# AdventHealth Research Institute

## 2021 ANNUAL REPORT


AdventHealth

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# **Welcome** Letter

*Science is an important way of thinking and working. Scientific methods are not intuitive but can be learned and perfected over time with good mentoring. Research as a whole progresses our knowledge and is creating new discoveries on a daily basis.*

*In this annual report, we bring forward not just a listing of the research and researchers at AdventHealth, but also stories of the people doing the research and the progress we are making every day.*

*Research is fundamental to a learning health care system and now, more than ever, we need science to create a brighter future for each of us and for future generations.*

*I hope you will enjoy this report and, as we move into the next year, we say a hearty "thank you" for your support.*

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

# **AHRI** Overview

AdventHealth is a preeminent, faith-based, consumer-focused clinical institution dedicated to delivering exceptional patient care. The AdventHealth Research Institute (often referred to as "the Research Institute" or "AHRI") plays a key role in helping our organization be exceptional by bringing groundbreaking research and scientific knowledge closer to home. Our clinical trials, involving more than 500 investigators and staff, have helped the medical community better understand and treat diabetes, develop a vaccine to protect against COVID-19, mediate cardiovascular and lung diseases, demonstrate scientific principles that underscore our whole-person approach to health and more.

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 pursuit to help people achieve wholeness in body, mind and spirit. The Research Institute utilizes experience from our two million-plus annual patient encounters in the Central Florida Division and shares 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.**

AdventHealth's mission and consumer focus are reflected in the Research Institute's Vision and Purpose Statement:

**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.**

Guided by this vision, our leadership collaborates to create bi-directional benefits for the community, our health system, our physician-investigators and PhD 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*

**Bret Goodpaster, PhD**
*Translational Research Institute Scientific Director*

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

**Delores Barnes**
*Director of Cardiovascular, Neuroscience, Transplant and Critical Care Research*

**Amanda Jones**
*Director of Clinical Research Translational, Orthopedic, Digestive Health and Surgery*

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

**April Turley**
*Director of Office of Sponsored Programs*

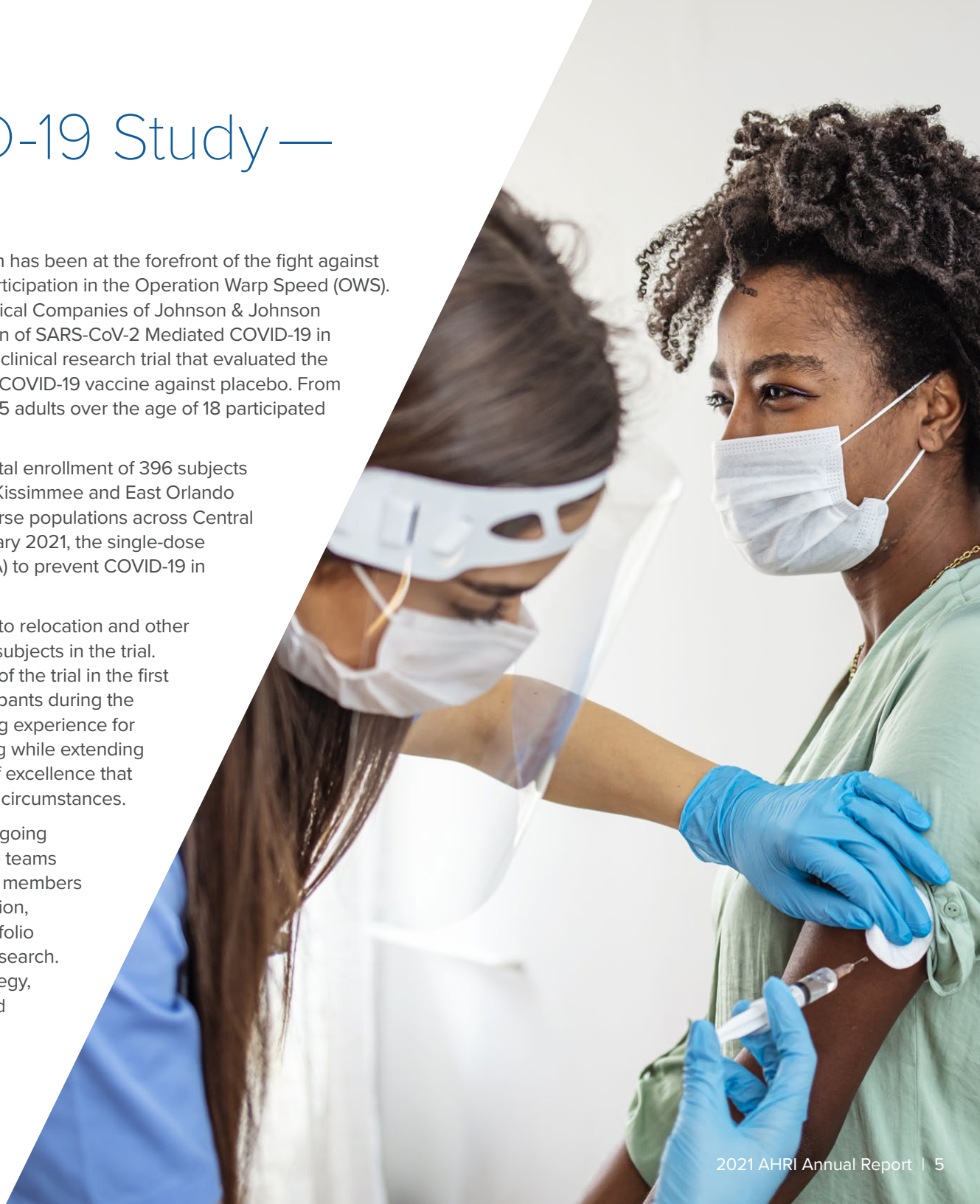
# Ensemble COVID-19 Study — **Post-Pandemic**

As Central Florida's leading health system, AdventHealth has been at the forefront of the fight against COVID-19 since it began, including collaboration and participation in the Operation Warp Speed (OWS). As part of OWS, AdventHealth and Janssen Pharmaceutical Companies of Johnson & Johnson partnered for A Study of Ad26.COV2.S for the Prevention of SARS-CoV-2 Mediated COVID-19 in Adult Participants (ENSEMBLE). ENSEMBLE is a phase 3 clinical research trial that evaluated the safety and efficacy of Johnson & Johnson's single-dose COVID-19 vaccine against placebo. From seven countries, including the U.S., approximately 44,325 adults over the age of 18 participated in the trial.

AdventHealth screened more than 500 subjects for a total enrollment of 396 subjects across three sites: The Translational Research Institute, Kissimmee and East Orlando AdventHealth campuses. AdventHealth's service in diverse populations across Central Florida made the organization an ideal partner. In February 2021, the single-dose J&J vaccine received emergency use authorization (EUA) to prevent COVID-19 in individuals 18 years of age or older.

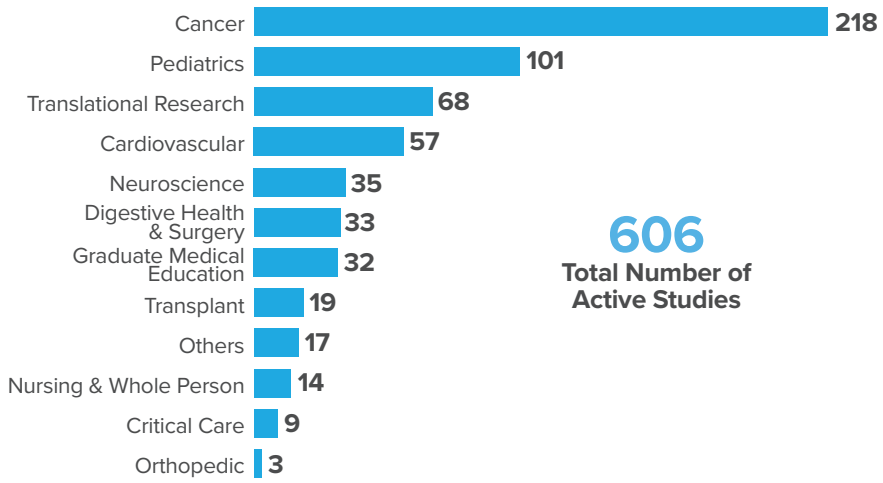
The trial is currently in its second year of follow-up. Due to relocation and other natural processes and reasons, currently there are 282 subjects in the trial. The participants will be followed until the expected end of the trial in the first quarter of 2023. Involvement with the trial and its participants during the pandemic for more than two years has been an enriching experience for members of the research team. Practicing self-well-being while extending caring commitment with due diligence has been a bar of excellence that members of the research team have honored under the circumstances.

The ENSEMBLE trial continues to garner support and ongoing collaboration of several AdventHealth Research Institute teams with the medical team's oversight. Collaborators include members of Translational Research Institute, Research Administration, Research Cores, Offices of Sponsored Projects and Portfolio Management, Internal Operations and Whole-Person Research. ENSEMBLE is a testament to AdventHealth's larger strategy, commitment and effort towards community outreach and health care with a vision of transformative medicine. ENSEMBLE also speaks to AdventHealth's capacity for conducting a trial with a large number of subjects and sustaining efforts over time during the pandemic.

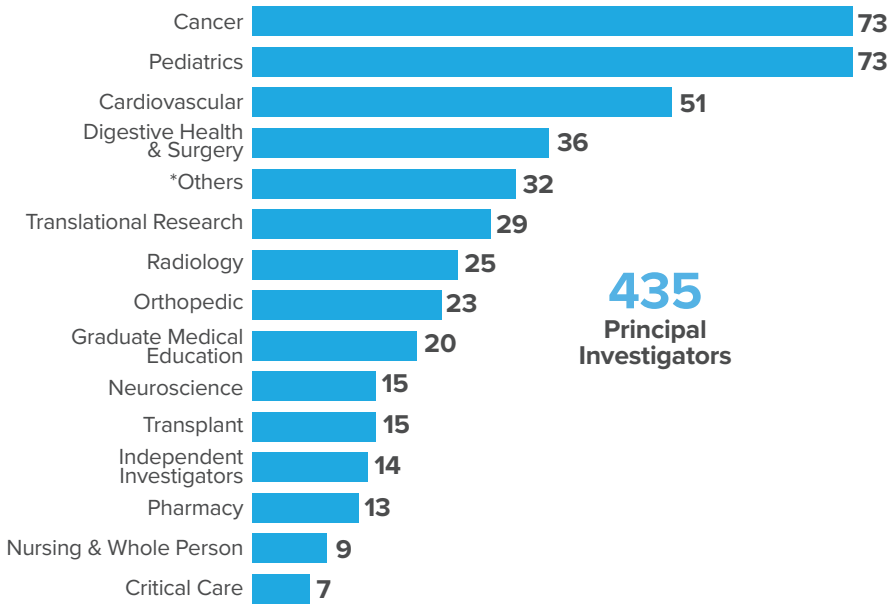


# AdventHealth **by the Numbers—2021**

## Active Studies

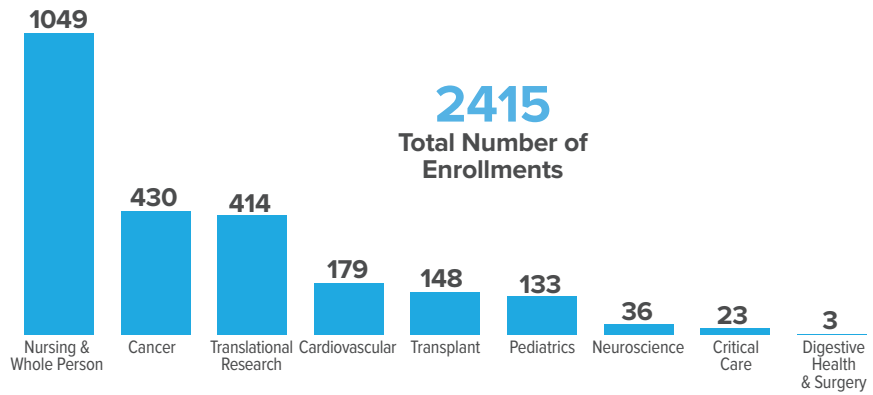



## Principal Investigators

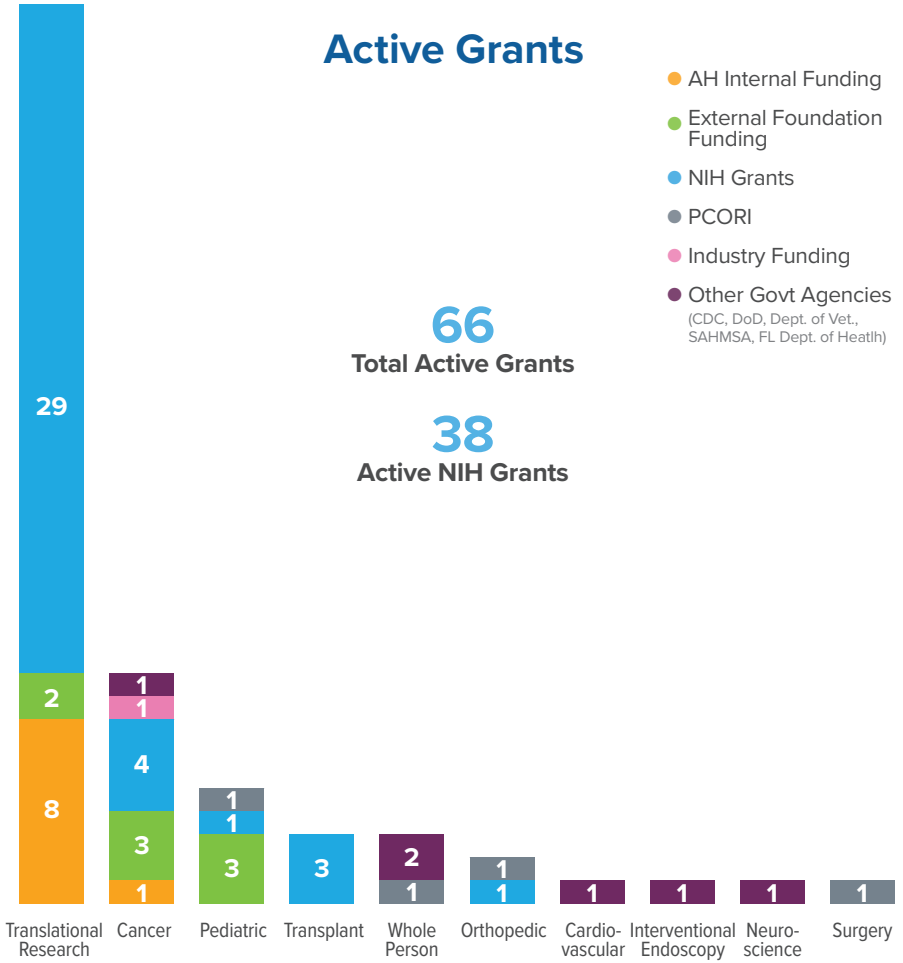



**AHU, CARE, Celebration, Global Robotics, Redmond*

## Enrollments



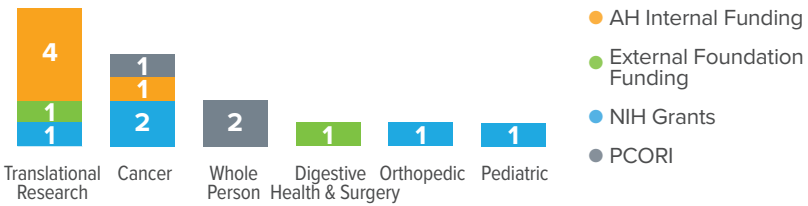
## Active Grants




**66**
**Total Active Grants**

**38**
**Active NIH Grants**

## New Grants Awarded




**15**
**Total Grants Awarded**

**5**
**NIH Grants Awarded**

# AdventHealth for **Children**

## Vision

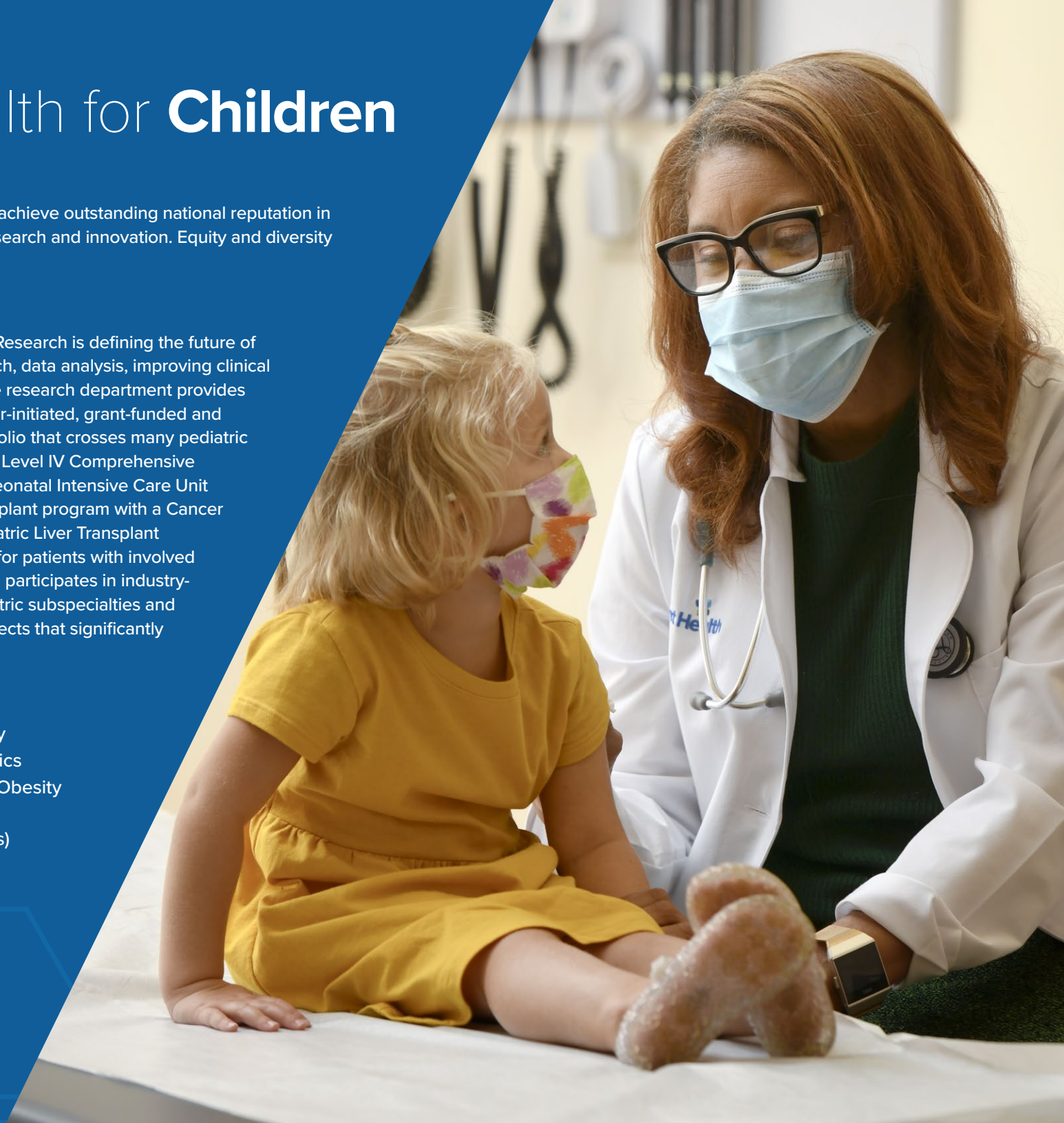
AdventHealth for Children strives to achieve outstanding national reputation in Pediatric care through education, research and innovation. Equity and diversity will be high priority in the process.

## Overview

AdventHealth's Center for Pediatric Research is defining the future of pediatric health care through research, data analysis, improving clinical performance and quality of care. The research department provides full-service support for all investigator-initiated, grant-funded and sponsored trials consisting of a portfolio that crosses many pediatric areas.  Sub-specialty care includes a Level IV Comprehensive Pediatric Epilepsy Center, Level III Neonatal Intensive Care Unit (NICU), Pediatric Bone Marrow Transplant program with a Cancer and Blood Disorder specialty, a Pediatric Liver Transplant Program and a Complex Care Clinic for patients with involved diagnoses. The Center seeks for and participates in industry-sponsored research of various pediatric subspecialties and focuses on investigator-initiated projects that significantly impact survival and outcomes.

## Areas of Focus

- Asthma
- Autism
- Cardiology
- Dermatology
- Epilepsy
- Hematology
- Hepatology
- Neonatology
- Neurology
- Orthopedics
- Pediatric Obesity
- Sepsis (Infections)
- Urology
- Vaccines



# 2021 Featured Researchers and Research

## Investigational New Drug Eases Treatment for Young Patient

After accidentally stepping on a splinter, Camilla Barbosa had a Mycobacterium kubicae skin/soft tissue infection, typically challenging to treat and requiring several antimicrobials to be taken simultaneously. Due to drug resistance, at least one of the medications often must be delivered intravenously. However, the Center's research team secured an investigational new drug approval from the FDA for Clofazimine, which allowed Barbosa to have a complete oral regimen for her entire course. The team joined the patient and her family in celebrating the end of her therapy at a special party.

## AdventHealth Research Institute Study Examines the Maternal Emotional Impact of Mothers' Recorded Voices Played to Their NICU Babies

**Dr. Raena Baptiste-Boles and her daughter**

Dr. Raena Baptiste-Boles has three children who all spent time in the Neonatal Intensive Care Unit (NICU). Her youngest child, Riley, was in the NICU at AdventHealth for Children last year for three months. Baptiste-Boles is participating in research that examines the effect of mother-child voice connections during the early stages of a child's life.

Separation from a child, especially a newborn, is traumatic for parents. This is why a research study sponsored by Dräger, manufacturers of medical and safety technology products, and conducted by AdventHealth Research Institute, seeks to discover how mothers can better cope with this separation. AdventHealth neonatologist Narendra Dereddy, MD is leading the study.

Mothers participating in the study were asked to record their own voices, speaking or singing, for use on nearly 100 specialized beds in the NICU. The recordings were played several times daily for babies staying in the NICU, with each infant hearing their own mothers' voices. The twist is that the voices were not there to soothe the babies. Instead, researchers hope to study the mother's reactions, knowing that their child hears their voice even when they are not present in the room.

Baptiste-Boles, a licensed clinical psychologist in Orlando, said she volunteered for the study because of her knowledge of attachment theory, which focuses on the developmental bonds between people, including parents and children. Baptiste-Boles recognizes positive results from her involvement in the study.

"It made me feel attached to her," Baptiste-Boles said. "It made me bond with her a little bit better. I hoped that she would recognize [my voice] when she came out of NICU, and she did. When I sing to her, she calms down. I think that is mostly because she recognizes my voice from singing." Results of the study are anticipated in December 2022.

# Key Research Study Accomplishments

**Hussnain Mirza, MD**

**Hussnain Mirza, MD,** published his data in the American Journal of Perinatology, describing the relationship between fluid intake during the first week of life and hemodynamically significant patent ductus arteriosus. Dr. Mirza states "this publication provides evidence that fluid restriction in preterm infants results in a lower incidence of chronic lung disease. The evidence will prompt a change in practice in many NICUs concerning fluid and electrolyte management in pre-term infants."

Mirza, H Garcia, J, Bell, C, Jones, K, Flynn V, Pepe J, and Oh W: Fluid Intake in the First Week of Life and Duration of Hemodynamically Significant Patent Ductus Arteriosus in Ex-tremely Preterm Infants. Amer J of Perinatology 2021 Aug 12. doi: 10.1055/a-1585-6093

### Wilson's Disease Registry

Regino Gonzalez-Peralta, MD

Ki Hyeong Lee, MD, MS

Angel O Claudio, MD

Michael Westerveld, PhD

The Wilson's Disease Registry highlights how cross-specialty collaborations can occur through research. For example, **Regino Gonzalez-Peralta, MD** (Pediatric Gastroenterologist and Hepatologist), **Angel O Claudio, MD** (Adult Neurologist), **Ki Hyeong Lee, MD, MS** (Pediatric and Adult Neurologist and Epileptologist), and **Michael Westerveld, PhD** (Neuro Psychologist) all came together to deliver whole-person care for those with Wilson's Disease, a rare genetic disorder causing excessive copper accumulation in the liver, brain and other organs. Their work on the research registry also has enhanced collaborations with other sponsors. Soon the Institute will participate in a first-of-its-kind gene therapy treatment trial for Wilson's Disease. AdventHealth will be one of three non-infusion sites in the United States.

## 2021 New Investigators

Brian Tullius, MD

**Brian Tullius, MD, Research Medical Director for Pediatric Cellular Therapy,** is the lead principal investigator for the study, *Edited Natural Killer Cells As an Immunotherapeutic Approach for the Treatment of Pediatric Cancers,* which encompasses bone marrow transplants and single cell-type cellular therapies, such as chimeric antigen receptor T cells. Natural killer (NK) cell adoptive cellular therapies are particularly interesting because NK cells have in-vitro efficacy against almost every form of pediatric cancer. Growing clinical evidence suggests they are beneficial in battling cancers in patients. In addition, NK cells are unique among the adoptive cellular therapies because they do not require any HLA matching, unlike their T cell counterparts. This characteristic allows for 3rd party NK cells to be used as a readily available, "off-the-shelf" adoptive cellular therapy—ready to treat patients.

AdventHealth's history with NK cell research and vision for the future contributed largely to Dr. Tullius's decision to join the team, along with the addition of the organization's partnership with Disney.

**"Disney brings to life its world-class theme parks through the innovation of its Imagineers. Cellular Therapy is nothing short of Cellular Imagineering. We imagineer hope through that same Disney Imagineer cocktail of science and creativity, and... with the same goal of keeping kids smiling for a long, long time."**

**— Brian Tullius, MD**

Akaluck "Ben" Thatayatikom, MD

**Akaluck "Ben" Thatayatikom, MD's** focus on clinical care and research includes common and perplexing systemic autoimmune/immune-mediated diseases and ultrasonography as a non-invasive diagnostic tool for children with rheumatologic diseases. Earning his medical degree in Thailand, he completed two fellowships in Pediatric Allergy/Immunology and Pediatric Rheumatology. Dr. Thatayatikom joined AdventHealth for Children to care for the considerable number of children with autoimmune or immune disorders in Central Florida, believing in AdventHealth for Children's recognition for delivering excellent health care service. His vision is to provide exceptional patient experiences and services while advancing science in rheumatology and immunology.

## Featured 2021 Publications

- Jonas MM, Rhee S, Kelly DA, Del Valle-Segarra A, Feiterna-Sperling C, Gilmour S, **Gonzalez-Peralta RP,** et.al. Pharmacokinetics, Safety, and Efficacy of Glecaprevir/Pibrentasvir in Children With Chronic HCV: Part 2 of the DORA Study. *Hepatology.* doi: 10.1002/hep.31841

- Krilov LR, Forbes ML, Goldstein M, **Wadhawan R,** Stewart DL. Severity and Cost of RSV Hospitalization Among US Preterm Infants Following the 2014 American Academy of Pediatrics Policy Change. *Infect Dis Ther.* doi: 10.1007/s40121-020-00389-0
- **Williams FZ, Clampitt-Holsenbeck A, Lopilato A, Nazari R, Zussman ME, Reyes A, Pigula FA.** Successful Surgical Management of Aortic Arch Thrombosis in the Neonate. *Ann Thorac Surg.* doi: 10.1016/j.athoracsur.2020.05.091
- Cohen S, Mietzsch U, Coghill C, **Dereddy N,** et.al. Survey of Quaternary Neonatal Management of Posthemor-rhagic Hydrocephalus. *Am J Perinatol.* doi: 10.1055/s-0041-1732417
- Perito ER, Squires JE, Bray D, Bucuvalas J, Krise-Confair C, Eisenberg E, **Gonzalez-Peralta RP,** et.al. A Learning Health System for Pediatric Liver Transplant: The Starzl Network for Excellence in Pediatric Transplantation. *J Pediatr Gastroenterol Nutr.* doi: 10.1097/MPG.00000000000029


# A Foundation Story:
# Father's Day Golf Tournament Raises Funds for NICU Research

Heather McCandless' annual Father's Day golf tournament raised over $35,000 in 2021 to support neonatal research at AdventHealth for Children. Her passion for the NICU is tied to her personal experience and commitment to advancing NICU care.

During a 26-mile offshore fishing trip, hundreds of miles from her Central Florida home, Heather's water broke, and she went into labor. She was airlifted to the nearest hospital where her daughter, Jocelyn, was born at 31 weeks. Her premature baby suffered from a level three head bleed, which the medical team believed would cause long-term complications walking, talking, learning and more.

"By the grace of God and all the wonderful people in the NICU, Jocelyn has no residual effects and just celebrated her 10th birthday," said McCandless. While she had generously supported children's programs in the past, McCandless felt inspired to find a bigger way to give back after her NICU experience. In her own Central Florida community,  Heather became actively involved at AdventHealth for Children, joining the Foundation Board and fundraising to support the research and care provided to families in her community.

"As someone who experienced it, I understand not everyone's story ends like mine," she said. "Some families are lucky to spend time with their new babies, even just once a week. It takes a large toll on families, but thankfully, programs like Child Life at AdventHealth for Children are available to support them. I feel incredibly grateful and want to improve that experience even further."

Everyone has different ways to contribute, from cuddling babies to knitting blankets. McCandless found her own way to do good and holds her annual charity event to do just that.

**Heather McCandless**

# **Cancer** Institute

## Vision

The AdventHealth Cancer Institute seeks to achieve the national recognition that provides patient access to value-based, personalized care through highly specialized, comprehensive and innovative destination cancer programs.

## Overview

The AdventHealth Cancer Institute (AHCI), one of the largest cancer care providers in Florida, is recognized worldwide for its comprehensive, state-of-the-art care and reputation as a destination cancer care facility. The program provides patients with access to the latest treatments and technology through a multi-disciplinary care model comprised of sub-specialists in cancer care.

AHCI research initiatives span clinical, translational and population health research, value-based care, precision medicine and pharmacogenomics. The Institute offers a wide range of clinical trials, giving patients access to leading-edge treatment options that are not widely available. Studying both FDA-approved and investigational medications and devices allows our specialists to pursue novel, efficient and enhanced cancer treatment options to improve care and quality of life.

In addition to advanced medical treatment, patients have access to spiritual and psychological support, educational programs and specially trained oncology nurse navigators who help guide patients through their personalized course of treatment.

## 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

# 2021 Featured Researchers and Research

Carlos Alemany, MD

**Carlos Alemany, MD, Medical Director, Clinical Research Department for AdventHealth Cancer Institute,** is a board-certified internal medicine, hematology and oncology physician. He has been recognized as one of the Best Doctors in America by Best Doctors, Inc. and Orlando Magazine for his dedication to research and superior patient care. He has directed clinical trials and authored and co-authored articles in several peer-reviewed medical journals on subjects including breast and lung cancer, urothelial carcinoma, lymphoma, anemia and multiple myeloma. Dr. Alemany specializes in genitourinary oncology, breast cancer and myeloma/lymphoma. Fluent in English and Spanish, Dr. Alemany is committed to providing his patients with the most advanced diagnosis and treatments using the latest technology available.

**Highlights:**

- Dr. Alemany was the first PI in the world to enroll a patient in a first-in-human multicenter study of OP-1250 in Adult Subjects with Advanced and/or Metastatic Hormone Receptor (HR)-positive, HER2- negative Breast Cancer.
- Dr. Alemany was a special guest and presenter at the October 2021 ACCR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics.

**"I participate in and promote clinical trial research to improve the quality of our treatments against cancer," Dr. Alemany said. "Thanks to the vigorous clinical research efforts in the US and other leading countries, we cure more cancer patients now than ever before."**

**— Carlos Alemany, MD**

Wassim Mchayleh, MD, MBA, FACP

**Wassim Mchayleh, MD, MBA, FACP, Clinical Program Director,** is a board-certified medical oncologist and hematologist. He joined AdventHealth Medical Group from one of the Southeast's largest oncology groups, Georgia Cancer Specialists, affiliated with Northside Hospital Cancer Institute. He previously served as Medical Director of Oncology Services and Hospice at WellStar West Georgia Medical Center, Assistant Professor at Emory University and Program Director of Oncology Fellowship at the Lebanese American University in Beirut. He also served as clinical faculty at the Philadelphia College of Osteopathic Medicine and the Florida State University College of Medicine. He was honored with the Georgia Cancer Coalition Distinguished Cancer Clinician and Scientist Award in 2011 and has contributed to multiple peer-reviewed journals in respected publications.

**Highlight:** Dr. Mchayleh's research expertise has been instrumental in the exponential growth of the oncology clinical research program at the AdventHealth Altamonte campus this year and sparked the community's interest in Seminole County's only research institute. The new program includes a variety of breast cancer trials.

**"I do clinical research because it allows my patients to access leading-edge oncology treatments and allows me to be part of a team changing the future of cancer."**

**— Wassim Mchayleh, MD, MBA, FACP**

George Simon, MD

AdventHealth Celebration's Clinical Research Unit (CRU), led by **George Simon, MD, Chair of AdventHealth Celebration's Department of Medical Oncology,** became operational in December 2020 and was established to bring the latest clinical research to patients in Central Florida. This research unit primarily focuses on phase I or early phase research, bringing novel, rationally developed and bio-engineered compounds to a group of patients who often do not have the resources to travel outside Central Florida to access these studies. More than half of their 20+ active studies are early phase or multi-tumor studies.

The CRU works closely with highly esteemed AdventHealth physician groups to offer a diverse range of studies with novel targeted therapies, monoclonal antibodies, antibody-drug conjugates, bispecific antibodies, novel checkpoint inhibitors and oncolytic viruses. An exciting portfolio of novel drugs has stimulated a 400 percent increase in CRU patient referrals and a 500 percent increase in patient accruals to CRU studies over the last year. The local availability of these unique treatments has enhanced patient retention in their communities, allowing them to continue seeing their primary oncologist with whom they know and trust. The CRU's investigations have resulted in eight publications from 2020-2021, with two additional manuscripts awaiting submission.

**Highlight:** One compound the CRU offers is a complement factor H inhibitor developed at the Duke Cancer Institute. This first-in-class compound is only available at three U.S. centers, including AdventHealth. In the future, the CRU will offer similar compounds fresh out of research labs, further enhancing the therapeutic options for our physicians and patients.

Mohamedtaki Tejani, MD

**Mohamedtaki Tejani, MD, Medical Director and Digestive Tract Cancers Medical Oncologist,** has authored numerous oncology-related publications in his field of gastrointestinal cancers, biomarkers and therapeutics, patient-provider communication and the culture of medicine. Dr. Tejani firmly believes that patient care is a privilege. Originally from Tanzania (East Africa), he is fluent in Swahili, Hindi, Urdu and Gujarati.

**Highlight:** Dr. Tejani had a poster presentation at the European Society for Medical Oncology (ESMO) Congress 2021: DKN-01 in Combination with Tislelizumab and Chemotherapy as a First-line Therapy in Unselected Patients with Advanced Gastroesophageal Adenocarcinoma (GEA): DisTinGuish Trial.

**"I conduct clinical research to give our patients access to the latest leading-edge therapies right here in Orlando."**

**— Mohamedtaki Tejani, MD**

Ahmed Zakari, MD

**Ahmed Zakari, MD, Clinical Program Director and Digestive Tract Cancer Medical Oncologist**, is board certified in Medical Oncology and Hematology, with expertise in Gastrointestinal Oncology and Malignant Hematology. He also serves as the Hematology Section chair within the Department of Internal Medicine at AdventHealth System while teaching as an Associate Professor at University of Central Florida, College of Medicine. In 2021, Dr. Zakari was a speaker at the following conferences:

- Winter Symposia: an update in Gastric and Esophageal Cancers in new Genomic Profiling World Puerto Rico
- Advances in Immunotherapy and Colorectal Cancer 2021 in Miami
- Clinical Impact of Genomic Diversity of Hepatocellular Carcinoma, University of Science Ben M'sik, Casablanca, Morocco

**Highlight:** Dr. Zakari's reputation and research expertise in GI Oncology at AdventHealth Orlando and Altamonte opened a great window for patients in our community to access AdventHealth system clinical trials and receive state of the art Oncology Care. A strong referral base from the Orlando tri-county area (Orange, Seminole and Osceola) had been established for Dr. Zakari through our clinical trial program.

Mark A. Socinski, MD

**Mark A. Socinski, MD, Executive Medical Director of the AdventHealth Cancer Institute,** is a board-certified, fellowship-trained medical oncologist specializing in all thoracic malignancies, including small and non-small cell lung cancers and mesothelioma. He is an internationally recognized expert in developing novel chemotherapy agents and treatment strategies for advanced non-small and small cell lung cancer. His research has focused on incorporating personalized medicine and molecular biomarkers to treat lung cancer. Dr. Socinski formerly served as Co-Chair of the Thoracic Malignancies Steering Committee for the National Cancer Institute. He also serves on the Respiratory Core Committee of the Cancer and Leukemia Group B (Alliance) and has been instrumental in developing many cooperative clinical trials.

"In the past 10 years, we have seen a transformation in how we think about lung cancer, especially non-small-cell lung cancer," explains Dr. Socinski. "NSCLC is a very generic term that encompasses several different types that are driven by varying molecular alterations. Understanding the specific mutation that caused the cancer allows us to treat the patient more effectively with an appropriate targeted therapy."

**Highlight:** Dr. Socinski published the lead article "MET Exon 14 Skipping Mutations in Non-Small-Cell Lung Cancer" in the American Society of Clinical Oncology's JCO Precision Oncology journal (April 2021 doi: 10.1200/PO.20.00516). Dr. Socinski and his colleagues discuss the complex genomic events leading to non-small-cell lung cancer (NSCLC) and review the specific considerations for detecting the MET exon 14 skipping mutation (METex14) using next-generation sequencing (NGS) genetic testing.

**"Comprehensive genomic testing is no longer an option. It should be the standard of care for every non-small-cell lung cancer patient. We know that the new generation of targeted therapies available to us can dramatically improve outcomes, so it is imperative that we properly identify the driving mutation."**

**— Mark A. Socinski, MD**

**Tarek M. Mekhail, MD, MSc, FRCSI, FRCSEd**

**Tarek M. Mekhail, MD, MSc, FRCSI, FRCSEd, Medical Director,** is board-certified in internal medicine, hematology and oncology. Dr. Mekhail serves as the Associate Medical Director of the AdventHealth Cancer Institute and the Medical Director of the Thoracic Cancer Program. He joined the team from the Cleveland Clinic, where he was the Lung Cancer Medical Oncology program director. In addition, he is an associate professor at the University of Central Florida.

**Highlight Publications:**


- Riely GJ, Neal JW, Camidge DR, Spira AI, Piotrowska Z, Costa DB, Tsao AS, Patel JD, Gadgeel SM, Bazhenova L, Zhu VW, West HL, **Mekhail T,** Gentzler RD, Nguyen D, Vincent S, Zhang S, Lin J, Bunn V, Jin S, Li S, Jänne PA. Activity and Safety of Mobocertinib (TAK-788) in Previously Treated Non-Small Cell Lung Cancer with EGFR Exon 20 Insertion Mutations from a Phase I/II Trial. *Cancer Discov.* doi: 10.1158/2159-8290.CD-20-1598
- Zhou C, Ramalingam SS, Kim TM, Kim SW, Yang JC, Riely GJ, **Mekhail T,** Nguyen D, Garcia Campelo MR, Felip E, Vincent S, Jin S, Griffin C, Bunn V, Lin J, Lin HM, Mehta M, Jänne PA. Treatment Outcomes and Safety of Mobocertinib in Platinum-Pretreated Patients With EGFR Exon 20 Insertion-Positive Metastatic Non-Small Cell Lung Cancer: A Phase 1/2 Open-label Nonrandomized Clinical Trial. *JAMA* Oncol. doi: 10.1001/jamaoncol.2021.4761
- Tao L, Miao R, **Mekhail T**, Sun J, Meng L, Fang C, Guan J, Jain A, Du Y, Allen A, Rzeszutko BL, Socinski MA, Chang CC. Prognostic Value of KRAS Mutation Subtypes and PD-L1 Expression in Patients With Lung Adenocarcinoma. *Clin Lung Cancer.* doi: 10.1016/j.cllc.2020.07.004


**Herbert Newton, MD**

**Herbert Newton, MD, Medical Director, Neuro-Oncology,** is a board-certified neuro-oncologist and neurologist with over 30 years of highly specialized experience treating adult cancer patients with brain and spinal cord tumors and the complications of brain tumors — particularly epilepsy. An acclaimed authority in his field, Dr. Newton specializes in the use of chemotherapy and molecular therapeutics. He has been recognized by U.S. News & World Report as one of America's Top Doctors.

**Highlight:** Dr. Newton is one of the country's most senior and experienced neuro-oncologists, with an extensive academic neurology and neuro-oncology history. He is well-published with over 200 peer-reviewed journal articles and book chapters, and is the editor or co-editor of nine published medical textbooks. He is interested in personalized approaches to medicine and cancer treatment and works closely with his patients and their family members. Dr. Newton's research focuses on understanding the causes of gliomas, including new findings on environmental and sex-specific molecular signature.

Rushang Patel, MD, PhD

**Rushang Patel, MD, PhD, Medical Director,** is a board-certified, fellowship-trained medical hematologist and oncologist. He specializes in hematologic malignancies, especially acute leukemias, aggressive lymphomas and myeloma. He brings a wealth of hematology and stem cell transplant knowledge through training at Fox Chase Cancer Center, Temple University and MD Anderson Cancer Institute. Dr. Patel conducts research to determine how agent orange works and its role in diseases, including cancer and inflammation, publishing various journal articles on the topic. He has also served as an expert on advisory panels for research, including clinical trials, related to identifying new treatments for patients with blood cancer and complications of stem cell transplant. Other projects he has supported include initiatives with the United Nations International Children's Emergency Fund (UNICEF), Alembic Pharmaceuticals and Sanofi-Aventis, along with studies focused on the mechanisms of cancer formation from toxic chemicals and the identification of new targets for cancer drug design. Currently, he serves as the Director of Malignant Hematology, Blood and Marrow Transplant and Cellular Therapy programs at AdventHealth, Orlando.

**Highlight:** Dr. Patel and his group published four articles in peer-reviewed journals in 2021 focusing on various topics related to leukemia and stem cell transplant. The publications include comparison of different types of chemotherapy being used before stem cell transplant and its effect on patient outcomes—along with data to further understand the importance of different gene mutations as they relate to acute leukemia.

- **Yu J, Du Y, Jalil A, Ahmed Z, Mori S, Patel R, Varela JC, Chang CC.** Mutational profiling of myeloid neoplasms associated genes may aid the diagnosis of acute myeloid leukemia with myelodysplasia-related changes. *Leuk Res*. doi: 10.1016/j.leukres.2021.106701
- **Yu J, Du Y, Ahmad S, Patel RD, Varela JC, Chang CC, Mori S.** Comparison of Myeloablative versus Reduced-Intensity Conditioning Regimens in Allogeneic Stem Cell Transplantation Recipients with Acute Myelogenous Leukemia with Measurable Residual Disease-Negative Disease at the Time of Transplantation: A Retrospective Cohort Study. *Transplant Cell Ther.* doi: 10.1016/j.jtct.2021.04.017
- **Yu J,** Sun J, **Du Y, Patel R, Varela JC, Mori S, Chang CC.** Adverse Impact of DNA Methylation Regulatory Gene Mutations on the Prognosis of AML Patients in the 2017 ELN Favorable Risk Group, Particularly Those Defined by NPM1 Mutation. *Diagnostics (Basel)*. doi: 10.3390/diagnostics11060986
- **Yu J, Diaz JD, Goldstein SC, Patel RD, Varela JC, Reyenga C, Smith M, Smith T, Balls J, Ahmad S, Mori S.** Impact of Next-Generation Sequencing Cell-free Pathogen DNA Test on Antimicrobial Management in Adults with Hematological Malignancies and Transplant Recipients with Suspected Infections. *Transplant Cell Ther.* doi: 10.1016/j.jtct.2021.02.025

Robert Holloway, MD

**Robert Holloway, MD, Medical Director** of AdventHealth's internationally recognized Gynecologic Oncology Program (AHGO), is a pioneer in robotic surgery, post-graduate training and clinical research excellence. The AHGO is renowned for excellence in clinical research, robotic surgery, innovation, treatment and novel investigations into immune therapy for gynecologic cancers.
Dr. Holloway is the principal investigator for several clinical trials and projects aimed at advancing effective treatments for gynecologic cancers, including innovative investigations of pelvic sentinel lymphatic mapping that improve surgical staging, bio-assays that predict oncologic drug therapy responses and genomic markers for neurotoxicity that may improve quality of life for patients on chemotherapy. Dr. Holloway is an acknowledged leader in his field and a frequent lecturer at major universities worldwide on robotic surgery, pelvic sentinel lymph node mapping and ovarian cancer therapies. His many awards include Excellence in Oncology, Orange County Medical Society's Surgeon of Year, Best Doctors of America, Patients' Choice Recognition, Doctor Honoris Causa Recognition, FH GME, Castle Connolly "Top Doctors" and SGO Committees & Awards.

**Highlights:** Dr. Holloway recently published a phase 1b study of intraperitoneal oncolytic viral immunotherapy in platinum-resistant or refractory ovarian cancer and is preparing to be the National Principal Investigator of the first enrolling site for the phase III continuation of this research study.

*A randomized phase 3 study assessing the efficacy and safety of olvi-vec followed by platinum-doublet chemotherapy and bevacizumab compared with chemotherapy and bevacizumab in women with platinum-resistant/ refractory ovarian cancer (onprime study) clin trial ID NCT05281471*

Olvi-Vec (olvimulogene nanivacirepvec, aka GL-ONC1, laboratory name: GLV-1h68) is an oncolytic vaccinia virus-based immunotherapy. This study tests the hypothesis that the combination of Olvi-Vec followed by further chemotherapy is particularly effective against established tumors by virus-mediated immune activation and re-sensitization of tumor cells to chemotherapy. Based on the PI's and Sponsor's recent experiences with phase 1b and phase 2 studies, data showed that Olvi-Vec (either as monotherapy or as combination therapy) was well-tolerated in heavily pre-treated platinum-resistant/refractory ovarian cancer without any Grade 4 adverse events. This provides a strong rationale for the proposed phase III study.

**"Impossible is just one opinion. With enough research and experience, we can find solutions for difficult clinical problems,"**

**– Robert Holloway, MD**

Nathalie Mckenzie, MD, MSPH, FACOG, DipABLM

**Nathalie Dauphin McKenzie, MD, MSPH, FACOG, DipABLM,** is a board-certified gynecologic oncologist with tremendous expertise in advanced surgical treatments, including laparoscopic and robotic-assisted procedures for women with all types of gynecologic cancers. A cancer survivor herself, Dr. McKenzie provides compassionate, holistic, integrative and state-of-the-art medical care. She is especially known for her expertise in radical debulking surgeries to remove advanced tumors and has a passion for cancer research.

Her innovative, early-career research initiatives resulted in research funding awards and recognition. Most recently, Dr. Mckenzie was selected as one of 16 oncologists from across the nation to participate in extensive leadership training with the highly esteemed American Society of Clinical Oncology (ASCO). As a program graduate, she sits on national committees that monitor and provide guidance to oncology practices throughout the country. In addition, she is the Program Director of the Gynecologic Oncology Fellowship at AdventHealth and holds faculty appointments with the Florida State University and University of Central Florida Colleges of Medicine—where she regularly mentors students and residents.

Dr. McKenzie was honored as the recipient of the Society of Gynecologic Oncology (SGO) 2021 Gynecologic Oncology Humanitarianism & Volunteer Award. In addition, she was recently elected to serve a one-year term on the Florida Society of Clinical Oncology (FLASCO) Board of Directors. In addition to teaching and research, Dr. Mckenzie also sits on numerous boards for charity organizations, embarks on surgical missions to impoverished populations internationally and frequently lectures across the globe.

**Highlights:** Dr. McKenzie recently published a chapter in a CRC Press, Taylor & Francis book, *Improving Women's Health Across the Lifespan:* "Modifiable lifestyle factors, such as obesity, lack of physical activity, stress and smoking, contribute greatly to cancer and chronic disease morbidity, mortality and quality-of-life (QoL) worldwide". This chapter appraises recent evidence on modifiable lifestyle factors for preventing endometrial, cervical and ovarian cancers and new evidence for lifestyle recommendations for patients living with or survivors of gynecologic cancers (GCc). Recent advances in next-generation sequencing have led to an increased understanding of the gut microbiome's role in human health.

**"I participate in and lead cancer research because it saves lives, extends life and improves the quality of life of people with cancer. Every single cancer success story is a direct result of cancer research. As a cancer survivor and an oncologist, I have lived and experienced the direct impact of cancer research and innovation in oncology."**

**— Nathalie McKenzie, MD**

## 2021 New Investigators

Brian Parkin, MD

Physician-scientist **Brian Parkin, MD,** studies the early detection and prevention of relapsed acute myeloid leukemia and related cancers, particularly in bone marrow transplantation. His internal medicine residency and post-doctoral Hematology/Oncology fellowship at the University of Michigan led him to the laboratory to solve questions he saw in the hospital, focusing on translational genomics to understand how DNA mutations and changes affect patient outcomes.

Dr. Parkin has bolstered the AHRI's translational oncology program by developing studies combining ultra-high sensitivity mutation methods and leading-edge single-cell immunoproteogenomics to detect and characterize low-level residual leukemia that often leads to relapse. Other studies he has initiated aim to understand the mechanisms by which high-risk leukemias with TP53 gene mutations resist chemotherapy and immune surveillance. Dr. Parkin also works with AHRI's processing lab to establish and cultivate a clinically annotated biorepository, collecting specimens from willing patients with acute leukemia or undergoing bone marrow transplants to understand why some respond to their treatments while others do not—zeroing in on clearer medical answers and practices. He is also partnering with academia and industry to build sound, correlative scientific aims into more efficient trials that allow deeper analysis of results.

**"As much as I love and value basic science, the connection with patients allows us to really ask and answer important questions. It provides a priceless resource."**

**– Brian Parkin, MD**

**Imran Mohiuddin, MD, PhD**

**Imran Mohiuddin, MD, PhD,** treats malignant and benign brain and spine tumors of the central and peripheral nervous system using various radiation oncology approaches, such as Gamma Knife radiosurgery, linear accelerator (LINAC) stereotactic radiotherapy and GammaTile intracranial brachytherapy. He also treats cancer of the head, neck and lungs. Dr. Mohiuddin's research focuses on understanding immune system regulation disorders to advance the treatment of oncologic and autoimmune conditions. He also studies data interpretation and visualization methods, including augmented reality and bioinformatics. Dr. Mohiuddin earned his MD and PhD degrees at University of Texas Southwestern Medical Center and completed his Radiation Oncology residency at the University of Iowa Hospitals and Clinics.

## 2021 New Fellows-in-Training Investigators

**Ahmad Awada, MD**

**Ahmad Awada, MD,** graduated from the American University of Beirut Medical Center and completed his obstetrics and gynecology residency at George Washington University Hospital in Washington, DC, where he received several awards. While completing his residency in Pennsylvania and New York, he developed a strong research interest in Septin inhibitors, HE- inhibitors and their effect on gynecologic cancer. Dr. Awada will focus the first year of his AdventHealth fellowship on clinical and translational research projects.

**Fernando O. Recio, MD**

**Fernando O. Recio, MD,** graduated from Stony Brook School of Medicine in New York and received his residency training in Obstetrics and Gynecology at The University at Buffalo, NY, where he received numerous awards for excellence in gynecologic oncology and minimally invasive surgery. He received the David H. Nichols Award for overall excellence in gynecologic surgery and the Shashikant Lele Award for excellence in gynecologic oncology. Dr. Recio's first year of his AdventHealth fellowship will have a clinical and research focus, building on his strong undergraduate background in basic science, clinical outcomes research and special interest in using molecular tumor testing and circulating tumor DNA in guiding treatment planning.

## Featured 2021 Publications

- **Manyam M, Stephens AJ, Kennard JA, LeBlanc J, Ahmad S, Kendrick JE, Holloway RW.** A phase 1b study of intraperitoneal oncolytic viral immunotherapy in platinum-resistant or refractory ovarian cancer. *Gynecol. Oncol.* doi: 10.1016/j.ygyno.2021.10.069
- **Fitzsimmons CK, Stephens AJ, Kennard JA, Manyam M, Pepe JW, Ahmad S, McKenzie ND, Kendrick JE, Holloway RW.** Carcinomatosis in early-stage cervical cancer treated with robotic radical hysterectomy: Recurrence patterns, risk factors, and survival. *Ann. Surg. Oncol.* doi: 10.1245/s10434-021-11052-4

- **Gwacham NI, McKenzie ND,** Fitzgerald E, **Ahmad S, Holloway RW.** Neoadjuvant chemotherapy followed by fertility-sparing surgery in cervical cancers size 2-4 cm: Emerging data and future perspectives. *Gynecol Oncol.* doi: 10.1016/j.ygyno.2021.06.006
- Garcia-Soto AE, **McKenzie ND,** Whicker ME, Pearson JM, Jimenez EA, Portelance L, Hu JJ, Lucci III JA, Qureshi R, Kossenkov A, Schwartz L, Mills G, Maity A, Lin LL, Simpkins F. Phase I trial of nelfinavir added to standard cisplatin chemotherapy with concurrent pelvic radiation for locally advanced cervical cancer. *CANCER.* doi: 10.1002/cncr.33449
- Oaknin A, Oza AM, Lorusso D, Aghajanian C, Dean A, Colombo N, Weberpals JI, Clamp AR, Scambia G, Leary A, **Holloway RW,** Amenedo Gancedo M, Fong PC, Goh JC, O'Malley DM, Armstrong DK, Banerjee S, García-Donas J, Swisher EM, Cameron T, Maloney L, Goble S, Ledermann JA, Coleman RL. Maintenance treatment with rucaparib for recurrent ovarian carcinoma in ARIEL3, a randomized phase 3 trial: The effects of best response to last platinum-based regimen and disease at baseline on efficacy and safety. *Cancer Med.* doi: 10.1002/cam4.4260


# A Foundation Story: **Melissa's Race for Brain Cancer Research**

Melissa Vosburg first experienced migraine headaches, a family bane, in the fall of 2012. The migraines became more frequent and severe over Thanksgiving, due to a lack of improvement by Christmas, and her family's insistence, she agreed to see the doctor after the holiday season.

However, on Christmas Day, her headache was so severe that she stayed in bed most of the morning and was so light-sensitive that she wore sunglasses in the house. The next day, her mom took her to the doctor, who said it was likely due to migraines based on her and her family's symptoms—scheduling a CT scan to be sure. The CT revealed swelling and shifting in her brain. She was advised to consult a neurosurgeon for an exam and surgical biopsy immediately.

On December 28, 2012, Melissa was diagnosed with glioblastoma multiforme (GBM), the most common and aggressive type of brain cancer. Despite enduring treatments, consults and surgery to partially remove the tumors in the weeks following her diagnosis, Vosburg's spirit and unbelievable courage remained unshaken. "It is what it is," she often said, refusing to dwell on "why" or show self-pity.

At one of her appointments, she noticed a flyer for a brain cancer awareness race and immediately decided to sign up. As a result, her family formed the first "Team Melissa" and participated in the Orlando Miles for Hope. She received a plaque for being in the top three fundraisers, spoke at the event and completed the survivor walk.

Unfortunately, Melissa passed away a week after the walk. When the Miles for Hope race left Orlando, her family stepped in and started their own 5K, Melissa's Race, in her honor to raise funds for brain cancer research. They've helped to begin clinical trials for new GBM patients through their efforts with the hope of extending life expectancy and curing GBM forever.

Melissa Vosburg was an engaging and happy daughter, sister, dear friend and teacher. But, above all, she was and is a hero. In 2021, Melissa's Race surpassed the cumulative giving of $315,000 to advance brain cancer research at AdventHealth.


**(from left to right) Jeff and Sue Vosburg; Herbert B. Newton, MD, FAAN; Chris Davis, PhD**

# Digestive Health and Surgery Institute

## Vision

The AdventHealth Digestive Health and Surgery Institute (DHSI) is a national destination for digestive-health and specialty-surgical care, leading the nation in exceptional quality by becoming a national top performer in quality and patient experience, and by building and expanding comprehensive research and educational programs.

## Overview

The AdventHealth Digestive Health and Surgery Institute (DHSI) is at the forefront of advanced care for complex diseases, housing the largest interventional endoscopy center in the U.S. and holding multiple accreditations for our subspecialty programs. Our well-connected, multi-specialty care team has made our institute a destination for digestive and surgical care. As a result, it is recognized as a Center of Excellence by the National Accreditation Program for Rectal Cancer (NAPRC). This section illustrates why AdventHealth Orlando is recognized by U.S. News & World Report 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.

## Areas of Focus

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

## Digestive Health and Surgery Ecosystem Wheels



## 2021 Featured Researchers and Research

John R.T. Monson, MD, FRCS, FASCRS, FACS

**John R.T. Monson, MD, FRCS, FASCRS, FACS,** is a colon and rectal surgeon, fellowship trained in colorectal surgery and surgical oncology. He graduated from Trinity College Dublin in Ireland and trained at the Royal College of Surgeons in Ireland, Mayo Clinic and The University of Leeds. His areas of expertise include the use of 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 U.K.'s National Training Program. He has performed over 10,000 resections for colorectal cancer. 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. He is a current member of the Commission on Cancer and Steering Committee for the National Accreditation Program for Rectal Cancer (NAPRC). He also serves as the Director of the Rectal Cancer Program at AHCI.

**Highlight:** The Digestive Health and Surgery Institute's Colon and Rectal Surgery team presented a new technique for reconstructing the perineal defect after Robotic Abdominal-Perineal Resection (APR) with V-Y gluteal flap. The case was unusual and the surgery performed was a resection of extramammary Paget disease of the anus. The procedure was published as a video highlighting the technical steps and pearls of a robotic TME for an appropriate, oncologic APR and a reconstructive option that, when performed correctly, offers coverage for an enlarged or radiated perineal defect.

Article: Diseases of the Colon & Rectum: September 2021 - Volume 64 - Issue 9 - p e526-e527 doi: 10.1097/DCR.0000000000002126. Wright, Jesse P. M.D; Sawh-Martinez, Rajendra F. M.D.; **Monson, John R.T. MD**

Muhammad Khalid Hasan, MD

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

Dr. Hasan completed his Internal Medicine residency and Gastroenterology fellowship training at the University of Oklahoma and advanced endoscopy trainings at Mayo Clinic in Jacksonville, FL and the Medical University of South Carolina, Charleston. He has been a staff physician at AdventHealth, Orlando since 2010 and helped establish the Center for Interventional Endoscopy (CIE) at Florida Hospital in 2013, which is now a premier endoscopy center serving the needs of over 6000 patients annually.

His interests include clinical research, trainee and professional education and innovation in endoscopic techniques. His research focuses on clinical outcomes associated with endoscopic procedures, as well as clinical disease states. He has initiated many research projects independently and has participated in multiple multi-center projects as a co-investigator, resulting in over 70 original publications, including premier journals such as Gut, Gastroenterology, Endoscopy and Gastrointestinal Endoscopy.

In 2013, Dr. Hasan established the Advanced Endoscopy Fellowship (AEF) at CIE and serves as the program director. During this time, he has trained 13 advanced endoscopy fellows from the USA and abroad, while also mentoring medical students and residents. He also has visited several underserved areas outside of the USA to help with endoscopic training while also engaging in professional societies and committees, including the American College of Gastroenterology, Royal College of Physicians and Surgeons Glasgow and the Annual Scientific Program Committee for American Society for Gastrointestinal Endoscopy and Digestive Diseases Week (DDW).

**Highlight:** The Digestive Health and Surgery Institute's Center for Interventional Endoscopy completes hundreds of ERCPs on a monthly basis. Patient safety and improvement are always at the forefront of the practice. Dr. Hasan and team were involved in a novel duodenoscope model with a disposable distal cap that may prevent transmission of pathogens or other potential health care-associated infections during an ERCP procedure. In this study, numerous samples were obtained with the aim to improve patient clinical outcomes and improve ERCP-associated infection rates.

Mark Soliman, MD

**Mark K. Soliman, MD, Chief of Colorectal Surgery and Program Medical Director of the AdventHealth Digestive Health and Surgery Institute,** is board certified in both colorectal and general surgery. He is an internationally recognized expert in advanced minimally invasive and complex robotic colorectal surgery for the treatment of both benign and malignant disease. His research focuses on pedagogical methodologies to teach surgeons how to navigate learning curves in the adoption of robotic surgery and also outcomes-based studies in the area of novel robotic colorectal surgical operations.

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

## 2021 New Investigators

Chikaodinaka Nkwocha, MD, MPH

**Chikaodinaka Nkwocha, MD, MPH,** was born and trained in Nigeria and earned her MPH from Texas A & M University. She joined AdventHealth's Digestive Health and Surgery Institute in May 2021 as a research fellow focusing on Surgery and Family Medicine. Dr. Nkwocha is enthusiastic about her role on the AdventHealth team and the great opportunity to learn and improve her research skills.

Leonardo Alfonso Bustamante-Lopez, MD

**Leonardo Alfonso Bustamante-Lopez, MD,** is a post-doctoral research fellow and colorectal surgeon from Venezuela and Brazil. He has a strong background in colorectal research to contribute to DHSI's research team. As a colorectal surgeon, Dr. Bustamante-Lopez says, "I am excited to have the opportunity to be part of the Colorectal Medical Group, which covers everything in our specialty. As a result, working with the best surgeons in the field, I can improve my research in colorectal cancer, robotic surgery, IBD, TAMIS, laparoscopic surgery and pelvic floor diseases."

## Featured 2021 Publications

- **Hasan MK,** Yousaf MS, Tehami N, Ala K, Arain UA, Ahmad S, Kadir S, Abbas Z, Niaz, SK. Optimal stent placement strategy for malignant hilar biliary obstruction: a management dilemma. *Gastrointest Endosc.* doi: 10.1016/j.gie.2020.08.019
- Ortiz O, Rex DK, Grimm IS, Moyer MT, **Hasan MK**, et.al. Factors associated with complete clip closure after endoscopic mucosal resection of large colorectal polyps. *Endoscopy.* doi: 10.1055/a-1332-6727
- **Albert MR.** Expert Commentary on the Management of Early Rectal Cancer. *Dis Colon Rectum.* doi: 10.1097/DCR.0000000000002247
- **Wright JP, Brady JT, Albert MR.** Perineal Proctosigmoidectomy with Levatorplasty (Altemeier) Procedure for the Management of Rectal Prolapse. *Dis Colon Rectum.* doi: 10.1097/DCR.0000000000002210
- **Elias AW, Albert MR.** Lateral Internal Sphincterotomy. *Dis Colon Rectum.* doi: 10.1097/DCR.0000000000002125

# Genomics and Personalized Health

## Vision

The AdventHealth Genomics and Personalized Health program looks to be a nationally recognized leader by accelerating the transformation of the health system into one that provides and demonstrates the value of individualized care through research and the deployment of precision health technologies. The team strives to leverage advances in molecular testing, data science and 'omics' technology to substantially improve the quality and effectiveness of care delivered across the populations served.

## Overview

Genomics is revolutionizing medicine. The Genomics and Personalized Health team believes whole-person care is truly individualized care and genomics enables physcians and clinical leaders to personalize care in ways never thought possible. The program applies precision health strategies across the entire clinical spectrum of wellness and disease in the domains of prevention, diagnosis and treatment. The work in Genomics and Personalized Health spans the continuums of clinical practice and research, testing and therapies, as well as inpatient and ambulatory care.

Through the implementation of an industry-leading clinic-genomics platform, Genomics and Personalized Health is combining genomic data with the clinical data in powerful, large-scale databases to develop new insights around disease progression, biomarker identification and novel potential drug targets.

Finally, the team is working closely with multiple industry partners to advance our data science capabilities to collaboratively develop new predictive models and algorithms to improve care across a variety of conditions.

## Areas of Focus

- Deploying precision medicine at scale to save lives and resources
- Enabling faster and more accurate diagnosis
- Using molecular testing to drive more tailored and effective treatments
- Utilizing an individual approach to avoid unnecessary testing and procedures

# 2021 Featured Researchers and Research

Rebecca Essner, PhD, and WholeMe Research

**Rebecca Essner, PhD,** is a statistical geneticist who recently joined Genomics and Personalized Health (GPH) after working for 10 years in other AdventHealth research roles. Dr. Essner is principal investigator for various population genomics studies, including WholeMe Florida, the first-of-its-kind DNA study enrolling 10,000 participants across three different protocols and providing them with clinically actionable genomic insights with a transition into clinical care—along with follow-up for those with pathogenic findings. WholeMe is a pilot study for implementing genomics into the health care system and educating physicians, patients and our community about genomics' power to predict, prevent, diagnose and treat diseases related to hereditary or genomic conditions. For example, familial hypercholesterolemia (FH) is often only diagnosed after a heart attack. WholeMe identified 41 participants with pathogenic variants for FH who received a transition into clinical care. Some of these participants were family members who were educated together and then encouraged other blood relatives to get tested.

In WholeMe Phase II, over 7,200 of the original participants were given additional genomic insights associated with 25-30 clinically actionable traits for various cardiovascular and hereditary cancer conditions. Those with positive findings (378 participants) also gained access to a care navigator to transition them into clinical care for their genomic condition and guide their next steps in the personalized health care journey. These pilot studies allow AdventHealth to gauge how genomic results translate into downstream care for our research participants and their family members.

## Genomics and Personalized Health Joins AdventHealth for Children

Majed Dasouki, MD

**Majed Dasouki, MD,** is a board-certified clinical and biochemical geneticist and cytogeneticist who served as Director of Newborn Screening and led the biochemical genetics lab at the esteemed King Faisal Specialist Hospital & Research Center in Saudi Arabia before joining AdventHealth for Children. He has also served as faculty and in various leadership roles at the University of Kansas, University of Missouri, Vanderbilt University and elsewhere. His research interests include 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 addition, Dr. Dasouki has completed elite fellowships in pediatric genetics at the University of Michigan and biochemical genetics at the University of Missouri.

At AdventHealth, Dr. Dasouki has selected critically ill babies that are ideal candidates for rapid whole genome sequencing (rWGS) to help identify or rule out genetic diseases in one step. This test empowers clinicians to intervene quickly with precision care and make disease-specific treatment decisions to improve the lives of our most vulnerable patients and their families. Thus far, AdventHealth Orlando has sequenced 62 babies in partnership with Rady Children's Institute for Genomic Medicine.

### Impact of Rapid Whole Genome Sequencing for Babies

- Improved health outcomes for babies by providing rapid diagnoses, leading to beneficial changes in care management.
- Improved family experience of care by providing timely diagnostic and prognostic information, thus reducing uncertainty and empowering families to make life-altering medical decisions.
- Improved clinician experience by bolstering their confidence in treatment decisions, comfort with the implications of their decision and satisfaction in fostering effective care delivery.
- Lowered the cost of delivering care by reducing unnecessary tests, procedures and time spent in the hospital.

**Highlights:**

- **Collaborating to provide new therapeutics to treat devastating, rare pediatric diseases** — Dr. Dasouki is working with the n-Lorem Foundation to provide investigator-sponsored novel and personalized gene therapies for rare genetic disorders. These rare childhood diseases are often noticeable at a very early age and are rapidly progressive if not treated. Genotyping these patients can enable identification of the causal mutation and provides the opportunity for mutation-directed treatment. The development of these novel therapeutics occurs on an individualized basis and includes antisense oligonucleotides (ASOs).

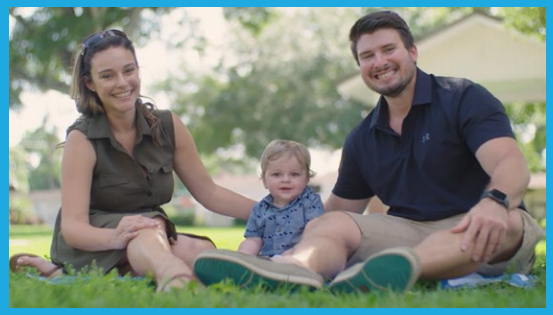
- **Developing new drugs for multiple diseases associated with inborn errors of metabolism** — Dr. Dasouki is collaborating with the biopharmaceutical industry to develop novel enzyme, oral chaperone and oral substrate drugs for various metabolic disorders.
- **Applying multi-OMICs platforms (NGS, OGM, aptamers, metabolomics and proteomics) to identify novel "diagnostic, prognostic and therapeutic" biomarkers in various genetic disorders** — As an example, Dr. Dasouki is investigating both adults and children with cardiovascular genetic disorders whose clinical genetic testing revealed variants of unknown significance, especially splicing variants. These variants are expected to affect splicing "causing alternative splicing/exon skipping"; this needs to be demonstrated through additional OMICs investigation and testing in order to confirm their pathogenicity.

### Michael's Case

**In February 2021, three-month-old Michael Fergus was admitted to AdventHealth Children's Hospital for failure to thrive after transferring from breastmilk to formula. He was pale, could not keep formula down and only weighed nine pounds. After performing Rady's rapid whole-genome sequencing, the results showed that Baby Michael had Hereditary Fructose Intolerance, a sugar allergy to fruit, vegetables and certain types of baby formula.**

**Today, Michael is a thriving, healthy baby boy. His parents said, "Without genetic testing, we would never have the answers. Dr. Dasouki and his team went completely out of their way to help us, which means the world to us. Now we have a healthy one-year-old."**

**Dr. Sarah Marsicek, another team member, remarked, "It solved a problem that would have taken several weeks to understand; we had results in less than three days."**



## 2021 Department Highlights

In 2021, AdventHealth also laid the foundation for a recently awarded Florida state appropriation of $750,000 in the 2022-2023 Florida budget. The appropriation will be used to expand the organization's advanced genomics program for critically ill newborns. Through partnership with Rady Children's Institute of Genomic Medicine, the Genomics Institute can conduct rapid and ultra-rapid whole genome sequencing to increase the speed at which extremely ill neonates can be diagnosed and treated.

In addition to developing new discoveries and insights, it is also increasingly important to understand how to implement new knowledge or practices in real-world settings. This is why research focused on Implementation Science is an integral part of the program. In phases 1 and 2 of WholeMe, AdventHealth has learned valuable lessons regarding effective communication strategies, efficient workflows, engaging providers and delivering genomic results to participants. This knowledge will enable the Program to continuously improve how to implement and scale AdventHealth's population genomics programs.

# Heart, Lung and Vascular Institute

## Vision

AdventHealth Heart, Lung and Vascular Institute is dedicated to transforming health care through groundbreaking, innovative, globally recognized whole-person research. Our teams and processes at AdventHealth Research Institute provide streamlined, detailed workflows to ensure we bring such research to our community.

## Overview

The Heart, Lung and Vascular Institute 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. With a world-renowned team of scientists and physicians, the team's researchers 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 preventative 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. They create a seamless research experience through our broad network of heart specialists and hospitals to simplify the "bench-to-bedside" process and ensure our patients receive the most effective care available.

This section of the 2021 AHRI Annual Report highlights how the COVID-19 pandemic placed physicians at the forefront of leadership and ingenuity. They rose to meet the challenge of defining a new normalcy in an unprecedented era of health care. The Institute also boasted a successful double lung transplant as a direct result of clinical trial participation. Finally, a clinical trial surrounding a device designed to combat cardiovascular disease, improving blood pressure, heart rate and quality of health is spotlighted for its impactful potential.

## Areas of Focus

- Cardiovascular Surgery
- Coronary Artery Disease
- Heart Failure
- Heart Rhythm Disorder
- Heart Valve Disease Treatment
- Interventional Cardiology
- Pulmonary Hypertension
- Vascular Disease Care

## AdventHealth Redmond

Julie Barnes MD, FACP

Cardiovascular research has expanded to **AdventHealth Redmond in Rome, GA,** adding this southeast region to AdventHealth's growing portfolio of clinical research. Guided by leaders like **Julie Barnes MD, FACP, Vice President and Chief Medical Officer of the Redmond campus,** this strong team of physicians enables patients in northwest Georgia to access relevant innovations in cardiovascular disease treatments.

"As a tertiary hospital, AdventHealth Redmond has a significant impact on the community," said Dr. Barnes, "including access to innovative trials, to which we can proudly contribute through the Cardiovascular Research Department. The research efforts extend into our Graduate Medical Education team and we look forward to AHRI's continued support for our resident education."

Kathy Jones, CRC II

**"Encouraging a research-positive culture is important to give patients wider access to clinical research and improve patient outcomes, quality of care and cost-effectiveness. The new and fresh approach AdventHealth brings to the table will strengthen understanding and prepare AdventHealth Redmond for the future. Through clinical research, we can be better positioned to test and adopt leading-edge products and practices that meet the unique health care needs of the patients in the communities we serve."**

**—Kathy Jones, Clinical Research Coordinator II (Non-RN)**

## 2021 Featured Researchers and Research

### 2020 THROMBOLEX Trial leads to Phase II RESCUE Trial in 2021

Rohit Bhatheja, MD, MBA, FACC, FSCAI

Massive pulmonary embolism (PE) is associated with significant morbidity and mortality. Treatment for massive PE can include systemic thrombolysis and catheter-directed therapy. **Dr. Rohit Bhatheja** and his specialized team of cardiologists moved forward with the phase II RESCUE Trial in 2021 based on the successful outcomes of the completed THROMBOLEX first-in-human phase I trial, initiated in 2020 at AdventHealth Orlando. This previous phase was designed to assess the safety and feasibility of Bashir Endovascular Catheter (BEC) for treating acute intermediate-risk pulmonary embolism.

The (BEC) is a novel pharmaco-mechanical device designed to enhance thrombolysis by increasing the exposure of thrombus to endogenous and exogenous thrombolytics. Patients with symptomatic PE and a right-ventricular-to-left-ventricular diameter ratio ≥0.9, as documented by computer tomography angiography, were eligible for enrollment. The primary safety endpoints were device-related death or adverse events and major bleeding within 72 hours after BEC-directed therapy.

Nine patients were enrolled across four US sites. The total dose of r-tPA (recombinant tissue-type plasminogen activator) was 14 mgs in bilateral PE and 12 mgs in unilateral PE over eight hours delivered via the expanded BEC. At the 30-day follow-up, there were no deaths or device-related adverse events. At 48 hours post-BEC therapy, the right ventricular to left ventricular diameter ratio decreased from 1.52±0.26 to 0.97±0.06 (P=0.0009 [95% CI, 0.33-0.82]; 37.0% reduction). The Modified Miller Index measured Thrombus burden decreased from 25.4±5.3 to 16.0±4.0 (P=0.0005; [95% CI, 5.5-13.4]; 37.1% reduction).

In this early feasibility study of the BEC for intermediate-risk PE, the investigators concluded there were no deaths or device-related adverse events along with a significant reduction in the right ventricular to left ventricular diameter ratio and thrombus burden.
Registration ID: NCT03927508.

## ECLIPSE Research Trial Enrolls First Cardiovascular Patient at AdventHealth Celebration

Deanna Allen, RN, Rohit Batheja, MD, Chantie Garvey, RN

Usman Siddiqui, MD

In February 2021, **Rohit Bhatheja, MD, MBA, FACC, FSCAI,** enrolled the first patient at the AdventHealth Celebration campus in the ECLIPSE research trial. This study is offered to patients with extensive calcification in their coronary arteries. The trial's purpose is to evaluate Orbital Atherectomy compared to the conventional balloon angioplasty technique for treating severely calcified lesions before implanting drug-eluting stents (DES).

**Usman Siddiqui, MD,** enrolled the first electrophysiology case in April 2021 in the Discover-US research registry. AdventHealth Celebration is the first Florida hospital to provide an innovative AcQMap High-Resolution Imaging and Mapping System. It uses ultrasound to reconstruct the heart chamber and then overlays high-resolution charge density maps of electrical activation on the heart surface. This technology is only available at the Celebration campus.

# 2021 Featured Research Collaborations

**Naushad Shaik, MD, FACC, FHRS, CCDS** (Electrophysiology), and **George Palmer, MD** (CV Surgery), collaborated to bring the (EVICD) Extravascular Implantable Cardioverter Defibrillator Pivotal Study to AdventHealth Celebration. The CV research team worked together to implant a complete single-chamber extravascular (EV) ICD system. This trial aims to demonstrate the safety and efficacy of the EVICD system with the lead implanted substernal.

Naushad Shaik, MD, FACC, FHRS, CCDS

George Palmer, MD

## Cardiovascular and Translation Research Collaborate on Hepatic Artery Sympathetic Denervation

Richard Pratley, MD

Rohit Bhatheja, MD, MBA, FACC, FSCAI

**Richard Pratley, MD,** and **Rohit Bhatheja, MD, MBA, FACC, FSCAI,** are collaborating on a PHASE I diabetic research trial to bring the most leading-edge technology to our patients.

Diabetes mellitus is a common disorder that affects a large percentage of our population nationwide and can have long-term effects on our organs and quality of life. Despite oral and injectable treatments, some patients continue having abnormal glucose ranges and suffer long-term impacts. Since the liver plays a role in maintaining glucose, this new intervention inhibits sympathetic signaling to the liver as a new potential therapeutic approach. The Hepatic Artery Sympathetic Denervation procedure was created to address these unmet clinical needs. Dr. Pratley's team screened and monitored the patients after Dr. Bhatheja and his team performed the procedure.

## The Advanced Lung Disease Program

James Tarver, MD

The Advanced Lung Disease Research Program (ALD) focuses on delivering the highest quality, leading-edge care for patients with pulmonary and pulmonary vascular diseases, such as Pulmonary Hypertension, Chronic Pulmonary Thrombo-embolic disease and Interstitial Lung Disease. The ALD program explores and delivers treatment options for patients with disease processes previously excluded from clinical trials or without current treatment options, new therapeutic pathways and quality of life and treatment tolerance due to advanced lung disease.

The ALD program recently participated in a study leading directly to the FDA's approval of a new drug, Tyvaso (treprostinil) Inhalation Solution (manufactured by United Therapeutics), for people with Group 3 pulmonary

hypertension caused by chronic lung disease or low oxygen levels. **James Tarver, MD,** served as the principal investigator at AdventHealth for the INCREASE trial and was a top enroller for the study.

Catherine Falardeau, who participated in the Tyvaso trial, said treatment has "significantly improved her ability to breathe and exercise and her quality of life." Before the trial, she could not walk to her mailbox. Now she walks her dogs nightly, changed her diet and lost 20 pounds.

"It meant so much to be part of a successful study," she says, "topped only by the feeling of hope. I feel so much better."

Interstitial lung disease causes shortness of breath with activity, labored breathing, fatigue, poor exercise tolerance and increased mortality, resulting in a poor quality of life. This affects approximately 30,000 people in the U.S. This new FDA-approved inhaled treatment is exciting news for patients and the physicians who manage their care.

Melisa Wilson, ARNP, DNP

**Melisa Wilson, ARNP, DNP, ALD's Operations Director and Clinical Coordinator,** has more than 15 years of experience managing Pulmonary Hypertension. She has published multiple articles on the role of risk assessment and the importance of palliative care in pulmonary hypertension clinical care. In addition, Wilson has been the principal investigator of many clinical trials and is currently the PI of three actively enrolling studies evaluating the role of the novel agent Sotatercept in treating patients with pulmonary hypertension. She completed her DNP degree at Duke University and has served as a mentor for other Advanced Practice Practitioners interested in participating in clinical research.

Stacey Mandras, MD

**Stacey Mandras, MD, Medical Director of the Pulmonary Hypertension/CTEPH Program,** joined AdventHealth from Ochsner Medical Center in 2020, serving as the Director of their Pulmonary Hypertension Program and the Advanced Heart Failure Fellowship Program. Dr. Mandras has over 10 years of experience managing pulmonary hypertension and has published multiple articles in the field. She also serves as Assistant Program Director for the Cardiology Fellowship Program at AdventHealth and actively mentors cardiology, pulmonary, critical care and internal medicine trainees in clinical research. She is currently the principal investigator of several clinical studies at AdventHealth.

## Featured 2021 Publications

- Gold MR, Lambiase PD, El-Chami MF, Knops RE, Aasbo JD, Bongiorni MG, Russo AM, Deharo JC, Burke MC, Dinerman J, Barr CS, **Shaik N,** Carter N, Stoltz T, Stein KM, Brisben AJ, Boersma LVA. Primary Results From the Understanding Outcomes With the S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) Trial. *CIRCULATION*. doi: 10.1161/CIRCULATIONAHA.120.048728
- Natale A, Calkins H, Osorio J, **Pollak SJ,** Melby D, Marchlinski FE, Athill CA, Delaughter C, Patel AM, Gentlesk PJ, DeVille B, Macle L, Ellenbogen KA, Dukkipati SR, Reddy VY, Mansour M. Positive Clinical Benefit on Patient Care, Quality of Life, and Symptoms After Contact Force-Guided Radiofrequency Ablation in Persistent Atrial Fibrillation Analyses From the PRECEPT Prospective Multicenter Study. *Circ Arrhythm Electrophysiol.* doi: 10.1161/CIRCEP.120.008867
- Sista AK, **Bhatheja R,** Rali P, Natarajan K, Green P, Piazza G, Comerota AJ, Parikh SA, Lakhter V, Bashir R, Rosenfield K. First-in-Human Study to Assess the Safety and Feasibility of the Bashir Endovascular Catheter for the Treatment of Acute Intermediate-Risk Pulmonary Embolism. *Circ Cardiovasc Interv.* doi: 10.1161/CIRCINTERVENTIONS.120.009611
- Moro RJ, **Accola KD.** Commentary: Identifying patients who do not improve following surgical ventricular reduction: Is diastolic dysfunction the culprit? *J Thorac Cardiovasc Surg.* doi: 10.1016/j.jtcvs.2019.10.003
- Lo MY, Sanders P, Sommer P, Kalman JM, **Siddiqui UR,** Sundaram S, Piorkowski C, Olson N, Madej SM, Gibson, DN. Safety and Effectiveness of a Next-Generation Contact Force Catheter Results of the TactiSense Trial. *JACC Clin Electrophysiol.* doi: 10.1016/j.jacep.2021.01.019

# A Foundation Story: **Helping Advance Cardiovascular Research**

After moving to the United States in 2014, Dr. Ann, a single mom, and her children got the flu. Her kids recovered, but she began suffering from intermittent fainting. A year and a half later, she sought help from AdventHealth specialists because she was continuing to have health complications. Her heart care team discovered she had viral heart failure directly connected to the flu she contracted over a year ago. Unfortunately, due to her weakened heart, she continued to experience severe tachycardia, fainting, and other symptoms for several years. In June 2018, she fainted on her way to the airport with a colleague, was taken to the ER and admitted to AdventHealth Orlando under the care of Chandra Bomma, MD. Using a loop recorder, Dr. Bomma and his team discovered that her heart kept stopping because her sinus node was damaged when she had the flu. They installed a pacemaker to help Dr. Ann overcome her fainting and return to normal.

Her health story does not end there, however. During a regular early morning workout in 2019, Dr. Ann was attacked and bitten by a rabid otter. The rabies treatment moved her pacemaker, requiring additional treatment at AdventHealth Altamonte to ensure her heart remained functional.

After enduring so much, Dr. Ann is incredibly grateful to the AdventHealth teams for their persistence and expertise in restoring her health.

“My situation was a complete anomaly, and yet, Dr. Bomma, Simon Shakar, MD, and the entire care team at AdventHealth went above and beyond to heal me,” Dr. Ann said, “I wouldn’t be here without them.”

Dr. Ann has since moved to Germany and experienced more heart complications—prompting Dr. Bomma and Dr. Shakar to stay in communication with her. In appreciation, she recently made a $100,000 gift that supported the WHOLE ME research project directed by Kapil Kapoor, MD, PhD, FAHA because of her passion for genetics research.

“Research allows us to find new ways to treat people and opens your mind,” said Dr. Ann. “You don’t know if you’ll succeed, but you must try. The partnership, discussions and discoveries are worth so much to enable us to be more proactive. Identifying key indicators or predispositions will help us remain healthy in the long term and can save lives.”

# **Neuroscience** Institute

## Vision

The AdventHealth Neuroscience Institute seeks to be a preeminent destination for brain and spine health while advancing knowledge through research and innovation.

## Overview

The AdventHealth Neuroscience Institute (NSI) aspires to build a world-class neurology and neurosurgery network recognized among the top 1% of programs in the country and to be known as a neuroscience research destination by 2030. Our goal is 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

- ALS
- Alzheimer's
- CMT
- Epilepsy
- MSA
- Neurosurgery
- Parkinson's
- SMA
- Stroke

# 2021 Featured Researchers and Research

## AdventHealth Epilepsy Center Reports Experience on Laser Interstitial Thermal Therapy (LITT) for MRI-Negative Insular and Cingulate Epilepsy

*(Study published in the Journal of Neurosurgery)*

Elakkat Dharmaraj Gireesh, MD

Epilepsy is a neurological disorder in which brain activity becomes abnormal, causing periods of unusual behavior, sensations, loss of awareness and sometimes convulsions. Epilepsy's long-term effects include injuries, increased intensity and frequency of seizures over time and memory problems. Around 3.4 million people worldwide have epilepsy, including 1% of the US population—and about 30-35% of these patients have drug-resistant epilepsy (DRE). Epilepsy surgery is an option for some patients whose seizure focus is established through presurgical evaluations. Patients with DRE can be treated with surgical strategies designed to remove the seizure onset zone or disrupt the epileptic network, such as resecting or disconnecting seizure onset zones, neurostimulation or laser interstitial thermal therapy (LITT)—a minimally invasive surgical option.

**Elakkat Dharmaraj Gireesh, MD,** and his Neuroscience Institute team have used the LITT procedure for selected patients since 2014. In the patients included in the study, Stereo Electroencephalography (sEEG) electrodes were implanted with robotic guidance and monitored in the neurological intensive care unit to capture typical seizures. Conventional surgical strategies for insula or cingulate brain regions are challenging due to their location near critical structures, but LITT proved advantageous for optimal interventions in these brain regions, minimizing risks compared to an open surgery approach. In this study involving patients suspected of having insula and cingulate onset epilepsy who underwent intracranial monitoring and LITT of the insula and cingulum, **67% achieved complete seizure freedom, and all patients had a favorable response with worthwhile improvement in seizures.** Furthermore, this group of patients had no permanent neurological or neuropsychological deficits. This experience suggests that sEEG followed by LITT is a reasonable treatment option for drug-resistant epilepsy originating from these difficult-to-access regions of the cerebral cortex, particularly for patients with non-lesional epilepsy.

## Severe Back Pain and Burning Pain All Over Can Be Seen in Atypical Presentations of Hereditary Neuropathy With Liability to Pressure Palsy

*(Poster abstract published in the Journal of the Peripheral Nervous System)*

Nivedita Jerath, MD, MS

Hereditary neuropathy with liability to pressure palsy (HNPP) is an autosomal dominant genetic disorder characterized by multiple episodes of focal weakness and sensory loss caused by compression or trauma. It commonly involves a deletion of chromosome 17p11.2 of the peripheral myelin protein 22 (PMP22). Given its variable presentation, it is possible that HNPP can be under-recognized. **Nivedita Jareth, MD, MS, Division Director for AdventHealth's Neuromuscular Program,** recently reported two cases of unrelated individuals with HNPP who were evaluated with clinical, laboratory, electrophysiological and genetic testing. Although HNPP is typically present with transient compressive mononeuropathies, this study suggested that HNPP can be present with various broad clinical symptoms, including severe back pain and painful burning sensations. The 2021 *Journal of the Peripheral Nervous System* published Dr. Jerath's report.

A second study, "Atypical Periodic Paralysis," published in Neurology, used clinical, electrophysiological and genetic testing to evaluate participants with a suspected periodic paralysis diagnosis. Periodic paralyses are a rare genetically heterogenous group of muscle channelopathies resulting from abnormal ion channel function. Dr. Jerath found that participants with pathogenic CLCN1 and SCN4A mutations were found to present with atypical periodic paralysis features, including normokalemic paralysis episodes, isolated hand cramps, digestive pain, paralysis episodes lasting for months, burning pain involving the arms, paralysis after headaches, chest pain, throat pain and prolonged excruciating pain lasting for weeks requiring multiple emergency room visits. Some of these atypical presentations resulted in a lack of diagnosis for years. Dr. Jerath determined that our understanding of this rare disorder is evolving, thus warranting more clinical research and new diagnostic criteria to improve the diagnosis and treatment of these conditions.

A board-certified Neurology and Neuromuscular Medicine specialist, Dr. Jareth is a Harvard graduate who received her medical degree at the Mayo Clinic College of Medicine. She completed consecutive neurophysiology and neuromuscular disease fellowships and a master's in translational biomedicine at the University of Iowa. Before joining AdventHealth as the Neuromuscular Program Director, she served as Director of the Charcot Marie Tooth Association Center of Excellence and as a clinical assistant professor at the University of Florida.

### Progress in Parkinson's Disease Therapy: The First Report on Efficient Clinical Workflow Using the Recent FDA-approved DBS Remote Programming Platform.

Access and optimization of DBS therapy for Parkinson's disease and essential tremor patients has been an ongoing challenge for patients, caregivers and clinicians—which was further aggravated during the COVID-19 pandemic. The FDA's recent first approval of true remote programming in DBS, the Abbott NeuroSphere™ Virtual Clinic platform, allowed researchers to move forward with a life-changing study for Parkinson's patients.

Anwar Ahmed, MD

Raul Rodas, DO

Chandan Reddy, MD, FAANS

**Anwar Ahmed, MD, Raul Rodas, DO,** and **Chandan Reddy, MD, FAANS,** collaborated with Abbot Neuromodulation in Austin, TX to hypothesize that using remote programming in the first three months of initial DBS programming, in addition to the usual in-person appointments, would optimize therapy more quickly and efficiently. They presented the first data on an efficient clinical workflow and utilization of this platform with full and hybrid (mixed) systems in the article, "Towards Improving Access and Therapy Optimization Using Remote Programming in Movement Disorders Patients with Deep Brain Stimulation (DBS)," published in the Annals of Neurology 2021.

Methods: After appropriate consenting, the patient's DBS controller device (iPod Touch or iPhone) was upgraded with the new app, and the patient's IPG was mapped to an authorized Clinician. The patient was required to initiate the remote programming with multi-factor authentication by the Clinician. The platform synchronized stimulation changes with integrated video allowing real-time assessments. A protected recovery mechanism ensured failsafe continuity of therapy in case of network failure.

Results: In just a few weeks after the technology became available, the team upgraded 17 patients and conducted over 50 remote sessions producing multiple patient testimonials reflecting improved access and perceived quality of care. They found the most efficient clinical workflow for the software upgrade on patient controllers is during IPG implantation, whether during de novo placement (S2) or replacement (S3). During S2, six patients were set up. During S3, one patient was set up. The remaining IO patients were set up in-clinic during their initial or follow-up programming sessions with training provided to all. Remote programming was also set up with patients in hybrid systems (non-Abbott DBS leads with Abbott IPGs). This may be an important clinical consideration for patients likely to benefit more from remote programming than diagnostic MRI or those with impedance issues precluding them from an MRI.

## 2021 New Investigators

Valeria C. Baldivieso Hurtado, MD

Board-certified geriatrician **Valeria C. Baldivieso Hurtado, MD, Medical Director for Memory Care at the AdventHealth Neuroscience Institute in Winter Park,** focuses on senior memory care, well-being, dementias, major depressive disorders and anxiety. In 2021, Dr. Baldivieso Hurtado contributed to the development of the international, landmark study, Davos Alzheimer's Collaborative (DAC). She completed her geriatric medicine fellowship at Jackson Memorial Hospital in Miami and a family medicine residency at Mayaguez Medical Center in Puerto Rico.

## Featured 2021 Publications

- **Gireesh ED, Lee KH, Skinner H, Seo J, Chen PC, Westerveld M, Beegle RD, Castillo E, Baumgartner J.** Intracranial EEG and laser interstitial thermal therapy in MRI-negative insular and/or cingulate epilepsy: case series. *J Neurosurg.* doi: 10.3171/2020.7.JNS201912
- Koh S, Wirrell E, Vezzani A, Nabbout R, Muscal E, Kaliakatsos M, Wickstrom R, Riviello JJ, Brunklaus A, Payne E, Valentin A, Wells E, Carpenter JL, **Lee K,** et.al. Proposal to optimize evaluation and treatment of Febrile infection-related epilepsy syndrome (FIRES): A Report from FIRES workshop. *Epilepsia Open.* doi: 10.1002/epi4.12447
- **Patel S, Parikh A, Okorie ON.** Subarachnoid hemorrhage in the emergency department - Critical Care. Int J Emerg Med. doi: 10.1186/s12245-021-00353-w

# **Nursing, Whole-Person and Academic** Research

## Vision

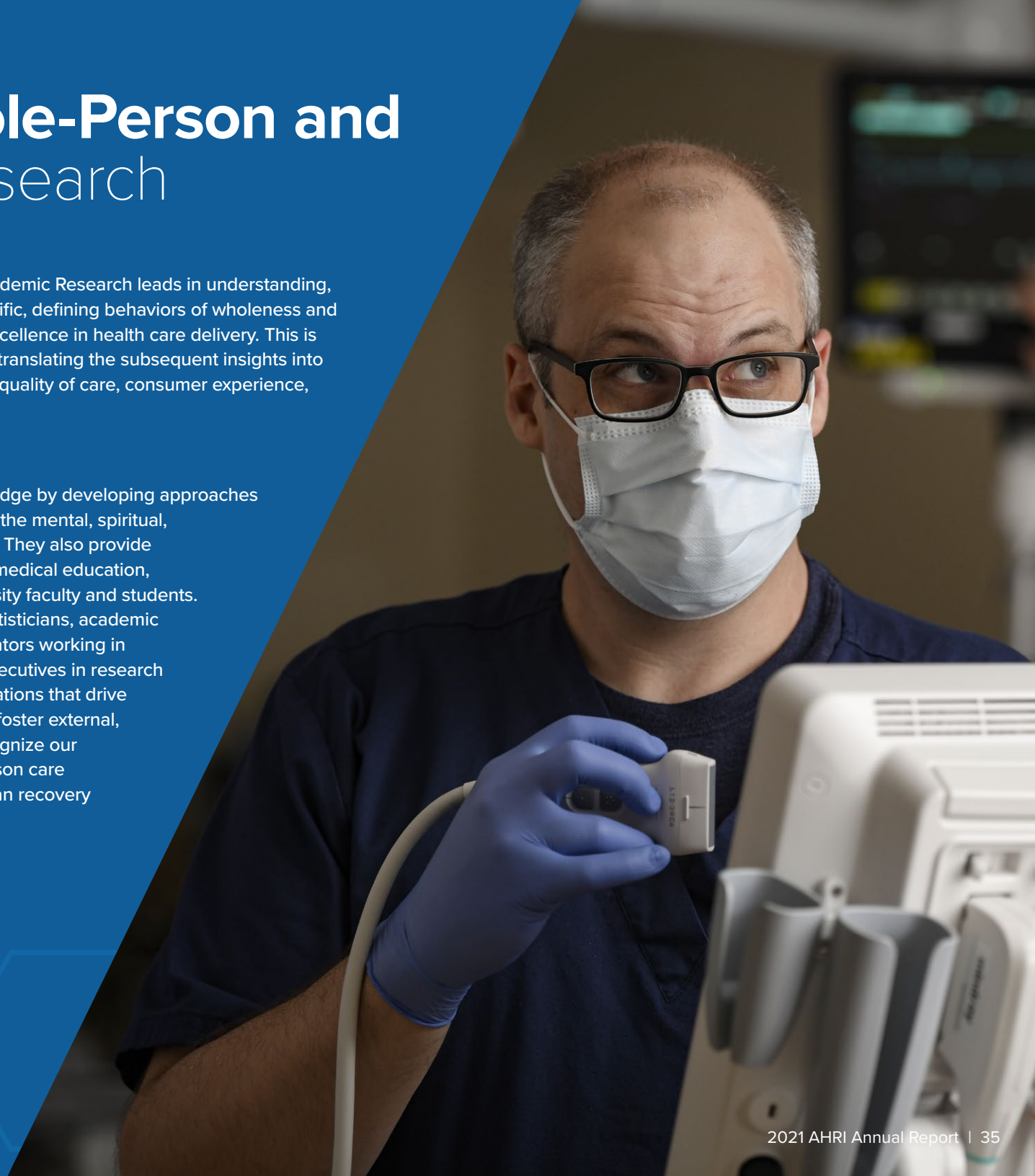
AdventHealth Nursing, Whole-Person and Academic Research leads in understanding, describing, delivering and measuring the specific, defining behaviors of wholeness and whole-person care as essential elements of excellence in health care delivery. This is set in motion through academic research and translating the subsequent insights into operations and clinical delivery that increases quality of care, consumer experience, health outcomes and population health.

## Overview

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. They also provide structured programming to support graduate medical education, nursing residencies and AdventHealth University faculty and students. The staff comprises research scientists, biostatisticians, academic advisors, research and administrative coordinators working in harmony to mentor junior investigators and executives in research methodologies and actionable program evaluations that drive change. In addition, they aim to establish and foster external, high-impact academic collaborations that recognize our health care system as the leader in whole-person care while creating high-quality evidence on clinician recovery and well-being.

## Areas of Focus

- Wellness of Body, Mind, Spirit and Social
- Transformative Whole-Person Health Care Delivery
- Scientific Foundation for Wholeness



# 2021 Featured Researchers and Research

## Hospital Chaplain Self-Care Workshops

Stephanie Harris, MLS

Self-Care in Pastoral Care: Impact of a Well-Being Workshop Series for Chaplains (IRBNet 1726819)

Principal Investigator: **Stephanie Harris, MLS**

Mentors: **Jeanette F. Green, PhD, APRN; Amanda Sawyer, PhD; Hong Tao, PhD, RN**

In response to chaplains' requests for psychological support during the pandemic, this mixed-methods pilot study is examining the acceptability and feasibility of a well-being workshop series focused on setting healthy boundaries, compassion fatigue, processing grief, post-traumatic growth, enhancing resilience, addressing secondary trauma and increasing self-compassion for chaplains. This study also examines any impacts of the workshop series on our chaplains' mental well-being.

## Effects of RISE© Participation on RN Retention During Pandemic

Amanda Sawyer, PhD

Employment Status During the COVID-19 Pandemic Among Registered Nurses who Attended the RISE© Program with Case Controlled Analyses (IRBNet 1762340)

Principal Investigator: **Amanda Sawyer, PhD**

This matched case-control study examined the long-term employment status of direct care nurses during the COVID-19 pandemic, comparing those who participated in the 2019 RCT of the psychoeducational group intervention to a matching group of nurses who had not attended. The results showed a lower turnover rate during the COVID-19 pandemic among direct care nurses who participated in the intervention (14.9%) compared to the matched controls who did not participate (34.8%). This resulted in a direct savings of $549,000 in RN turnover costs—an unanticipated benefit of the intervention.

## RISE© for Nurse Managers Pilot

A Pilot Study of RISE© for Nurse Managers (IRBNet 1504917, NCT04987697)

Principal Investigator: **Amanda Sawyer, PhD**

This pilot study aimed to determine the acceptability and feasibility of the RISE © Program for nurse managers and examine any program impacts on their post-traumatic growth, resilience, insight, self-compassion, empowerment or mental well-being—personally or professionally. Pilot study results showed higher post-traumatic growth and psychological empowerment after the intervention compared with baseline scores. Six themes emerged most consistently from the qualitative interviews: feasibility of RISE©, benefits of peer support, sources of stress, barriers to self-care, sources of strength and sustainability of effects. A randomized controlled trial with 80 nurse and assistant nurse managers is underway in Florida.

## Translational Research

Amanda Bailey, LMHC

RISE© for direct care nurses was operationalized in 2021. **Amanda Bailey, LMHC,** the program creator and original facilitator, conducted a manualized three-day facilitator training with ten employee-facing, licensed Central Florida mental health professionals to roll out the RISE© intervention to direct care nurses. She maintains intervention fidelity by clinically supervising RISE© deployment in the workforce. Therapists in multi-state markets will be trained in 2022.

## Interdepartmental and interinstitutional collaborations:

## Fanchao Yi, PhD, and the Translational Research Institute (TRI)

Fanchao Yi, PhD

Biostatistician **Fanchao Yi, PhD,** joined the Translational Research Institute in 2012 after receiving two master's degrees in Agronomy from the University of Florida, and Statistics from the University of Central Florida (UCF). Yi is the main statistical consultant on obesity, diabetes, exercise, aging and translational research projects. His research applies statistical methods in clinical trials and translational research, particularly in experimental design, sample size calculation,

multivariate data analysis, missing data estimation, longitudinal data analysis and "omics" data analysis. He works with investigators at AdventHealth Research Institute throughout the scientific research process, including statistical analysis plan development, experiment design, sample size estimation, randomization process, data auditing, data analysis and publication. In 2021, Yi was listed as a co-author in six peer-reviewed publications.

### Patricia Robinson, PhD, APRN and the University of South Florida (USF)

Patricia Robinson, PhD, APRN

**Patricia Robinson, PhD, APRN,** is the site principal investigator for the Examination of the Evidence-Based Care Transitions Intervention Study in partnership with Kyaien Conner, PhD, LFW, MPH, USF Associate Professor of Mental Health Law and Policy. The study will be conducted at AdventHealth Kissimmee, one of three study sites. AdventHealth is responsible for recruiting African American and Latino/Hispanic adults (60 years and older) living with a chronic illness who are being discharged home. This study aims to evaluate the Care Transitions Intervention (CTI) model with the addition of peer support, compared to usual care, to reduce racial disparities and negative outcomes post-hospitalization.

### Monica Davila, MD, PhD and AdventHealth University (AHU)

Monica Davila, MD, PhD

**Monica Davila, MD, PhD,** is the Lead Academic Mentor and mentor supervisor at the Center for Academic Excellence. Dr. Davila earned her medical degree from the Universidad Central de Venezuela before completing her Ph.D. in molecular biology. After two years of post-doctoral training at the University of Central Florida, Monica joined the AdventHealth Center for Thrombosis Research in 2005, where she conducted basic and translational research studies resulting in several peer-reviewed publications and conference presentations. She has also been a peer reviewer for several hemostasis and thrombosis journals. Dr. Davila transitioned to the Center for Academic Excellence in 2018 and is now the primary contact for all academic researchers, AdventHealth University (AHU) faculty and students. Her team has supported 43 student and faculty projects, ranging from lab science to community-based research projects, over the past several years. Dr. Davila supports AHU collaborations as a guest speaker for faculty development sessions and service on numerous steering committees. In addition, she has developed processes for integrating AHU research into the AdventHealth corporate research structure.

## 2021 Featured Publications

- **Bailey A, Sawyer AT, Robinson PS.** A psychoeducational group intervention for nurses: Rationale, theoretical framework, and methods. *J Am Psychiatric Nurses Assoc.* 2021; 10783903211001116. doi: 10.1177/10783903211001116.
- **Harris SL, Green JG, Tao H, Robinson PS.** Examining associations with mentaL well-beIng and faiTh in Nurses (LIFT). *JONA: J Nurs Admin.* 2021;51(2):106-11. doi: 10.1097/NNA.0000000000000978
- **Harris S, Tao H.** The impact of US nurses' personal religious and spiritual beliefs on their mental well-being and burnout: A path analysis. *J Relig Health;* 2021. doi:10.1007/s10943-021-01203-y
- **McManus K; Robinson P.** Evaluation of NICU health care providers' experience of Patient Ethics and Communication Excellence (PEACE) rounds, *Adv Neonatal Care.* 2021;21(2):142-151. doi: 10.1097/ANC.0000000000000774.
- **Sawyer AT, Bailey A, Green J, Sun J, Robinson PS.** Resilience, Insight, Self-compassion, and Empowerment (RISE): A randomized controlled trial of a psychoeducational group program for nurses. *J Am Psychiatr Nurses Assoc.* 2021;10783903211033338. doi: 10.1177/10783903211033338

# **Orthopedic** Institute

## Vision

The AdventHealth Orthopedic Institute provides communities with high-quality, integrated orthopedic care by leveraging the academic pillars of Research, Education and Innovation, to become a national leader in patient care and outcomes.

## Overview

The AdventHealth Orthopedic Institute (AHOI) academic program strategically invests in investigator-initiated studies that advance innovation, quality and clinical excellence to improve patient outcomes. These efforts enhance our value and recognition among study sponsors, philanthropy and industry in an effort to guide a cohesive educational program and collaborations.

The Institute's partnership with the well-established Rothman Orthopaedics group has enabled us to build an Academic Ecosystem, expand physician and subspecialty recruitment, develop access to novel therapies and integrate our Research, Education and Innovation pillars into clinical orthopedic practice. AHOI is also implementing an academic strategic plan focusing on innovation, motion analysis and biomechanics, bioskills, surgical simulation labs, clinical outcomes research and a Center of Excellence in orthopedic care. Part of this vision is to build a team of the best and brightest physician-scientists, fellows and residents to bring real-time, transformative innovations, fueling a world-class, comprehensive musculoskeletal program that elevates brand value, contributes to high-quality whole-person care and improves collaboration with other systems and scientists.

## Areas of Focus

- Biomechanical Devices
- Investigational Drug Therapy
- Joint Replacement
- Musculoskeletal Function and Performance
- Osteoarthritis Treatment
- Sports Medicine
- Surgical Techniques

## Key AHOI Pillars Under Development

- **Motion Analysis/Biomechanics Lab**
  A collaboration with AdventHealth Rehabilitation and Physical Therapy, Neurology, Sports Medicine and Exercise Physiology to provide a platform for real-world comprehensive patient care
- **Orthopedic Innovation Lab**
  A modular and flexible state-of-the-art environment for all-in-one designing, fabricating, researching and testing of novel devices, equipment and implants
- **Orthopedic Bioskills Lab**
  A partnership with AdventHealth Nicholson Center that provides space and equipment for human and animal cadaveric and tissue-specific education, research and testing of novel surgical techniques and devices
- **Orthopedic Surgical Simulation**
  One of only a handful of laboratories in the nation to provide Augmented Reality, Virtual Reality and Physical Simulator space designed specifically for advancing health care innovation, research and education

## Clinical Outcomes Research

Research is critical and heavily integrated with education and innovation. Validation research drives continuous quality improvement through evidence-based medicine and best practice training, lowering organizational costs. In addition, AHOI uses a data-driven approach to design and test innovative products and techniques utilizing big data analytics through the Clinical Research Outcomes team. This integrated Academic ecosystem is institutionally unique and agile, supporting medical advancement from concept to therapeutic practice, resulting in excellent patient care.

A cornerstone of clinical outcomes research is investment into evidence-based analysis, allowing the development of best practices, quality improvement, increased access to care, decreased costs and enhanced training. Investigator-initiated clinical trials are supported by research staff and protected time for research. A robust clinical outcomes research database developed in conjunction with Rothman Orthopaedics also allows for key quality and patient outcomes data to be collected heavily in areas that will lead to patient care excellence and future recognition and accreditation opportunities as a Center of Excellence, both nationally and internationally.

## 2021 Featured Investigator

Daryl C. Osbahr, MD

**Daryl C. Osbahr, MD,** an internationally renowned Orthopaedic Sports Medicine Surgeon, is Chief of Orthopaedic Surgery and Managing Partner for Rothman Orthopaedics Florida, Chair and Executive Medical Director of the AdventHealth Orthopedic Institute, and the Orthopedic Residency Director for AdventHealth. Dr. Osbahr is also the Co-Chief Medical Officer for USA Baseball, a Team Physician for the US Soccer Men's National Team, and the former Medical Director and Head Orthopedic Team Physician of the Orlando City Soccer Club, among other state and local professional, collegiate and youth sports programs.

Dr. Osbahr is actively involved in surgical, clinical and basic science research, inspired by his earliest career experience as a clinical research coordinator at Duke University Medical Center, where he developed a strong understanding of the underpinnings of clinical research. Today, he is recognized as an award-winning international leader in orthopedic sports medicine with grants recognizing his high-level research activities, including the AOSSM O'Donoghue Sports Injury Research Award, AOSSM Fellows Research Award, Major League Baseball Grant, Major League Soccer Grant and American Shoulder and Elbow Surgeons Research Grant.

Dr. Osbahr has authored 70 articles and chapters and is an expert speaker at international, national, regional and local orthopedic-related meetings. He has led research initiatives for the Shoulder Research Committee for Major League Baseball, the Research Committee for Major League Soccer and educational initiatives to prevent youth and adult sports injuries. He advocates locally for youth athlete safety and prevention through his role as former President and current Board of Directors for the Florida Alliance for Sports Medicine, Committee Member of the Florida High School Athletic Association Sports Medicine Advisory Committee and the Medical & Safety Committee Member and Advisory Board Member of the Sunshine State Athletic Conference.

## 2021 New Investigators

Harrison Youmans, MD

**Harrison Youmans, MD,** is a board-certified, non-surgical orthopedics and sports medicine specialist at Rothman Orthopaedics. Dr. Youmans uses non-surgical treatments, such as medications, physical therapy, activity modifications and immobilization to treat sports-related injuries and other orthopedic conditions, such as osteoarthritis. He uses musculoskeletal ultrasound to diagnose orthopedic conditions and aid in properly placing medication during injection therapies, such as corticosteroid, viscosupplementation and regenerative therapies, including platelet-rich plasma (PRP) and biologic therapies.

Ibrahim M. Zeini, PhD, PMP, SA, CCRP

**Ibrahim M. Zeini, PhD, PMP, SA, CCRP,** is a research scientist with the Orthopedic Institute. He leads the development of the Orthopedic Institute's Academic Ecosystem in partnership with Rothman Orthopaedics. This program offers a unique opportunity to integrate AdventHealth stakeholders in clinical practice and Academics (Research, Education and Innovation).

Dr. Zeini is an expert in program development, strategic planning, management, consulting, evaluation, governance and analytics. He has authored 19 peer-reviewed articles and chapters, with presentations at national, regional and local meetings. Dr. Zeini also holds titles as Adjunct Professor, Lecturer and Graduate Faculty Scholar in the Graduate Health Systems Engineering Program and Department of Industrial Engineering and Management Systems at the University of Central Florida.

In addition, Dr. Zeini currently serves as a Board Member on the Mechanical Engineering Industry Advisory Board at Embry-Riddle Aeronautical University. He earned a PhD in Health Services Management and Research and a Master of Science in Health Services Administration from the University of Central Florida. He is certified in Project Management, SAFe® 5 Agilist and Clinical Research.

## Featured 2021 Publications

- Mason EM, Pumilia CA, Richey B, Garrett C, **Zeini IM,** Service BC, **Osbahr DC.** Low-Cost, Lo Fidelity, Self-Made Arthroscopic Surgical Simulators: A Systematic Review. *Int J Ortho Res.* doi: doi.org/10.33140/IJOR.04.03.10
- Wynn A G, Collins A P, Nguyen E, Sales E, **Youmans H, Osbahr D C, Zeini I M,** Henne M. Interval Kicking Program for the Punting and Place-Kicking Athlete: A Systematic Literature Review and Need Analysis. *Cureus.* doi: 10.7759/cureus.19725
- Collins A P, Service BC, Gupta S, Mubarak N, **Zeini I M, Osbahr D C,** Romeo A A. N95 respirator and surgical mask effectiveness against viral respiratory illnesses in the health care setting: A systematic review and meta-analysis. *JACEP Open.* doi: 10.1002/emp2.12582
- Sales E, Gupta S, Daines B, Baker A, Landgrabe M, **Zeini I M, Youmans D H, Osbahr D C.** Bicompartmental Bucket Handle Meniscal Tear with Chronic ACL Deficiency Causing a Rare Triple PCL and Triple Cruciate Sign: A Case Report. *JBJS Case Connector.* doi: 10.2106/JBJS.CC.20.00694

# Pharmacy **Investigational Drug Services (IDS)**

## Vision

Pharmacy Research 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.

## Overview

Pharmacy Research focuses on providing safe, efficient and fiscally appropriate medication management across AdventHealth by rigorously collecting data on medication use and patient outcomes. With their substantial post-graduate residency program of 32 first-year (PGY-1) and 24 second-year (PGY-2) trainees, the department focuses on research projects that analyze medication safety, pharmacoeconomic impact and efficacy comparisons of standard of care regimens—all to help advance clinical care nationwide.

The department supports the AdventHealth Research Institute by actively serving on various committees, including the COVID-19-specific Scientific Review Committee (SRC), the Institutional Review Board (IRB) and the external Institutional Biosafety Committees (IBC).

Investigational Drug Services (IDS), located at the Orlando and Celebration campuses, are fully equipped pharmacies with dedicated staff that are USP 797, USP 800 and Biosafety Laboratory (BSL-2 for work with recombinant or synthetic nucleic acid molecules) compliant. IDS is responsible for receiving, storing, sterile compounding, dispensing and accounting for investigational products.

## Areas of Focus

- Receipt and Storage
- Dispensing
- Accountability

## Department Highlight

Presenters at the meeting of the Society for Critical Care Medicine

In 2021, IDS managed investigational medications for approximately 200 active studies across all AdventHealth clinical research areas and opened a new investigational pharmacy with dedicated pharmacy staff in the Clinical Research Unit (CRU) on the AdventHealth Celebration campus. Additionally, the department contributed to 15 publications of medical literature—six relating to the COVID-19 pandemic. The Pharmacy team also shared 15 presentations on the national or local level, including two relating to COVID-19. The department was further strengthened in 2021 by 20 pharmacists earning board certification in recognized specialty areas, such as Oncology, Infectious Diseases, Critical Care, Pharmacotherapy, Sterile Compounding, Pediatrics, Ambulatory Care and Cardiology.

## 2021 Featured Investigators

Patricia Louzon, PharmD, RPH, BCCCP

**Patricia Louzon, PharmD, RPH, BCCCP, Clinical Manager, Critical Care and Emergency Department,** was chosen as one of 2021 University of Florida's "40 Gators Under 40" for her outstanding contributions to the field of Critical Care Medicine. Three of her 2021 publications include research on the impact of a pharmacist-led, intensive care unit and sleep improvement protocol on sleep duration and quality.

Another publication, in collaboration with medical intensivists, focuses on ICU outcomes and survival in patients with severe COVID-19 in the largest health care system in Central Florida. In addition, her presentations at the Society of Critical Care Medicine focus on pulmonary hypertension and the utility of urinary neutrophil gelatinase-associated lipocalin to dose vancomycin.

## Featured 2021 Publications

- Andrews J, **Louzon PR, Torres X, Pyles E,** Ali MH, Du Y, Devlin JW. Impact of a pharmacist-led intensive care unit sleep improvement protocol on sleep duration and quality. *Ann Pharmacother.* doi: 10.1177/1060028020973198
- **Ezeude GI, Glover KR, Nieves Santiago AA, Repella E, Tang E.** Roadblocks and successes in preparing COVID-19 vaccination clinics: Perspectives from pharmacy residents. *Am J Health Syst Pharm.* doi: 10.1093/ajhp/zxab347
- **Rainess RA,** et al. Evaluating the addition of a clinical pharmacist service to a midlevel provider-driven culture follow-up program in a community emergency department. *J Pharm Technol.* 2021 March. doi: 10.1177/87551225211000363
- **Oliveira E, Parikh A,** Lopez-Ruiz A et al (**Louzon P** #12). ICU outcomes and survival in patients with severe COVID-19 in the largest health care system in central Florida. *PLoS ONE* doi: 10.1371/journal.pone.0249038
- **Louzon PR, Heavner MS, Herod K, Wu TT, Devlin JW.** Sleep-promotion bundle development, implementation, and evaluation in critically Ill adults: Roles for pharmacists. *Ann Pharmacother.* doi: 10.1177/10600280211048494

# **Translational Research** Institute (TRI)

## Vision

With diligent respect to the mission and values, the AdventHealth Translational Research Institute develops and conducts world-class translational research addressing diabetes, obesity, the metabolic origins of cardiovascular disease and aging.

## 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. Basic scientists provide clinical researchers with tools and model systems to employ in human studies, and 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.

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 through National Institute of Health (NIH), Foundations, Biotech and Pharma-funded projects to enroll and execute scientifically rigorous and high-quality research studies. In 2021, TRI investigators engaged in **50 active clinical trials and published 63 articles in major journal publications.**

## Areas of Focus

- Aging and Muscle Wasting
- Cardiometabolic Disease
- Diabetes
  - Prediabetes
  - Type 1 Diabetes
  - Type 2 Diabetes
- Exercise and Bioenergetics
- Metabolism and Obesity
  - Adipose Tissue and the Gut Microbiome
  - Nutrition
  - Weight Loss

# 2021 Featured Researchers and Research

## MoTrPAC: Clinical Trial Strives to Identify the Molecular Benefits of Exercise

Bret Goodpaster, PhD

Despite decades of research establishing the benefits of exercise to our overall health, researchers still do not know precisely what happens deep within the body, at a molecular level, during and after exercise. It is well-documented that cardiovascular fitness is a predictor of health, but why? Muscle strength positively impacts function and mobility, but how? Why do some respond to certain types of exercise and other people do not? These questions led the TRI to partner with the National Institutes of Health's (NIH) Molecular Transducers of Physical Activity Consortium (MoTrPAC) six-year research study. The AdventHealth Translational Research Institute is one of 10 clinical sites across the country chosen to participate in this groundbreaking research alongside institutions like Duke University, University of California-Irvine, Ball State University and University of Texas Health Science Center. **Bret Goodpaster, PhD, TRI's Scientific Director,** is the site principal investigator.

Supported by a $240 million grant, the largest NIH investment of its type to date, MoTrPAC aims to discover and characterize "the molecular map" that underlies the effects of physical activity in humans. Dr. Goodpaster and his team hypothesize there are discoverable molecular transducers that communicate and coordinate the impact of exercise on specific cells, tissues and organs within the body. They believe that identifying and characterizing these specific molecular transducers will help us better understand how exercise improves health and prevents disease.

### SOMMA Examines Muscle, Mobility and Aging

Dr. Goodpaster is also leading the TRI research team in the Study of Muscle, Mobility and Aging (SOMMA), a longitudinal observational study of more than 875 older men and women at risk of mobility disability. The study seeks to understand the roles that skeletal muscle mass and key properties of muscle tissue contribute to mobility disability.

### The MoTrPAC Study Design

MoTrPAC is unprecedented in its sheer scale, numerous procedures and voluminous data collection. It involves 1,980 volunteers, including 150 at our site, participating in a mechanistic randomized controlled trial. AHRI researchers are collecting extensive data using participants' blood and tissue samples before and after each exercise session and performing height and weight measures, body composition and fitness testing, strength measurements, blood pressure and heart checks, rhythm evaluation using electrocardiograms and dietary pattern assessments.

The first segment of our research focuses on healthy individuals; the next phase could evaluate people with specific health conditions like Type 1 diabetes, Parkinson's and Alzheimer's to better understand how and why exercise benefits them. The data-collection phase of this trial is set to wrap up in the Summer of 2024. Once complete, all data will be sent to MoTrPAC's nine chemical analysis sites, where bioinformatics will be applied, including machine learning and artificial intelligence, to begin analyzing and identifying the specific molecular outcomes. This process can take up to three years to uncover exercise-specific biomarkers.

### The Future of Exercise as Medicine

The Future of Exercise as Medicine focuses on prevention and precision. MoTrPAC's knowledge base will underlie future studies of exercise's prevention, treatment role and the specific factors influencing response to exercise. Ultimately, this will facilitate a precision medicine approach to prescribe and individualize the type and amount of exercise to achieve the best possible health outcome.

### Exerkines Could Provide a Customized Approach

One of MoTrPAC's goals is discovering how exerkines, defined as signaling molecules released into the circulatory system in response to acute and/or chronic exercise, may be linked to exercise's benefits; specifically, how exerkines can improve health and disease. Exerkines are a new frontier in molecular medicine that could play a role in improving cardiovascular, metabolic, immune and neurological health. For example, they could be an important means by which exercise improves cardiovascular disease, type 2 diabetes, obesity and healthy aging.

As another example, it might be discovered that unique exerkines are produced with weight training and others are unique to aerobic training and could determine how each individual exercises. In addition, these exerkines could reveal unique targets for exercise programs, and even non-exercise therapies, to treat common diseases and other conditions.

## Type 1 Diabetes (T1D) is a growing worldwide epidemic

Five million people in the U.S. are expected to have T1D by 2050. According to the American Diabetes Association, an average of $16 billion is spent annually on associated health care costs and lost income. Although there is nothing anyone can do to prevent it, and there is no known cure, advancements are being made every day in research labs across the globe to stop the disease and help improve the lives of those living with it.

Incredible advancements are being made every day at AdventHealth, as the TRI research team delves into how and why diabetes occurs, how it affects major organs and its connection to other diseases. TRI investigators are focused on extending and improving the quality of life for people with Type 1 Diabetes. They hope to contribute to the cure through innovative new pathways and developments.

Richard Pratley, MD

**Richard Pratley, MD, Medical Director and Diabetes Program Lead at the TRI,** is the principal investigator for several clinical trials to achieve TRI's T1D goals, including a trial called AIDE: A Randomized Cross-over Trial Evaluating Automated Insulin Deliver Technologies on Hypoglycemia and Quality of Life in Elderly Adults with Type 1 Diabetes. The study aims to determine if features of an automated insulin delivery system (study system) can reduce low blood sugar (hypoglycemia) in older adults with Type 1 diabetes. Sponsored by the NIH, the study examines whether an insulin pump with different treatment modes can reduce the incidence of low blood sugar and increase the quality of life in people ages 65 and older who have had Type 1 diabetes for at least one year.

## Pat Wloch, an AIDE participant, traded in diabetes testing "pinpricks" for an automated insulin pump

AIDE trial participant Pat Wloch and her family

Diagnosed with T1D in 1968 at age 22, newly married Pat Wloch was told she had 10-15 years to live. Her dreams were shattered. She decided not to let this prognosis stop her by diligently managing her disease, first with 10 to 12 urine testing strips daily and later with a glucose monitor. As part of the AIDE trial, Pat now uses the Dexcom G6 device to see her glucose level without finger sticks. A slim, easily removable device is placed just under the skin, and an easily removable sensor on the outside of the skin continuously measures glucose levels sending data wirelessly to her smartphone.

## TRI Researcher has first-hand experience with T1D in children

Anna Casu, MD, von Weller Family Chair in Type 1 Diabetes Research, with Richard Pratley, MD, and Steven R. Smith, MD

Endocrinologist Anna Casu, MD grew up on the beautiful Italian island of Sardinia—the first place dedicated as a Blue Zone, meaning the people who live there have exceptional longevity according to a research study*. Unfortunately, the location also has one of the highest incidences of Type 1 diabetes. This provides Dr. Casu an interesting perspective—not only as someone who has dedicated her life to helping people with T1D, but also, as someone living with this disease since her diagnosis at age 6. At that time, the treatment involved injecting porcine and bovine insulin since human recombinant insulin did not exist. Her diagnosis was a driving force behind her medical school training and subsequent research in Italy and the U.S. to help others with T1D to live their best lives. She joined the TRI in 2018 as the first **von Weller Family Chair in Type 1 Diabetes Research,** an honor allowing her to focus her research on areas that will have the greatest impact.

One study aims to understand how islet cells interact with other cells in the pancreas.

"Type 1 diabetes is not just due to the immune system attacking the pancreas, but the pancreas itself is doing something harmful. What starts this process? Hopefully, as we learn more about the mechanisms of why it happens, we will learn how to delay and even prevent it." Casu said.

She is also focusing on T1D biomarkers to find evidence of diabetes before it develops. "We are getting so close to being able to delay the onset of T1D," Dr. Casu states. She hopes that finding these answers will help improve millions of people's lives, believing that science will prevail in the future, as it has done in the past, in the fight against diabetes.

"I want people to be confident that research will bring us better things," she said. "A better quality of life and better treatments."

**A population where men live as long as women: villagrande strisaili, Sardinia - doi:10.4061/2011/153756*

## 2021 New Investigators

Melissa L. Erickson, PhD

TRI's newest investigator, **Melissa L. Erickson, PhD,** joined the faculty in July 2021 after completing a PhD in Exercise Physiology from the University of Georgia and post-doctoral training at Cleveland Clinic and Pennington Biomedical Center, focused on obesity and metabolic disease. Her transdisciplinary work merges the fields of exercise physiology, metabolic pathophysiology and chronobiology. She is ready to use her knowledge to work with and learn from established TRI investigators, like Drs. Bret Goodpaster and Lauren Sparks, who are changing how we think about exercise as a therapeutic intervention.

Supported by a new National Institutes of Health Career Development Award, Dr. Erickson's research focuses on circadian biology, an understudied topic emerging as a new metabolic health theme. She is developing a novel research portfolio that addresses circadian biology as a cause of metabolic disease and an intervention point to improve health using translational research approaches. These methods would consider the underlying molecular machinery that generates biological time. Erickson is also examining how time-of-day responses to energetic stressors impact our metabolism and physiology. Long-term, this will help us learn new principles about how and why our circadian system modulates our metabolic health. This new scientific information will enable us to optimize our health and resilience within the context of our ever-changing 24-hour society.

**"I am eager to leverage the TRI's world-class resources and facilities, which make a strong environment that supports new research designed to tackle the big scientific questions, ultimately and create meaningful change."**

**– Melissa L. Erickson, PhD**

## Featured 2021 Publications

- Gerstein HC, Sattar N, Rosenstock J, Ramasundarahettige C, **Pratley R,** et.al. Cardiovascular and Renal Outcomes with Efpeglenatide in Type 2 Diabetes. *N Engl J Med.* doi: 10.1056/NEJMoa2108269
- Vendrame F, Calhoun P, Bocchino LE, **Pratley RE, Casu A.** Impact of bariatric surgery and weight loss medications in adults with type 1 diabetes in the T1D Exchange Clinic Registry. *J Diabetes Complications.* 2021. doi: 10.1016/j.jdiacomp.2021.107884
- Heymsfield SB, Coleman LA, Miller R, Rooks DS, Laurent D, Petricoul O, Praestgaard J, Swan T, Wade T, Perry RG, **Goodpaster BH,** Roubenoff R. Effect of Bimagrumab vs Placebo on Body Fat Mass Among Adults With Type 2 Diabetes and Obesity: A Phase 2 Randomized Clinical Trial. *JAMA Netw Open.* 2021. doi: 10.1001/jamanetworkopen.2020.33457
- Pinckard KM, Shettigar VK, Wright KR, Abay E, Baer LA, Vidal P, Dewal RS, Das D, Duarte-Sanmiguel S, Hernandez-Saavedra D, Arts PJ, Lehnig AC, Bussberg V, Narain NR, Kiebish MA, **Yi FC, Sparks LM, Goodpaster BH, Smith SR, Pratley RE, Lewandowski ED,** Raman SV, Wold LE, Gallego-Perez D, **Coen PM,** Ziolo MT, Stanford, KI. A Novel Endocrine Role for the BAT-Released Lipokine 12,13-diHOME to Mediate Cardiac Function. *CIRCULATION.* doi: 10.1161/CIRCULATIONAHA.120.049813
- Brennan AM, Standley, RA, Anthony SJ, Grench KE, Helbling NL, **DeLany JP,** Cornnell HH, Yi FC, Stefanovic-Racic M, Toledo FGS, **Coen PM,** Carnero EA, **Goodpaster BH.** Weight Loss and Exercise Differentially Affect Insulin Sensitivity, Body Composition, Cardiorespiratory Fitness, and Muscle Strength in Older Adults With Obesity: A Randomized Controlled Trial. *The Journals of Gerontology.* 2021. doi: 10.1093/gerona/glab240

# **Transplant** Institute

## Vision

AdventHealth Transplant Institute is partnering 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.

## 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. The Institute's researchers strategically select protocols that offer new or improved treatments that would not otherwise be available to patients. The Institute is committed to offering patients opportunities to access the most current treatments, even as they are being developed.

## The AdventHealth Transplant Institute is home to Florida's #1 Heart Transplant and #1 Pediatric Liver Transplant Programs.

Since 1973, the Institute has performed over 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. In 2023, the Institute will welcome a Pediatric Heart Transplant program, further expanding transplant care capabilities for pediatric patients.

## Liver Transplant

- Median wait time for liver transplant is 2.1 months, compared to a national time of 8.2 months*
- Comprehensive care for liver-disease patients, one of the nation's first Liver ICU
- #1 Pediatric Liver Transplant Program in Florida*

## Lung Transplant

- One-year survival rates exceed the national average*
- Median wait time for lung transplant is 0.5 months, compared to a national time of 2.1 months*
- The first and only lung transplant program in Central Florida

## Kidney Transplant

- Founded in 1973 as one of Florida's first programs
- Over 1,000 Living Donor kidney transplants performed
- Median wait time for kidney transplant is 19.4 months, compared to a national time of 35.8 months*

## Heart Transplant

- #1 program in Florida*
- Performed more heart transplants than any other program in the region*
- Median wait time for heart transplant is 1.3 months, compared to a national time of 4.9 months*

**based on the Scientific Registry of Transplant Recipients*

# 2021 Featured Researchers and Research

Scott Silvestry, MD

Cardiac surgeon, **Scott Silvestry, MD's** expertise and experience with extracorporeal membrane oxygenation (ECMO) were at the forefront of clinical care for patients with COVID-19 who needed ECMO in 2021. Dr. Silvestry and his research team also obtained data for the ECMO COVID-19 Registry that contributed to several publications. One publication looked retrospectively at the characteristics and outcomes of a multicenter study. Another publication presented an in-depth approach to ECMO placement, operations and management during the COVID-19 pandemic. A third study discussed outcomes by cannulation methods of venovenous extracorporeal membrane oxygenation during COVID-19 and how this relates to the patient's outcome.

**Highlights:**

- Saeed O, Tatooles AJ, Farooq M, Schwartz G, Pham DT, Mustafa AK, D'Alessandro D, Abrol S, Jorde UP, Gregoric ID, Radovancevic R, Lima B, Bryner BS, Ravichandran A, Salerno CT, Spencer P, Friedmann P, **Silvestry S,** Goldstein D. Characteristics and outcomes of patients with COVID-19 supported by extracorporeal membrane oxygenation: A retrospective multicenter study. *J Thorac Cardiovasc Surg.* doi: 10.1016/j.jtcvs.2021.04.089
- Saeed O, **Silvestry S.** Extracorporeal membrane oxygenation support during the coronavirus disease 2019 pandemic: Outcomes and technical considerations. *JTCVS Open.* doi: 10.1016/j.xjon.2021.09.022

This paper discusses an ECMO working group's findings concerning the use of ECMO in COVID-19 patients and shares the developed best practices. Key takeaways to improve patient outcomes include:

1. Developing risk models to optimize patient selection regarding the use of ECMO
2. Use protocols that employ close monitoring of critical patients to provide ECMO early
3. Plan for technical issues with circuit management
4. Assess case capacity daily
5. Use a multidisciplinary approach to create diversion policies

The ECMO unit has grown substantially over the past year under Dr. Silvestry's leadership, from eight beds (with additional overflow) to a 32-bed ECMO-specific unit. The practical applications are seen deep in the community, especially for those requiring invasive mechanical ventilation due to diffuse lung injury, acute respiratory distress syndrome (ARDS), and cardiopulmonary collapse. Dr. Silvestry and his team's use of ECMO as a last-resort therapy provided time for pulmonary injuries to resolve, and gave patients a chance at survival.

### Piero Saenz and Terry Greear's Cases

**"Sadly, not every patient recovers," says Dr. Silvestry, "but two extraordinary patients stand out—Piero Saenz and Terry Greear." Despite initially mild symptoms, Piero was later diagnosed with ARDS and transferred to the Advanced Cardiac Surgical Unit for ECMO treatment. He spent 110 days on ECMO before being discharged home to continue healing.**

**Terry Greear found himself in the ER just a few days after a positive COVID-19 diagnosis and was soon transferred to the ICU, where he spent 72 days battling the virus and 27 days on ECMO. Although he lost 50 pounds and his lungs collapsed twice, the ECMO machine and the skilled team administering his clinical care were his lifesavers. Cases like Piero's and Terry's demonstrate how research like Dr. Silvestry's impacts patient care.**

**Piero Saenz and AdventHealth Nursing Staff**

**Terry Greear**

**Terry Greear and Scott Silvestry, MD**

## Surveillance HeartCare® Outcomes Registry (SHORE)

**Nirav Raval, MD**

Board-certified cardiologist **Nirav Raval, MD,** significantly contributes to the CareDx study SHORE (Surveillance HeartCare® Outcomes Registry). This study examines early predictors of heart transplant rejection based on blood draws and DNA with the goal of being able to depend on blood draws as an early predictor vs. routine biopsies status post-transplant. SHORE is one of the first types of these studies, and this science continues to grow.

AdventHealth was in the top five in enrollment of 66 SHORE sites around the country. The study's significance extends beyond heart transplantation alone because the gained knowledge is also being used in kidney and lung transplantation. As an early user of DNA as a predictor, Dr. Raval is excited about future studies that specifically build upon this technology, designed to limit the number of biopsies heart transplant patients will need and be a predictor of rejection. This could help further shape medical management for individuals.

Dr. Raval also collaborated with a team of researchers from the Biomedical Acoustic Research Lab at the University of Central Florida in a study, *Spatial Distribution of Seismocardiographic Signal Clustering (SCG),* published by *Picone Press.* Seismocardiographic (SCG) signals are chest wall vibrations that correlate with cardiac activity and are often measured using accelerometers on the chest surface. SCG may be generated by valve movements, heart muscle contraction and blood flow momentum changes. Respiration is a source of variability and studying the SCG signal "clustering" with respiration may help define physiological mechanisms related to this SCG variation. Grouping similar SCG events into clusters may also help reduce SCG variability and possibly increase its diagnostic utility. Previous studies often measured SCG signals at one location that varied among studies (e.g., xiphoid process, 4th ICS, etc.) [2-4]. However, SCG clustering may depend on SCG measurement location.

Dr. Raval and his colleagues aimed to investigate the dependence of SCG clustering on the measurement location. This distribution may be of diagnostic value and can help compare results from different studies and define locations where clusters are best separated, which may help optimize choices of SCG measurement location. The results demonstrated the dependence of SCG clustering on measurement location, which suggests that care needs to be taken when comparing study results that recorded SCG at different locations. Results also showed that the highest classification accuracy and SNR occur at the 4th quadrant near the left sternal border, which suggests that this region would be optimal for measuring SCG. More studies are needed to explore the utility of the observed clustering differences in assessing cardiac health.

Article: Ahdy S, Azad M, Sandler R, **Raval N,** Mansy H. Spatial Distribution of Seismocardiographic Signal Clustering. doi: 10.1109/SPMB52430.2021.9672298

## Featured 2021 Publications

- Pagani FD, Mehra MR, Cowger JA, Horstmanshof DA, **Silvestry SC,** et.al. Clinical outcomes and health care expenditures in the real world with left ventricular assist devices - The CLEAR-LVAD studyTagedEnd. *J Heart Lung Transplant.* doi: 10.1016/j.healun.2021.02.010
- Marczin N, de Waal EEC, Hopkins PMA, Mulligan MS, Simon A, Shaw AD, Van Raemdonck D, Neyrinck A, **Gries CJ,** et.al. International consensus recommendations for anesthetic and intensive care management of lung transplantation. An EACTAIC, SCA, ISHLT, ESOT, ESTS, and AST-approved document. *J Heart Lung Transplant.* doi: 10.1016/j.healun.2021.07.012
- Crespo MM, Lease ED, Sole A, Sandorfi N, Snyder LD, Berry GJ, Le Pavec J, Venado AE, Cifrian JM, Goldberg H, Dilling DF, **Gries C,** et.al. ISHLT consensus document on lung transplantation in patients with connective tissue disease: Part I: Epidemiology, assessment of extrapulmonary conditions, candidate evaluation, selection criteria, and pathology statements. *J Heart Lung Transplant.* doi: 10.1016/j.healun.2021.07.014
- **Silvestry SC,** Rogers JG. Rinse, Wash, Repeat The Evolution of the UNOS Heart Transplant Allocation System COMMENT. *JACC Heart Fail.* doi: 10.1016/j.jchf.2021.10.010
- Bakaeen FG, Gaudino M, Whitman G, Doenst T, Ruel M, Taggart DP, Stulak JM, Benedetto U, Anyanwu A, Chikwe J, Bozkurt B, Puskas JD, **Silvestry SC,** et.al. 2021: The American Association for Thoracic Surgery Expert Consensus Document: Coronary artery bypass grafting in patients with ischemic cardiomyopathy and heart failure. *J Thorac Cardiovasc Surg.* doi: 10.1016/j.jtcvs.2021.04.052

# The Office of the **Vice President of Research**

## Vision

The AdventHealth Research Institute 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 550 active clinical studies, placing AdventHealth at the forefront of novel treatment options for current and future patients. This opens the door to accelerate destination programs and develop nationally leading centers of excellence across all major treatment areas and institutes.

The visibility of a fully functioning and productive research program and infrastructure is vital to recruiting clinical thought leaders from nationally prominent academic medical centers. Most of these clinical program 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 meet standards that will achieve industry-leading results while supporting our passage to world-class clinical research and shaping the future standards of care. This means more treatment options at every stage of disease for patients, growth and discovery for clinical investigators and teams, plus a reduced cycle time for discovery, sponsors and collaborators.

## The Research Institute:

- Participates in more than 640 clinical studies annually
- Supports more than 350 Principal Investigators
- Won 66 active grant awards during 2021 (38 of the 66 current active grants are federal or federal flow down)

**The Office of the Vice President encompasses Research Administration, Research Services, Research Operations, Business Development, the Center for Academic Research Excellence (CARE) and other support services.**

## Research Services

Research Services comprises the Offices of Research Integrity, Sponsored Programs and Intellectual Property Development, which support our clinical operations teams and investigators in research, from early pre-clinical to grants and clinical trials.

### Office of Research Integrity and Compliance (ORIC)

- Ensures researchers and staff comply with regulatory requirements governing research
- Collaborates interdepartmentally across the institution to foster communication and align policies and procedures that build a more integrated and robust compliance
- Facilitates AdventHealth Institutional Review Board (IRB) reviews evaluating 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

### Office of Intellectual Property and Development (OIPD)

- Supports technology transfer, including intellectual property assessment and protection, marketing, development and prototyping, startup, licensing and agreement management for new inventions and discoveries

## Research Operations

Research Operations teams provide the structure to evaluate and execute AHRI clinical trials and research studies. Built with subject matter expertise in the therapeutic areas they serve, Research Operations collaborates with other investigators, departments and teams to select financially and operationally feasible opportunities and develop trial and study portfolios targeted to address the barriers to the health and wholeness of 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 Centralized Core services all AHRI departments for internally and externally sponsored projects.

- 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
- Imaging Core
- Nutrition Core
- Energy, Metabolism and Calorimetry Core
- Exercise and Bioenergetic Laboratory

## Research Business Development

Business Development initiates, establishes and supports relationships with research sponsors and partners to access innovative therapies and medical devices providing benefits to patients. The department oversees all stages of identifying, implementing and supporting opportunities for partnerships with AdventHealth physicians and scientists to promote growth in clinical research.

### The Business Development Team

- Develops pipeline portfolios across therapeutic areas
- Leverages business intelligence tools to identify potential gaps in research portfolios
- Evaluates the credibility and profitability of projects and external partnerships
- Anticipates the business needs of our internal and external stakeholders
- Streamlines the clinical trial delivery process
- Hosts specialized therapeutic area pipeline events to vet new therapies, compounds and innovative studies
- Fosters partnerships by creating individualized tours of imaging, pharmacy, laboratories, clinical settings and other key research areas

## Investigator Support: Center for Academic Research 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. CARE partners with faculty, fellows, residents, 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
- Standardizes and centralizes the research volunteer process
- Brings together statisticians to form a stronger core

# **Donate**
# to Research

Philanthropic contributions empower us to help more people live their best, most vibrant lives. Your donations expand research capabilities across our vast network, expanding across nine states, making AdventHealth an ideal platform to increase 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.

We 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. There are many ways to support whether you make an annual contribution, multi-year pledge, sponsor an event or establish a legacy gift. Some of our most dedicated supporters consider making gifts through their will or trust. Other popular giving options include gift annuities, gifts of stock or real estate as well as 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.

Join us today in **Extending the Healing Ministry of Christ** by advancing scientific discovery that will help more people experience a life of whole health.

Contact AdventHealth Foundation Central Florida at **407-303-2784** or **ResearchGive@AdventHealth.com** to learn more.

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