and fellowships in sports, shoulder and elbow surgery at the University of Southern California in Los Angeles, CA. He was also a visiting fellow on the shoulder and elbow service at the Mayo Clinic in Rochester, MN.

Dr. Huffman is a highly experienced shoulder and elbow expert. As an associate professor at the University of Pennsylvania for 16 years, he directed Penn's Shoulder and Elbow Fellowship for over a decade, training the next generation of shoulder and elbow surgeons in surgical solutions to complex shoulder and elbow problems. He has over 100 combined book chapters and peer-reviewed scientific publications and has taught, volunteered and lectured regionally, nationally and internationally.

Dr. Huffman's clinical expertise includes arthroscopy of the shoulder and elbow, tendon and ligament reconstructions of the elbow, simple and complex shoulder stabilization surgeries, joint shoulder and elbow replacement and reconstructive surgeries. Currently, he is conducting multicenter trials at AdventHealth, looking at investigational and traditional shoulder and elbow replacement implants. He is a member of several American Shoulder and Elbow Society research committees.



**Amir Kachooei, MD, PhD**

**Amir Kachooei, MD, PhD**, is a board-certified orthopedic hand, wrist and elbow surgeon, specializing in degenerative and traumatic conditions like arthroplasty, arthroscopy, reconstruction and fracture repair. Dr. Kachooei completed his medical degree and orthopedic

residency at Mashhad University of Medical Sciences in Iran. He ranked first nationally in the Orthopedic Board Exam and was promoted to Associate Professor in Orthopedic Surgery.

Following his residency, Dr. Kachooei spent over two years as a Research Fellow in hand and elbow surgery at Massachusetts General Hospital, Harvard Medical School. He then earned a clinical PhD in elbow surgery at the University of Amsterdam where he also mastered in elbow arthroscopic surgery. He became ECFMG-certified in the U.S. and then completed a Clinical Fellowship in Foot and Ankle Surgery and a Clinical Hand and Upper Extremity Surgery Fellowship at Rothman Orthopedics and Thomas Jefferson University in Philadelphia, PA. Dr. Kachooei's research led to nine patents, more than 100 peer-reviewed articles on elbow surgery, books, book chapters and presentations nationally and internationally.

“Clinical research allows doctors to decide how to treat patients best,” Dr. Kachooei states. “It is what makes the development of new medicines, new procedures and new tools possible. Without clinical research, we cannot decide if new treatments are better than our current treatments.”

**Featured Research:** Dr. Kachooei is currently involved in several studies, including one which tests the efficacy of the blocking screw technique coupled with the intramedullary screw fixation for managing metacarpal fractures. This research could aid in lowering long-term complications and other risks associated with the procedure.

*Kwan SA, Wang W, Kachooei AR, Beredjikian PK, Rivlin M, Tulipan JE. Blocking Screw Technique for Maintaining Reduction during Intramedullary Screw Fixation of Oblique Metacarpal Fractures. Arch Bone Jt Surg. 2022. doi: 10.22038/ABJS.2022.63453.3062.*

Additionally, Dr. Kachooei published the results of a systematic review and meta-analysis comparing the functional outcome, revision rate, complication rate and survival rate of total ankle replacement (TAR) between inflammatory arthritis. The results showed that TAR is a safe procedure in inflammatory ankle arthritis, specifically in rheumatoid arthritis patients with relatively minor and major complications close to other reasons for ankle replacement.

*Mousavian A, Baradaran A, Schon LC, Daniel J, Pedowitz D, Kachooei AR. Total Ankle Replacement Outcome in Patients with Inflammatory Versus Noninflammatory Arthritis: A Systematic Review and Meta-analysis. Foot Ankle Spec. 2022. doi: 10.1177/19386400221136591.*

Finally, Dr. Kachooei contributed to a systematic review and meta-analysis comparing the outcomes of surgical repair of type II superior labrum from anterior to posterior (SLAP) injuries between surgical positions for patients. They hypothesized no statistically significant differences in the functional, pain and motion outcomes between the two positions after type II SLAP repair.

*Baradaran A, Sabzevari S, Godshaw B, Kachooei AR, Mousavian A, Lin A. The Impact of Lateral Decubitus vs. Beach Chair Positioning on the Clinical Outcome of the Patients with Isolated SLAP Type II Repair: A Systematic Review and Meta-analysis. Arch Bone Jt Surg. 2022. doi: 10.22038/ABJS.2022.63501.3063.*



**Luke Oh, MD, MS**  
Medical Director,  
Orthopedic Sports  
Medicine, AdventHealth  
Research Institute

**Luke Oh, MD, MS**, is a renowned board-certified surgeon, medical educator, research scientist and entrepreneur serving as the Medical Director of Orthopedic Sports Medicine at AdventHealth Orthopedic Institute. After a residency at the Hospital for Special Surgery, Dr. Oh completed multiple subspecialty Sports Medicine and Arthroscopy fellowships at Massachusetts General Hospital in Boston, Shoulder and Elbow Surgery at the Mayo Clinic and an apprenticeship with Dr. James Andrews to master the techniques for Tommy John surgery for pro baseball players.

Dr. Oh spent 14 years as a full-time faculty member at Harvard Medical School and Massachusetts General and is the Emeritus Program Director of the Harvard-MGH Orthopedic Sports Medicine Fellowship. He was also a team physician for the Boston Red Sox, New England Patriots, New England Revolution, Boston Bruins and Harvard University for over 12 years.

His clinical and research interests include treating shoulder and elbow injuries in the throwing athlete, rotator cuff tears, ACL rupture, meniscus tears and osteochondritis dissecans. Dr. Oh is studying artificial intelligence for diagnosis and treatment in orthopedics, biomechanical investigation of various surgical techniques and tissue engineering to improve rotator cuff, biceps, ACL and meniscus healing. Dr. Oh's clinical reputation and cutting-edge research have garnered national and international recognition. Most recently, he was awarded the 2021 American Shoulder and Elbow Surgeons Research Grant Award to investigate the role of collagen telopeptides in the healing of rotator cuff tears.

# Pharmacy Investigational Drug Services (IDS)

## Overview

Investigational Drug Services (IDS) is a support department highly integrated into the research patient's clinical care. The staff seeks to improve individuals' lives by researching medications and disease states that affect patients participating in clinical research studies—transforming medication management for whole-person health. Patient safety is their highest priority, ensured through accurate investigational drug preparation and clinical dosing. This goal is achieved by properly storing and inventorying drugs and supplies, maintaining regulatory-compliant cleanrooms, engaging in continuous training in protocols and amendments and preparing medications under the optimal preparation conditions required by the clinical trial protocol.

IDS works closely with study intake managers to assess each trial's feasibility and protocol to ensure all needs can be met. The department also collaborates with the principal investigators and study coordinators to ensure patients meet the clinical parameters to receive the investigational drug before each dose, thus assuring patient safety.

The IDS pharmacists provide needed drug information for investigational products so that the prescriptions and orders can be accurately built into the electronic medical record and discharge prescription platforms. These data include drug interaction screenings to alert prescribers of medications that may interact unsuitably with the investigational drug or are prohibited by the protocol, thus enhancing patient safety.

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**“The staff and I highly value research as a care option, and we take our role in a patient’s care very seriously. Many patients seek a clinical trial when they have run out of standard care options, and others participate as soon as they are diagnosed with a serious or rare illness. Patients who choose research as a care option are treated with the same health and safety standards as patients treated with standard care.”**

— Rebecca Prevost, PharmD

## Featured Researchers and Research



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

The number of Phase 1 clinical trials has increased at Celebration's Clinical Research Unit (CRU). IDS works closely with **Guru Sonpavde, MD**, CRU Medical Director of Genitourinary (GU) Oncology and Executive Medical Director for the AdventHealth Cancer Institute CRU, and his research team to accurately prepare Phase 1 compounds — many considered “first-in-human.” In addition, IDS often works with the study sponsor to develop or amend guidance documents on investigational product preparation because of the team's expertise and practical knowledge of supply components.

In 2022, IDS significantly expanded the preparation of investigational compounds involving recombinant or synthetic nucleic acid molecules, also known as Gene Therapy, at the Orlando and Celebration locations. These studies have supported research as a care option for patients with Alzheimer's, Parkinson's, other neurological disorders and several types of cancer. The department's state-of-the-art facilities provide an excellent and safe environment for storing and preparing these novel, innovative compounds that will be standard care in the future.



Left to Right: Megan Leiser, David Matthews, Douglas Ramirez

# 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. Their “bench-to-bedside” approach in translational research is a two-way street. 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 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 aimed at understanding the molecular underpinnings of metabolic disease. 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

**“The biology of human disease is highly complex and multifaceted, leading to inadequate one-size-fits-all approaches to detect, treat and cure. At the Translational Research Institute (TRI) our Scientists collaborate as subject matter experts in the areas of exercise, nutrition, metabolism, cellular and mitochondrial bioenergetics, tissue heterogeneity and microbiota-host interaction to study the molecular drivers of disease pathways and mechanisms. Our all-hands-on-deck approach focuses on the ‘Why’ behind human disease. This enables our Scientists to translate laboratory benchtop findings into actionable bedside early detection, cutting-edge treatment options and eventually cures for our patients in the communities we serve.”**

— Bret Goodpaster, PhD



## Featured Research and Researchers

### AdventHealth Participates in Groundbreaking First and Only FDA-approved Treatment to Delay the Onset of a Stage of Type 1 Diabetes



**Anna Casu, MD,**  
*von Weller Family Chair in  
Type 1 Diabetes Research*

The Food and Drug Administration (FDA) recently approved a new drug to treat Type 1 diabetes, made possible by a large global screening initiative that included AdventHealth's participation. This groundbreaking milestone enabled AdventHealth to become one of a few hospital systems approved to distribute this medication.

This breakthrough treatment, called TZIELD, is the first drug that can delay the progression of Type 1 diabetes by up to three years in adults and up to eight years in children. First, a simple blood test is performed to determine eligibility for the treatment. Then, if the blood test is positive, an oral glucose tolerance test is administered to determine whether the blood glucose is increasing.



**Konda M. Reddy, MD**  
*Medical Director, Pediatric  
Endocrinology and  
Diabetes, AdventHealth  
for Children*

“For the first time, a disease we thought was inevitable can now be delayed,” said **Anna Casu, MD**, an associate investigator in Type 1 diabetes research at the AdventHealth Translational

Research Institute (TRI). “Now there’s a reason to screen for Type 1 diabetes because its burden can be delayed. This innovation drives me to continue our research to uncover a cure.”

The study, leading to TZIELD approval, was conducted by the Type 1 Diabetes TrialNet Consortium, which screened roughly 200,000 participants for Type 1 diabetes. AdventHealth served as a screening site. Over the last four years, the findings were analyzed, published in the *New England Journal of Medicine* and sent to the FDA for approval.

“Diabetes is a disease that never goes away, so a delayed diagnosis with treatment like this drug can significantly impact the quality of life for the patient and their family,” said **Konda M. Reddy, MD**, Medical Director of

Pediatric Endocrinology and Diabetes at AdventHealth for Children. “This is a historic moment for the Type 1 diabetes community. It means there’s more time to live without the burden of the disease and complications.”

Type 1 diabetes is a disease that occurs when the immune system attacks and destroys the cells that make insulin. According to the Juvenile Diabetes Research Foundation, some 1.45 million Americans live with Type 1 diabetes, and 64,000 are diagnosed annually in the U.S.

Clinical research makes life-changing medical advancements, like the TZIELD study, possible.

### MoTrPAC on the TODAY Show

The AdventHealth Translational Institute (TRI) is the research site for the Molecular Transducers of Physical Activity Consortium (MoTrPAC) study, featured on the TODAY show in 2022. The study seeks to understand what happens in the body when a person exercises and why that leads to positive health outcomes that are well-established in literature.

The study involves creating a “map” of the body’s protein, gene and hormone response to physical activity. Early results are slated to be published as soon as next year.





## AdventHealth Chief Scientific Officer Receives National Award Related to Obesity Research

The Obesity Society awarded **Steven R. Smith, MD**, Chief Scientific Officer and Senior Vice President of AdventHealth, the Take Off Pounds Sensibly (TOPS) Research Achievement Award for his research on obesity, diabetes and the metabolic origins of cardiovascular disease. Dr. Smith is one of 15 clinicians recognized by the international professional society for a singular achievement or contribution to research in the field of obesity.

“The Obesity Society is honored to recognize Dr. Smith for his many contributions to our understanding of the roles that dysfunction in adipose tissue and skeletal muscle play in the development of obesity and Type 2 diabetes,” said Dan Bessesen, MD, President of The Obesity Society. “He has been a leader in obesity research for many years and continues to make fundamental scientific contributions which aim to help improve the health of people with obesity.”

At the AdventHealth Translational Research Institute, Dr. Smith and his colleagues are investigating why people develop obesity, particularly abdominal adiposity.

“We’re working on how genes can be programmed in the womb or during development to influence where fat is stored, either in the abdomen or in the hips and thighs,” he said. “The epigenomic



**Steven R. Smith, MD**

*Chief Scientific Officer, Senior Vice President, AdventHealth*

programming of adipose tissue has the potential not only to help develop obesity treatments but also to prevent the downstream metabolic diseases, like diabetes, cancer and heart disease, that occur in people with abdominal obesity—diseases that are lower in people with a predisposition to store fat below the waist.”

In addition, Dr. Smith is specifically focused on understanding how individuals differ in their ability to adapt to diets high in fat and how obesity leads to Type 2 diabetes.

Using the translational medicine approach, he and the AHRI research team discovered that many obese people cannot burn fat which may be affected by a hormonal control system to increase fat, and energy metabolism. Most importantly, the team’s discovery that the inability to burn fat is programmed into muscle cells, which provides a novel way to identify and test new treatments for obesity and diabetes.

“The world of research inspires me to find better solutions for patients,” said Dr. Smith. “We’ve just finished an exciting study to be published in the coming months that helps us understand how the gut microbiome affects energy balance. We believe this will change how our colleagues think about preventing weight gain across the lifespan and help people lose weight and keep it off.”

## The TRI Featured in the Orlando Sentinel

*The Orlando Sentinel* featured the Translational Research Institute’s “Decade of Discovery” celebration, showcasing the Institute’s research capability. The article highlighted some of their largest studies, including MoTrPAC and TRI’s gut microbiome-based studies.

“People think about Boston or San Francisco (for medical research) they don’t think about Central Florida. AdventHealth is changing that.”

— *Rob Herzog, Vice President, Research Operations, AdventHealth Research Institute*

In early 2022, Dr. Smith assumed the role of Chief Scientific Officer, providing scientific and research oversight and operational leadership across AdventHealth's nearly 50 hospitals in nine states.

Throughout his career, Dr. Smith has contributed to more than 200 peer-reviewed publications, including scientific manuscripts, reviews and chapters. He has also served as President of The Obesity Society and has long advocated for persons affected by obesity. As Chief Scientific Officer, he provides scientific and research oversight and operational leadership across AdventHealth's nearly fifty hospitals in nine states.

### **A Decade of Discovery — Reflecting on the Research and Innovation at the Translational Research Institute (TRI)**

AdventHealth and the community celebrated the 10th anniversary of the Translational Research Institute (TRI) at the recently opened Innovation Tower. The TRI clinicians tackle some of today's biggest health problems — obesity, diabetes, exercise and healthy aging, bridging the gap between scientific discoveries and clinical care.

The TRI had two primary goals when its doors opened 10 years ago in 2012. The first was to advance the science and understanding of metabolic diseases. The second was to advance research at AdventHealth to attract the best and brightest physicians to the Central Florida community.

Over the past decade, the TRI has conducted more than 200 studies and produced more than 350 peer-reviewed published works. Last year, AdventHealth's translational researchers participated in 22 studies and authored 50 published works. In 2020, the TRI research team conducted 30 studies and authored 56 publications — their most productive year to date.

AdventHealth is one of only a few hospital systems in the country to combine a state-of-the-art 54,000-square-foot facility with unique equipment to conduct clinical research, connecting practicing physicians and their patients to active clinical trials designed specifically for their condition.

In one recently completed study, for example, participants spent more than 24 hours in an air-sealed room while researchers monitored every breath to determine exactly how much energy they burned. In another current study, participants exercise with a personal trainer and have



*TRI Decade of Discovery Event, hosted at the newly opened Innovation Tower*

blood and biopsy samples taken to determine how their body responds to exercise. TRI Investigators are even studying cells in space and how the microgravity of spaceflight alters muscle function.

**Steven R. Smith, MD**, AdventHealth's Chief Scientific Officer and Senior Vice President, was the TRI's founding scientific leader.

**Bret Goodpaster, PhD**, is currently the Scientific Director of the TRI.

"I was hired 13 years ago to create the TRI and serve as the first scientific director," Dr. Smith states. "Looking back now, I'm most proud that our researchers can bring medical discoveries from the laboratory to the communities we serve for further testing through various clinical trials. Engaging patients in research is what AdventHealth leadership envisioned back in 2008; they believed we are obligated to learn from our patients to tackle the diseases of the 21st century — and this philosophy is thriving today."



*Dr. Steven R. Smith speaking on Channel 9 News*

### **Steven R. Smith, MD, Visits the Channel 9 (WFTV) Central Florida Spotlight**

Chief Scientific Officer and Senior Vice President of AdventHealth Steven R. Smith, MD, spoke with Channel 9 WFTV in Orlando early in 2023 to discuss a great milestone for the Translational Research Institute (TRI). The Institute, cultivated and led by Dr. Smith, celebrated its 10th year in March 2022 and the array of groundbreaking metabolism and diabetes research conducted by its scientists over the past decade.

“This is world-class research in metabolism, diabetes and obesity research,” Dr. Smith stated. “...Our goal is to transform that information into new programs and ways of thinking about and preventing disease, and disseminate that information throughout the health care system.”

The TRI takes a translational research “bench-to-bedside and back” approach. Patients who benefit from cutting-edge research, and its results, help investigators refine their discoveries further to produce new knowledge that will impact the standard of care in the present and future.

The TRI and AdventHealth have proven that Central Florida is more than a place for “tourism and sunshine” but also an up-and-coming medical research hot spot.

“The conditions here are just right for this kind of research. We have a vibrant health care system, and patients trust us with their health care. Translational research in Orlando is new and exciting and offers many opportunities for interorganizational collaboration to share what we’ve learned and to learn from others about how to do our work better.”

Dr. Smith and the TRI are proud of their accomplishments but eagerly look forward to what they have yet to discover.

“We are proud to have the largest NIH-funded clinical research program in Central Florida, but there is a lot of work to still be done to extend the work from the last 10 years and push it into the next decade.”

## Milestones Over the Last Decade

The TRI is built on a strong foundation of ongoing achievements in key areas, such as grant funding, innovation, growth and published papers. The TRI's many achievements include:

- 2010:** First grant funded by National Institutes of Health (NIH)
- 2011:** Recruited key investigator Richard E. Pratley, MD
- 2012:** Current TRI building opened
- 2012:** First time published in the Journal of the American Medical Association (JAMA)
- 2012:** First phase I study conducted in partnership with Takeda to evaluate a combination product targeting diabetes
- 2013:** Bret Goodpaster, PhD, joined TRI
- 2016:** NIH funding was awarded to the study “Molecular Transducers of Physical Activity Consortium (MoTrPAC),” reflecting NIH's largest targeted investment of funds into how physical activity can improve and prevent disease
- 2017:** First time published in New England Journal of Medicine (NEJM)
- 2019:** TRI opened the Cancer Translational Research Lab

## Leading the Way in Groundbreaking Studies

Several groundbreaking studies also are underway at the TRI, offering patients hope and quality care through research:

- **RECODE study, Richard E. Pratley, MD, completed January 2023:** Researchers examine how long COVID-19 affects those with diabetes using MRI images to measure changes to various organs, such as the heart, lungs, liver, kidney, pancreas and spleen.
- **SOMMA-AT study, Lauren Sparks, PhD, underway through May 2024:** This multicenter study investigates how the role of adipose tissue changes with age.
- **MoTrPAC study, Bret Goodpaster, PhD, underway through summer 2023:** Researchers in this landmark study explore what happens deep within the body during and after exercise and map the molecular changes.

## The Future of Research and Medicine

TRI's mission is to improve the quality of life through world-class, innovative research that leads to discoveries—and ultimately cures—for diabetes, obesity and diseases of aging. These discoveries prosper as the institute finds ways to translate research into the practice of medicine.

The research conducted at TRI lays the foundation for future studies to find new ways to prevent and treat diseases better using precision medicine—prescribing and customizing care to each individual to achieve the best possible health outcomes.

“I'm continually inspired by the creativity and rigor of TRI research and proud to be a part of TRI's growth beyond its original focus and into aging and aging-associated diseases. Our studies have integrity, efficiency, impact and aim to solve some of the most pressing medical needs today, advancing health care quality into the future.”

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

# 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

### Abdominal

- Advanced Liver Failure
- Kidney Transplant

### Cardiac

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

### Lung

- Advanced Lung Failure
- Lung Transplant

**“The AdventHealth Transplant Institute provides our patients access to cutting-edge research through clinical trials and protocols, enabling them to receive potentially life-saving advances today without the long wait. As clinical trial participants, our patients contribute to the advancement of the field to help other patients and doctors worldwide. It is our privilege to bring these trials to Central Florida.”**

— Scott Silvestry, MD



## Featured Researchers and Research



**Bobby Nibhanupudy, MD**, is a board-certified surgeon experienced in kidney and pancreas transplants and laparoscopic surgeries. He joined the Transplant Institute from the Kidney Transplant Program at Bert Fish Medical Center in New Smyrna Beach, FL, where he served as Co-Director and Primary Transplant Surgeon.

**Bobby Nibhanupudy, MD** In a study published in 2022, Dr. Nibhanupudy evaluated post-vaccination cellular and antibody (Ab) immunity in single blood samples from 17 kidney transplant (KT) recipients who had received the COVID-19 vaccination. The results revealed transplant patients without antibody response to COVID-19 vaccines also lack a cellular immune response to the vaccine. Furthermore, this lack of response was more associated with certain antirejection drugs and combinations than others.

More than ever, research can quickly lead to care options when none are available. For example, the Food and Drug Administration (FDA) approved certain therapeutics for Emergency Use Authorization (EUA) during the COVID-19 pandemic based on good research without necessarily going through all the steps needed for commercialization. At the same time, the EUA was appropriately revoked when follow-up research proved a lack of efficacy as the illness changed. All of this suggests a more dynamically adaptive response to active research.

## FDA Approves the Use of New Technology for Donation After Circulatory Death After Groundbreaking Trial



**Scott Silvestry, MD**  
*Surgical Director,  
Thoracic Transplant,  
AdventHealth Transplant  
Institute*

In April, the U.S. FDA granted premarket approval of TransMedic's OCS™ Heart System (OCS Heart) for use with organs from donors after circulatory death (DCD). AdventHealth was one of 13 transplant centers nationwide that participated in a multicenter clinical trial to investigate the safety and effectiveness of this new technology, performing Florida's first DCD transplant in July 2020. The transplant was a team effort in partnership with AdventHealth Translational Research Institute and the organ procurement agency OurLegacy.

The OCS Heart system keeps a heart, which was stopped prior to donation, viable for hours. This system keeps it in a near-physiological, beating state with a warmed, donor-based perfusate supplemented with nutrients and oxygen. OCS also allows surgeons to assess the heart's functional quality and viability for transplant.

DCD heart transplantation gives hope to patients and physicians faced with a growing organ shortage across America. According to the U.S. Department of Health & Human Services Organ Procurement and Transplantation Network, over 3,000 people are currently on the national heart transplant waiting list.

“DCD provides us access to many additional hearts,” explains **Scott Silvestry, MD**, Surgical Director for Thoracic Transplant at the AdventHealth Transplant Institute. “The hearts that will be transplanted as a result of this new technology would have been buried before.”

Dr. Silvestry served as a principal investigator for AdventHealth Orlando in the national OCS DCD Heart Trial. The results were presented at the 2022 Annual Meeting of the International Society of Heart and Lung Transplantation in Boston, Massachusetts. In addition, the results were recently published in *The Journal of Heart and Lung Transplantation*. In the trial, patients awaiting heart transplantation were randomized three to one to a DCD-eligible arm or donors before death (DBD) cold-stored hearts arm. Endpoints included 6- and 12-month patient survival post-transplantation, OCS DCD heart utilization rate, and incidence of Heart Graft-related Serious Adverse Events (HGRSAEs) in the first 30 days post-transplant. A total of 180 patients were randomized and transplanted in the trial. It demonstrated that using the OCS Heart resulted in a high rate of DCD heart utilization for transplantation with excellent patient and graft survival outcomes compared to DBD donor hearts.

“The results support the increased use of DCD hearts,” says Dr. Silvestry. “DCD transplants have been conducted in the U.S. with other organs, including the lungs, liver and kidney, for years. However, until the availability of the OCS system, the use of DCD hearts has been limited. In addition, traditional cold storage techniques did not allow us to evaluate a heart’s function and check for any damage before transplantation. This new technology can significantly expand the donor pool and save even more lives.”

## New Investigator



**Ahmad Zeeshan,  
MD, FACS**

**Ahmad Zeeshan, MD, FACS**, is a board-certified cardiothoracic surgeon with expertise in performing various procedures, including heart and lung transplantation, aortic surgery, minimally invasive heart valve surgery, mitral valve procedures, aortic valve surgery and bloodless cardiac surgery. After medical school, Dr. Zeeshan trained in general surgery at the University of Pennsylvania and the University of Maryland. He then completed a fellowship in cardiothoracic surgery at Yale University. In addition, he received specialized training in aortic surgery, including endovascular techniques, heart and lung transplantation and mechanical circulatory support surgery at Cleveland Clinic, Ohio.

His research focuses on clinical heart failure and aortic research. He chose to join AdventHealth because of its excellent workplace environment, health care prowess, clinical excellence and exceptional teamwork. Dr. Zeeshan believes in providing the best approach for every patient based on their specific needs and conditions for optimal results—using the latest minimally invasive approaches for a lower risk of complications and a faster, more comfortable recovery.

“Research as a care option refines how we do things and allows us to find solutions to the issues we need to address,” Dr. Zeeshan says. “This approach ultimately improves the quality of patient care and offers great publicity and awareness to our organization’s quality of work.”

# 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 700 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.

Our research leaders are engaged in a transformational journey to exceed standards that will achieve industry-leading results through world-class clinical research. This work will shape the future standards of care through better treatment options at every stage of disease, growth and discovery for clinical investigators and teams and a reduced 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 important function in our research infrastructure, aligning with our commitment to producing better outcomes within the organization and beyond, through our commitment to Diversity, Equity and Inclusion in our workforce, study methods and research data.



**Participates in more than 700 clinical studies annually**



**Supports 200 active principal investigators**



**Won 17 grant awards in 2022**



## System Support:

### Research Administration and Business Development

Research Administration and Business Development keep the institute functioning and communicating efficiently and seek to build external relationships with various stakeholders.

- Research Administration facilitates organization-wide initiatives, employee onboarding, retention, internal communication among team members, and standardizes and centralizes the research volunteer process.
- Business Development initiates, establishes and supports relationships with research sponsors and partners to access innovative therapies and medical devices that benefit patients.

### 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
- Collaborates across the institution to foster communication, align policies and procedures 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 to provide the operational structure to evaluate and execute AHRI clinical trials and research studies. Built with subject-matter expertise in the therapeutic areas we serve, 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 life-saving 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 Excellence (CARE)

CARE features a team of data and nurse scientists, biostatisticians, medical editors and research professionals who support and conduct data-driven research to meet some of the biggest health care challenges. The team collaborates with fellow data scientists to develop protocols and analysis plans and solve problems for all AdventHealth-Orlando-aligned research departments. Additionally, CARE partners with faculty, fellows, residents and doctoral and medical students to support quality projects within our academic group, focused on enriching patient care and nurse and physician wellness. Biostatistical and medical editing services include preliminary and advanced study design and implementation, completed study analysis and reporting and publication development.

### 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 expanding nine-state network. This makes AdventHealth an ideal platform to increase patient access to clinical trials and support translational studies targeting vital health discoveries that lead to cures.

As one of the largest health care providers in Florida and nationwide, AdventHealth's commitment to excellence is evident in our clinical outcomes and relentless pursuit of innovation that leads to the highest degree of personalized care. The clinical outcomes are partly powered by research happening at our hospitals. We believe that research is a care option and are grateful to the many individuals who contribute to research at AdventHealth.

Donors have a unique opportunity to revolutionize care delivery and impact the health and well-being of this and future generations by supporting the AdventHealth Research Institute. There are many ways to support our programs—an annual contribution, a multi-year pledge, event sponsorship or establishing 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 activities is by establishing endowed chair positions for promising investigators. An endowed chair enables AdventHealth to attract and retain the best clinical providers and researchers by providing a permanent, stable funding source. They can be named after the donor or a loved one and exist in perpetuity while recognizing a family's legacy of generosity.

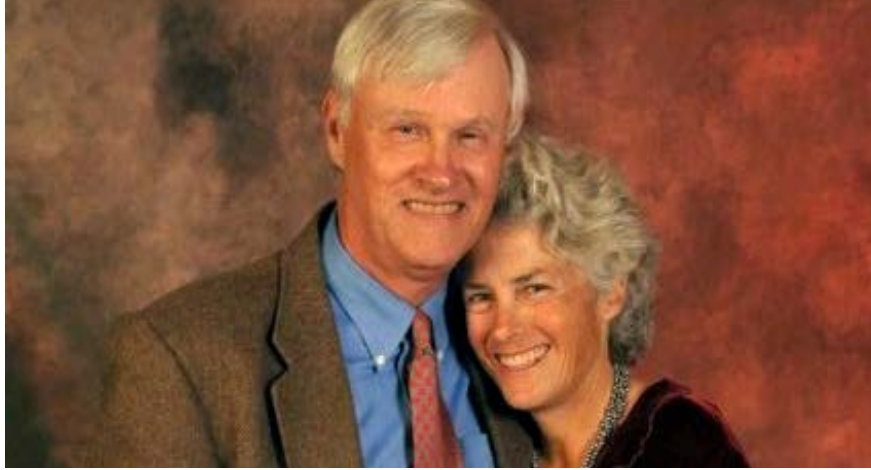
## Generosity Heals



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](mailto:ResearchGive@AdventHealth.com) to learn more.

**Scan to Give**





*Chris and Muffy Glanz*

## Muffy and Chris

For Muffy and her family, her charitable giving comes from a personal place. Her husband, Chris, was diagnosed with a rare bladder cancer about 10 years ago and endured a difficult battle with the disease before passing away.

“At the time, there was no cure and little research that would help us find answers,” Muffy said. “It was very hard.”

Recently, Muffy was impressed with AdventHealth’s metabolomics and cell research work. So, when she heard that AdventHealth was recruiting Guru Sonpavde, MD, a top U.S. bladder cancer physician and researcher, to join the AdventHealth Cancer Institute, she was excited to support his work by creating the Christopher K. Glanz Endowed Chair in Bladder Cancer Research.

Dr. Sonpavde emphasized the indispensable value of the endowed chair toward the future of cancer care. “Funding is very competitive. Having regular, consistent, annual support for research allows me to expand my work and gain momentum to do more,” he said. “Having met Muffy and hearing about her husband, Chris, I am honored that my research will give meaning to his journey and help others.”

That, Muffy said, has always been her goal. “When I met Dr. Sonpavde, I could hear that he shared the same passion for finding answers to the puzzle of cancer. His work towards a cure for bladder cancer will make a difference in many lives,” she said. “With all that Chris went through, to have bladder cancer research done to honor him means that his struggle was not in vain.”

## Karen and Mardian

Karen Wrenn held Mardian J. Blair in high regard and grew to value his leadership and friendship as a member of the Florida Hospital Operating Board (now known as AdventHealth). Karen was also passionate about battling Alzheimer’s disease, which affected her beloved aunt. In honor of Mardian J. Blair and his exemplary service to AdventHealth, the Estate of Karen L. Wrenn and its Trustee, Marjorie Bekaert Thomas, were pleased to announce a gift to establish the Mardian J. Blair Endowed Chair in Neuroscience Research. This chair has allowed AdventHealth to recruit a leading Neuroscience Researcher, Kirk Erickson, PhD, to join AdventHealth and lead Neuroscience Research in Alzheimer’s disease and healthy aging research.

Marjorie Thomas believes this gift fulfills the wishes of Karen and that having Mardian’s name grace this chair brings the appropriate respect and significance to the research that will be carried out by Dr. Erickson and his team with the endowment proceeds. Establishing this endowment is a milestone in AdventHealth’s history that will advance our understanding of brain health and Alzheimer’s disease.

We are pleased to recognize Mardian’s lifelong commitment to extending the healing ministry of Christ and Karen Wrenn’s generosity in making this possible by establishing the Mardian J. Blair Endowed Chair in Neuroscience Research.



*Mardian J. and Joan Blair*



*Karen Wrenn*

## Cancer Research receives funds from Golden Gala 41

Proceeds from one of AdventHealth Foundation's signature events, Golden Gala 41, benefit patients throughout Central Florida so that they may receive the best treatment options close to home. Increasing access to clinical trials can provide more time with loved ones, eliminate the need to travel for care and support whole health for the future. With more than \$700,000 raised for Cancer Research during this event, AdventHealth will continue to transform research into hope by accelerating today's most exciting discoveries into life-saving care.



Mark Socinski, MD speaking at the 2022 AdventHealth Foundation Gala



Susan and Ed Provost

### If I Can, I Will.

After more than a decade of various cancer treatments, Susan ran out of standard treatment options. A clinical trial was an answer to her prayer. Robert Holloway, MD, found an evidence-based trial approach for Susan. As a result, she and her husband, Ed, continue to inspire more patients not to lose hope. "This clinical trial gives me hope and willingness to fight."

In addition, Ed and Susan give monthly to Gynecologic Oncology Research because they know how important consistent giving is for the future of health care for them and others.

"We are grateful for the care we've received, and this is our way of saying thank you."



Scan to Watch Susan's Story

# Participate in Research

## Be Part of a Breakthrough

By joining a research study, you could be part of the next medical breakthrough that changes everything. As a research participant, you could access new and innovative therapies that may not be available otherwise, help advance medical knowledge and benefit future generations, receive expert care and support from our experienced, compassionate team and earn compensation for your time and travel expenses.



Scan to Learn More

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