

# AdventHealth Research Institute

## 2020 ANNUAL REPORT



# 2020 Annual Report

## AdventHealth Research Institute

### Table of Contents

Welcome Letter	3
Overview	4
An Unprecedented Year	8
Excellence in Translational Research	10
Research Responding to the COVID-19 Pandemic	11
AdventHealth Research by the Numbers	19
Whole-Person	25
Translational Research Institute (TRI)	29
Cancer	34
Cardiovascular	38
Neuroscience	41
Digestive Health and Surgery	44
Orthopedics	46
Pediatrics	49
Genomics	51
Transplant	53
The Office of the Vice President of Research	55
Pharmacy: Investigational Drug Services (IDS)	60
Looking Forward	61

# Welcome Letter

Welcome to our first annual report of the AdventHealth Research Institute. Inside you will find key statistics defining our progress last year. But, more importantly, you will find stories of how research is changing the lives of our community by advancing the science of whole-person care. Of course, these stories are just the tip of the iceberg. Our overarching goal is to do research that matters, as evidenced by our publications and the effects of our research on the broader medical community.

In these challenging times, our staff, researchers, and community rose to the occasion, and together we found creative ways to contribute in the fight against SARS-CoV-2 pandemic. In several key instances, these studies resulted in new knowledge. But, more crucially, they enabled immediate changes to how we care for our patients and the communities we serve.

As you read through this report, I hope you will feel the same energy and hopefulness that we feel every day as we work to advance our Mission.



**Steven R. Smith, MD**

Senior Vice President & Chief Scientific Officer

# Overview

As AdventHealth continues to expand its expertise and discover new and groundbreaking ways of treating illness, we remain true to our Mission of Extending the Healing Ministry of Christ and our pursuit of helping people achieve wholeness in body, mind, and spirit. Guided by our faith-based Mission and whole-person approach, we utilize what we have learned from our two million-plus annual patient encounters and share that knowledge across our system and beyond.

The AdventHealth Research Institute (referred to often as the “Research Institute”) provides a solid scientific foundation upon which we can define and extend the borders of standard clinical practice in the 21st century.

**AdventHealth’s Mission and consumer focus is reflected in the Institute’s Vision and Purpose Statement:**

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

Our leadership, guided by the Research Institute vision, collaborates to create bi-directional benefits for the community, our health system, and our physician-investigators and Ph.D. researchers.

## AHRI Leadership Team



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



**Rob Herzog**  
*Vice President Research*



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



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



**Bret Goodpaster, PhD**  
*Scientific Director*



**Patricia Robinson, PhD**  
*Scientific Director*



**Bryan Allinson**  
*Director of Institute  
Development Office*



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



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



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



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



**Patty Winger**  
*Interim Director of Oncology  
and Pediatric Research*

# Our Clinical Partners

The AdventHealth Research Institute conducts hundreds of clinical trials and studies each year to improve healthcare and find cures for a wide range of diseases. Research is primarily conducted through 13 different therapeutically specialized research teams across AdventHealth:

- Cancer
- Cardiovascular
- Critical Care
- Digestive Health and Surgery
- Infectious Disease
- Genomics
- Neuroscience
- Orthopedics
- Pediatrics
- Pharmacy/Investigational Drugs
- Translational Research Institute
- Transplant
- Whole-Person



**13** therapeutically focused research teams

SUPPORTED BY

**285** research employees



**330+**  
INVESTIGATORS



**21** ACTIVE R01 GRANTS  
From National Institutes of Health (NIH)



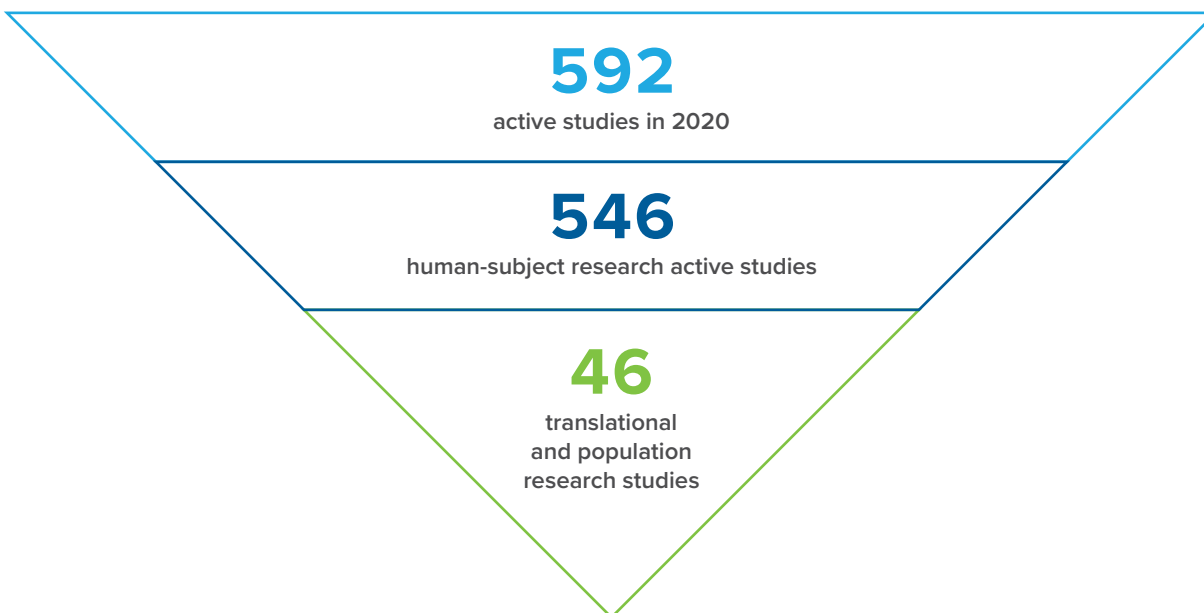
**337** research publications  
IN PEER-REVIEWED  
JOURNALS (2020)



NATIONALLY ACCREDITED IRB  
(through AAHRPP)



**592** active clinical studies  
studying lifespan –  
from NICU to seniors  
RANGING FROM PHASE 0 – 4



## Five AdventHealth Physicians and One PhD Scientist Named Among the Top 2% of Scientists Worldwide

With specialties ranging from endocrinology to surgery to oncology, five physicians and one scientist from AdventHealth have been named among the top 2% of scientists worldwide based on an analysis published in the peer-reviewed journal PLOS Biology.



**Bret Goodpaster,  
PhD: Endocrinology  
and Metabolism**

Investigating the pathophysiology of human aging, obesity, insulin resistance, and diabetes, Dr. Goodpaster has published peer-reviewed papers, reviews, and book chapters and has served on several editorial boards. Dr. Goodpaster has received many awards and honors for his work, including the Nathan Shock Award from the National Institute of Aging in 2008.

In Endocrinology  
& Metabolism

**265**

Published Works



**John R.T. Monson,  
MD: Surgery**

Dr. Monson is a board-certified colon and rectal surgeon with expertise in minimally invasive technologies. As an author of hundreds of original published papers, four books, and more than 250 book chapters, his research encompasses a broad range of cancer-related areas, including developing national standards and co-founding the Commission on Cancer's National Accreditation Program for Rectal Cancer.

In Surgery

**398**

Published Works



**Herbert Newton,  
MD: Oncology and  
Carcinogenesis**

A board-certified neuro-oncologist and neurologist, Dr. Newton has over 30 years of highly specialized experience treating cancer patients, particularly adult patients with brain and spinal cord tumors. His research is well published in peer-reviewed journal articles and book chapters, and he has served as editor or co-editor of 10 medical textbooks.

In Oncology &  
Carcinogenesis

**157**

Published Works



**Vipul "Vip" Patel,  
MD: Urology and  
Nephrology**

One of the world's most experienced urologic robotic surgeons, Dr. Patel has personally performed nearly 15,000 robotic prostatectomies and travels around the globe to educate physicians and help start robotic programs internationally. He has authored scientific articles, served as an editor on six robotic textbooks, and contributed to more than 20 textbooks.

In Urology &  
Nephrology

**209**

Published Works



**Richard Pratley, MD:  
Endocrinology and  
Metabolism**

A board-certified internal medicine physician, Dr. Pratley is an internationally recognized diabetes expert with advanced training in gerontology, geriatrics, and metabolism. He is a leading authority on new and emerging treatments for diabetes and its comorbidities. Dr. Pratley has 206 published works.

In Endocrinology &  
Metabolism

**206**

Published Works



**Mark A. Socinski,  
MD: Oncology and  
Carcinogenesis**

Dr. Socinski is a board-certified, fellowship-trained medical oncologist and is an internationally recognized expert in developing novel chemotherapy agents and treatment strategies for advanced non-small cell lung cancer and small cell lung cancer. Since 2005, his research has focused on incorporating personalized medicine and molecular biomarkers in lung cancer treatment. Dr. Socinski has 327 published works.

In Oncology &  
Carcinogenesis

**327**

Published Works



George R. Simon, MD

### New Research. New Treatments. New Hope.

Our new state of the art Moffitt-AdventHealth Clinical Research Unit (CRU) located on the Celebration campus serves as a joint research facility for early phase trials.

Dr. George Simon joined the Moffitt-AdventHealth by way of MD Anderson (Houston, TX).

The CRU provides patients across Central Florida access to early stage cancer trials and personalized medicine.

## An Unprecedented Year

Moffitt Cancer Center and AdventHealth have partnered to provide world-class cancer treatment and better access to cancer prevention, education, cancer screenings, and early phase clinical trials critical to developing improved cancer care. The trials are implemented through the newly developed Cancer Clinical Research Unit (CRU), a state-of-the-art clinical research facility located at the AdventHealth Celebration campus.

The CRU works to provide innovative treatments, such as novel targeted therapies intended to block the growth and spread of cancer by targeting cancer cells and immunotherapy treatments.

Researchers from both organizations are conducting early phase clinical trials to develop new drugs at the Central Florida site, allowing patients across Central Florida to participate in Phase 1 research trials to investigate and test new cancer therapies.

The Moffitt Cancer Center is one of only two National Cancer Institute (NCI)-designated Comprehensive Cancer Centers in Florida and among the country’s largest Cancer Centers with extensive pre-clinical and clinical-translational cancer research expertise. In 2019, Moffitt and AdventHealth announced their partnership to obtain a National Cancer Institute (NCI) Consortium Designation by 2026, and the establishment of the CRU is a critical first step.

### The importance of clinical research

Clinical research is fundamental to clinical care as precision therapeutics with novel targeted therapies and immunotherapies become the norm. Rational drug design and molecular, profile-based patient selection have rapidly accelerated drug development. Many of these drugs have replaced older, less effective (and often more toxic) drugs developed in the 1980s and 1990s. The anticipated response rate in early phase studies in the 1990s and early 2000s was 4 to 6%. In 2020, a single-institution study reported a 26% cumulative response rate when patients were enrolled in more modern early-phase studies.

The Moffitt-AdventHealth CRU team works to ensure that tomorrow’s treatments are available to patients today, aligning with the unit’s vision to “bring hope, compassion, and innovation to every patient touched by cancer.” As Moffitt and AdventHealth continue to expand research, CRUs like AdventHealth Celebration will become critical for translating new therapies to patients in Central Florida and other areas of the state where next-generation treatments may not be available.

The CRU is directed by **George R. Simon, MD**, recruited from MD Anderson Cancer Center in Houston, TX, where he served as Professor of Medicine and Section Chief for Translation Research at the Department of Thoracic and Head/Neck Medical Oncology.

Dr. Simon is an internationally renowned expert in Lung Cancers and other thoracic malignancies with extensive early drug development experience. He and his team are ramping up their clinical trial portfolio in anticipation of the CRU’s fall 2021 formal opening.



“Dr. Simon’s translational research experience and ability to work with clinicians, researchers, patients, and community partners to increase clinical trial awareness and enrollment is key to better serving our patients and advancing care.”

*Dr. Steven R. Smith, Associate Center Director of the AdventHealth – Moffitt Partnership and Chief Scientific Officer of AdventHealth.*



## Early-phase studies in the Clinical Research Unit (CRU) by Dr. George Simon

The Clinical Research Unit (CRU) brings the latest in clinical research to the patients in the Central Florida region. Clinical trials are currently open with antibody-drug conjugates, BiTe Antibodies, targeted therapies, epigenetic therapies, and novel immunotherapies that will either target the tumor directly or indirectly through the tumor micro-environment. In addition, in the near future, we will be bringing in studies with therapeutic viruses, anti-tumor RNA vaccines, and select cellular therapies. The CRU also offers our patients state-of-the-art facilities where they can receive exemplary care, working seamlessly with their primary oncologists.

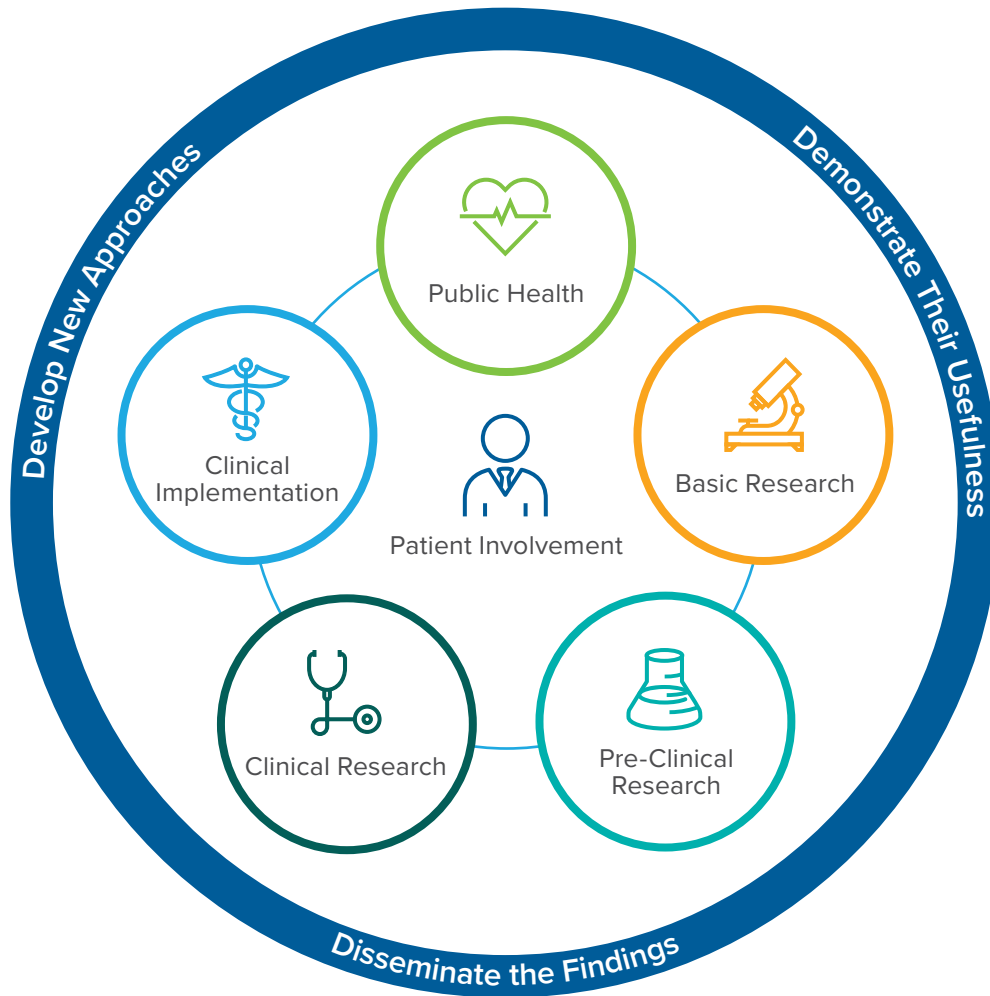
To our physicians in the Central Florida region, the CRU enhances their capabilities to retain patients by increasing the number of therapeutic options they can offer to patients, essentially eliminating the need for patients to travel to other cities and states to access the latest in cancer research. Incorporating more modern targeted and rationally designed treatments (which tend to carry the possibility of higher benefit rates) early on in the course of the disease allows for saving established standard treatments (often developed decades ago) for future use. To our sponsors, we offer our advanced capabilities to do pharmacokinetics, pharmacodynamics, onsite tissue processing, and tissue storage.

In addition to novel studies brought in from outside sponsors and research institutions, the CRU will offer an enhanced number of investigator-initiated trials. This ability allows us to design trials that best suit our patients and provides a golden opportunity to design correlative translational studies around the clinical trials, thus enhancing the ability of scientists to work with patient-derived samples. Therefore, the CRU will play a crucial role in facilitating scientific enhancements that will benefit clinical and basic investigators.



# Excellence in Translational Research

The Translational Research Institute (TRI)'s Mission is to extend and improve the quality of life through the conduct of world-class, innovative translational research that leads to discoveries — and ultimately cures — for obesity, diabetes, cardiovascular diseases, and other diseases associated with aging.



Our “bench-to-bedside” approach in translational research is a two-way street. Scientists engage in bench and pre-clinical studies to provide clinical researchers with tools and model systems to employ in human studies, while clinical researchers make novel observations and conduct clinical trials. This method allows us to understand the nature and progression of disease and evaluate the efficacy of new therapies and treatments. Thus, the combined efforts of scientists, researchers, and physicians make translational research a truly interdisciplinary approach to improving the public's health through innovation, leading to discoveries and, ultimately, cures.

The TRI scientists, clinicians, and partners are committed to early-phase clinical studies to understand the molecular underpinnings of Metabolic Disease. The Institute specializes in proof-of-concept and proof-of-mechanism research studies funded through National Institutes of Health (NIH), biotech companies, and pharma companies to enroll and execute scientifically rigorous and high-quality research studies.

## Research Responding to the COVID-19 Pandemic

While COVID-19 has undeniably impacted the world, nowhere has its effects been more apparent than in the healthcare sector. More specifically, the pandemic has immensely affected the manner and speed at which we conduct clinical trials. AdventHealth has been at the forefront of the fight against this devastating illness, as evidenced in part by our participation in the ENSEMBLE Trial — the largest COVID-19 vaccine trial to date. AdventHealth’s efforts didn’t stop with our patients, though – we also made a concerted effort to prevent staff burnout through support programs like RISE®, ensuring that our team could continue providing the best care for our patients using their Resiliency, Insight, Self-compassion, and Empowerment.

AdventHealth’s commitment of resources and people to orchestrate this monumental trial in Central Florida reflects its investment in preventive measures for our community’s safety, delivered through the hands of our skillful research team, to extend the healing ministry of Christ. The ENSEMBLE Trial garnered support from multiple internal departments and 17 outside vendors.

- Information Technology and Information System Network Campus Support Teams
- HR Regulatory Services
- AH Call Center
- Office of Design and Construction
- Investigational Drug Service and Orlando Campus Pharmacy Team
- Operation Warp Speed
- Marketing, Communications, and Creative Teams
- Government Relations
- Community Impact
- Leadership at AH Kissimmee and East Orlando Campuses

## Search for a Vaccine



As Central Florida’s leading health system, AdventHealth was selected by the Departments of Health and Human Services and Defense to participate in Operation Warp Speed (OWS).

As part of OWS, AdventHealth and Johnson & Johnson partnered to roll-out the ENSEMBLE Trial. Janssen Pharmaceutical (Johnson & Johnson)’s phase 3 clinical research trial evaluated the safety and efficacy of their COVID-19 vaccine candidate. The vaccine is based on Janssen’s AdVac® technology, and the clinical trial evaluated the single-dose vaccine candidate versus placebo in approximately 44,325 adults aged 18 + from seven countries, including the U.S. Participants included volunteers with and without comorbidities associated with an increased risk for progression to severe COVID-19.

AdventHealth’s commitment to diversity and the diverse populations we serve in many locations across Central Florida made AdventHealth an ideal partner.

ENSEMBLE required the ongoing collaboration of many AdventHealth Research Institute teams with our executives’ oversight. Collaborators included members of our Research Administration, Research Cores, Offices of Sponsored Projects and Portfolio Management, Internal Operations, Whole-Person Research, Translational Research Institute, many of whom were redeployed to help with this major trial.

The effort is part of a larger strategy at AdventHealth to help keep our community safe and foster a sense of hope for access to innovative medicine.

## AdventHealth Opens New Research Department to Develop COVID-19 Treatments

Research institutes across the globe experienced substantial slowdowns, if not shutdowns, at the onset of COVID-19. In addition, government restrictions made it difficult to access drug trials, and vulnerable populations could not visit sites if self-isolating.

Through careful adaptation, AdventHealth quickly responded to these challenges, shifting to remote patient monitoring (including monitoring glucose levels and blood pressure), updated staff safety procedures, and the direct delivery of study medications. As a result, AdventHealth became home to three COVID-19 studies on antiviral medications, four on anti-inflammatory medications, three on devices/tests, and four COVID-19 related research registries.

The Research Institute engaged operational teams in the inpatient and outpatient settings to include medical oversight by a Physician Principal Investigator (PI) and an APRN/PA with prior infectious disease experience. Highlights included access to PIs with extensive research and publication experience, access to the AdventHealth Institutional Review Board (IRB), and access to the central external IRBs to allow for expedited response time, expedited trial launches, and remote monitoring.

### The New Normal

As life with COVID-19 became our new normal, AdventHealth continued to shift toward effective management of new and existing trials, including introducing electronic consenting (eConsenting), designing trials with contingencies, and implementing shorter visits with minimal contact. Given the widescale yet necessary adaptations, we will continue to see these permanent changes in the future conduct of clinical trials.



## Innovation and Transformation in the Response to COVID-19: Seven Areas Where Clinicians Need to Lead

In a 2020 publication featured in *The New England Journal of Medicine/Catalyst*, AdventHealth leaders **Victor Herrera, MD, Neil Finkler, MD, and Julie Vincent, RN** shared the management model implemented at AdventHealth to make agile and informed decisions in our clinical responses.



The team defined seven core areas or branches that the system's steering committee found to be essential in managing the day-to-day challenges associated with the COVID-19 response. These branches are defined as **clinical standards, capacity, ethics, science, analytics, resilience, and communication and education**.

The system's Central Florida Division (CFD) has more than 4,400 beds and 20 hospitals alone. Due to the CFD's size and complexity, the hospital required a coordinated clinical response to ensure that the COVID-19 response was unified.

### Clinical Standards Branch

The Clinical Standards branch is the heart of the model, acting as a basis for all other workflow actions. The AdventHealth team asked leading researchers and clinicians from all specialties to review the literature and create summaries of best practices, emphasizing the importance of visual aids. Within 72 hours, a comprehensive COVID-19 document had been developed using information garnered from more than 142 clinicians.

### Science and Innovation Branch

Due to the massive influx of information related to the epidemiology, pathophysiology, treatment, and prevention of COVID-19, clinical leaders found themselves inundated with information sent by all areas of the organization to consider incorporating into practice. As a result, the main goal in developing the Science and Innovation Branch was to create a repository of this growing literature, emphasizing accelerating processes to improve patient care. This branch then made recommendations to the AdventHealth system based on the emerging literature's scientific validity, efficacy, and information safety.

### Capacity Branch

Capacity management continues to become increasingly important as emerging evidence supports the use of dedicated units for COVID-19 patients and potential COVID-19 patients. Therefore, it was necessary to develop capacity management plans that adjusted to different pandemic phases, making innovative thinking necessary to improve capacity while keeping physicians, nurses, and patients safe.

### Clinical Analytics Branch

The Clinical Analytics Branch worked with clinicians to collect and report data in an actionable manner, providing insight and predictive value to support the clinical response to the disease. As a result of the multidisciplinary collaboration in this branch, the thinking has evolved to incorporate scoring systems such as APACHE (Acute Physiologic Assessment and Chronic Health Evaluation) to provide frontline clinicians with actionable data with predictive value to use while treating patients.



## Ethics Branch

A rapid increase in patients presenting to all care settings — some of them requiring hospitalization and rapid escalation of care — created a demand that could quickly overwhelm the available clinical capacity. In addition to experiencing personnel and supplies constraints, difficult ethical challenges arose, ranging from who should be tested to more difficult situations like allocation of life-saving treatments; similar consideration applied to the risks to health care workers and the use of personal protective equipment. The work of the Ethics branch is intended to focus on defining clear and practical guidelines that can be applied when making clinical decisions based on solid ethical principles.

## Communication and Education Branch

Disseminating important information generated by the other branches to the clinical staff is critical in fighting against COVID-19. With the advent of the pandemic, the system needed to disseminate large amounts of rapidly changing information to large audiences. Thus, the method and format used to communicate pertinent information needed to be altered, redefining the standard used during COVID-19 and beyond. To balance the compliance standards around information sharing and the need to support the psychological safety of the teams, AdventHealth is committed to maintaining an environment of data transparency that is HIPAA compliant.

## Resilience Branch

Clinicians worldwide are experiencing heightened stress levels in response to COVID-19, leading to associated risks such as post-traumatic stress disorders. As a result, the Resilience Branch started a series of activities for all members across our hospitals, focusing on stress-relief techniques, strategic rest plans, and remote access group activities.

While the COVID-19 Seven Branches Clinical Management Model was initially developed as a practical approach to organizing the clinical response to COVID-19, its efficacy and functionality make it a sustainable model that will extend beyond the pandemic.

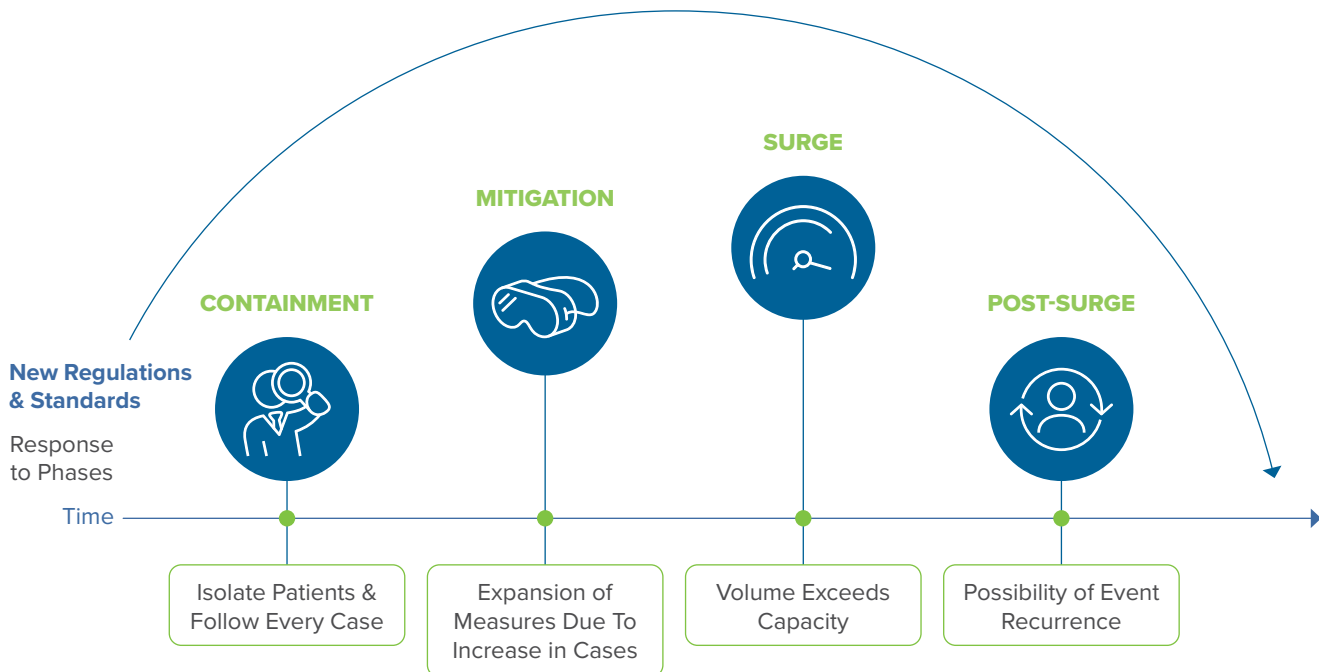
*Source: NEJM Catalyst, 2020. Authored by Victor Herrera, MD, Neil Finkler, MD, and Julie Vincent, RN. doi:10.1056/CAT.20.0087.*



## Impact to our Communities

As the 2020 COVID-19 pandemic evolved, AdventHealth Research Institute took a proactive approach toward keeping patients, staff, and research investigators safe while preserving and maintaining research as a care option for patients across therapeutic areas, including COVID-19. These efforts continued through all stages (containment, mitigation, surge, and post-surge) of the pandemic, culminating with several effective initiatives that continue to evolve rapidly as new information and opportunities become available. The actions taken by the AdventHealth Research Institute demonstrated that our organization stands among the leaders in research.

Airborne viruses like the coronavirus often generate dangerous new variants that affect people in the community. Our position as a leader for research in Central Florida means that AdventHealth will be able to provide early access to innovative new therapies under development by our biopharmaceutical sponsors.





## AdventHealth Physicians Help Improve Outcomes in the Intensive Care Unit (ICU)

AdventHealth clinicians helped improve the lives of COVID-19 patients in the Intensive Care Unit by developing and supporting compliance with standard of care measures.

Observational studies had consistently described poor clinical outcomes and increased ICU mortality in patients with severe coronavirus disease 2019 (COVID-19) who required mechanical ventilation (MV). These findings prompted a group of AdventHealth physicians to conduct a retrospective study on the clinical characteristics and outcomes of patients admitted to the health system's ICU due to severe COVID-19 from March 11th until May 18th, 2020.

Patients were characterized based on demographics, baseline comorbidities, severity of illness, and medical management, including experimental therapies, laboratory markers, and ventilator parameters. Major clinical outcomes analyzed at the end of the study period were hospital and ICU length of stay, MV-related mortality, and overall hospital mortality of ICU patients.

Out of 1,283 patients with COVID-19 admitted, 131 met the criteria for ICU admissions. Of the 131 patients, 109 required MV, with 9 receiving extracorporeal membrane oxygenation (ECMO). With ECMO, blood is pumped outside of the body to a machine that removes carbon dioxide before returning oxygen-filled blood back into the body. COVID-19 survivors also displayed a longer MV length of stay.

Ultimately, the study demonstrated an important improvement in the mortality of patients with severe COVID-19 who required ICU admission and MV compared to previous observational reports, emphasizing the importance of standard of care measures in managing COVID-19.

*Source: Plos One, March 2021. Authored by AdventHealth Orlando physicians Eduardo Oliveira, Amay Parikh, Arnaldo Lopez-Ruiz, Maria Carrilo, Joshua Goldberg, Martin Cearras, Khaled Fernainy, Sonja Andersen, Luis Mercado, Jian Guan, Hammad Zafar, Patricia Louzon, Amy Carr, Natasha Baloch, Richard Pratley, Scott Silverstry, Vincent Hsu, Jason Sniffen, Victor Herrera, Neil Finkler. <https://doi.org/10.1371/journal.pone.0249038>.*





## Clinical Leader Series

The work of our clinical leadership teams was essential at AdventHealth during the COVID-19 pandemic, with competing challenges related to patient care, staffing, and clinical demands. As our leaders addressed their own responsibilities and witnessed their staff members struggling, it became clear that many of them were also suffering the mental and emotional health consequences of the pandemic.

As a result, **Trish Celano, MSN, RN**, Associate Chief Clinical Officer and Chief Nurse Executive, challenged the Nursing and Whole-Person Research teams to develop and deliver a two-part virtual mental health initiative for AdventHealth clinical leaders.

This project, called the Clinical Leader Series (CLS), was led by **Amanda Bailey, MA, LMHC**, a research psychotherapist and program developer, and **Amanda Sawyer, PhD**, a biobehavioral research scientist. The program was open to nursing leaders, from assistant nursing managers to chief nursing officers and chief nursing executives.

With the goal of helping leaders care for themselves and their teams, CLS offered a one-hour introductory overview of concepts related to common stressors, signs and symptoms of distress, leader self-care, and practical steps to provide psychological support to teams. It also explained how to access support services and use counseling referrals. For those interested in learning more, the six-week CLS equipped nurse leaders with the tools for self-care and team-care through learning, self-reflection, and skill acquisition related to communication, decision-making, and boundaries.

Voluntary surveys regarding coping, psychological empowerment, burnout, and quality of life indicated that these factors did not worsen as the pandemic progressed. Additional data collected validated the program's need-meeting value to help individuals achieve better work-life balance and overcome the difficulties of leadership during a crisis.

The CLS curriculum is now available on the AdventHealth Learning Network, and nurse leaders can earn Continuing Education Units, or CEUs, for completing these modules. This project will be presented in an interactive workshop at the Schwartz Center's 2021 Compassion in Action Healthcare Conference.



## RECOVER-19 Real World Data Registry for COVID-19 Tested Patients

Established early in the pandemic, the Registry and Biorepository of COVID-19 for AdventHealth (RECOVER-19) is a registry of all patients tested for SARS-CoV-2 within the Central Florida Division. The registry collected inpatient and outpatient data and demographics, medical and social history, medications, and lab results, in addition to administering COVID-19 vaccines.

The biorepository, which is linked to the registry through unique identifiers, now holds remnant plasma from COVID-19 patients and adheres to the standards of the International Society for Biological and Environmental Repositories (ISBER) and the College of American Pathologists (CAP).

“This registry was instrumental in supporting multiple AdventHealth research studies, including collaborations with external academic and private partners. Of note, one large collaborative study analyzed all COVID-19 patient data generated in 2020 through a Bayesian artificial intelligence platform, run on one of the most powerful computers in the world. This analysis generated new insights for COVID-19 related mortality and identified a commonly used FDA-approved drug as a potential treatment for mechanically ventilated COVID-19 patients,” said AdventHealth Senior Research Scientist **Daniel Lupu, MD, PhD**.

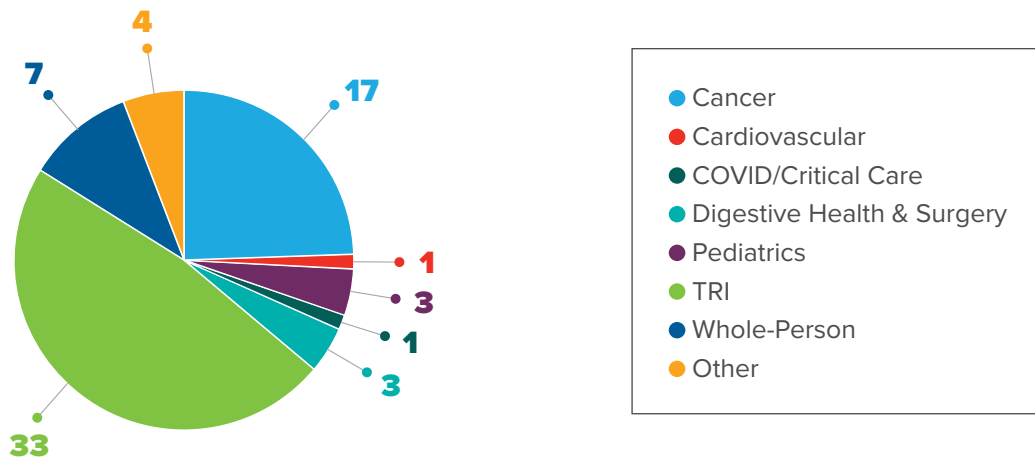


**Daniel Lupu, MD, PhD**

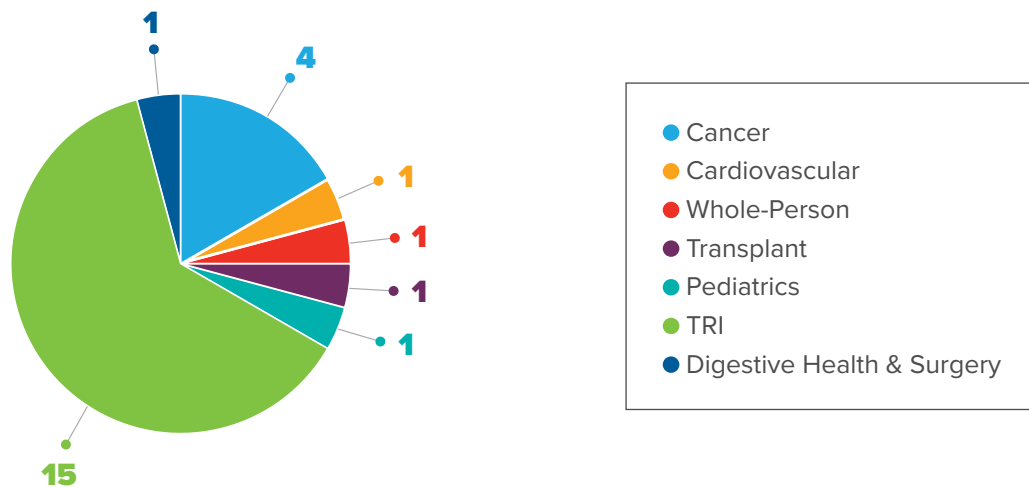
# AdventHealth Research by the Numbers

AdventHealth Research Institute investigators submitted 69 grant proposals which are reviewed by peers and sponsoring agencies. These proposals led to 24 new grants and 65 active grants awarded to AdventHealth in support of innovative, new therapies and understandings.

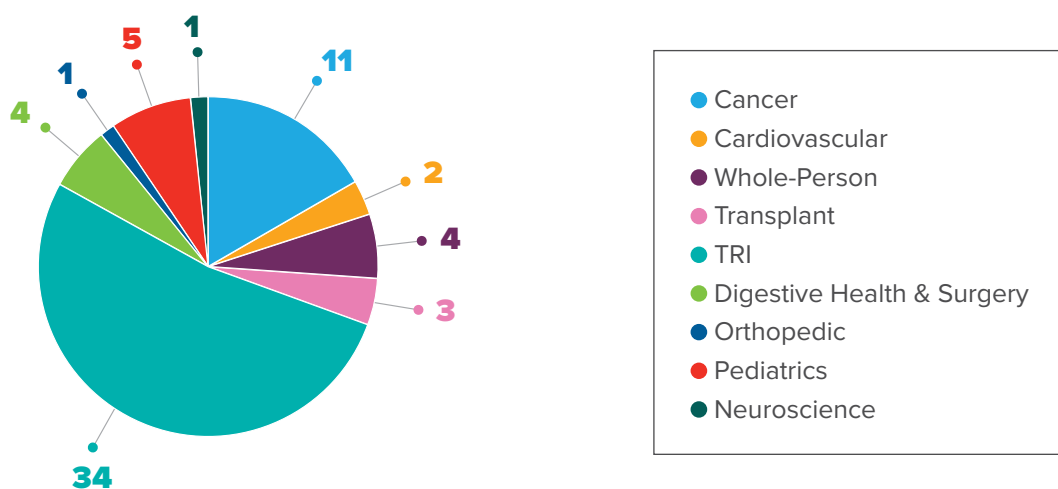
## 2020 Grant Proposals Submitted



## 2020 New Grants Awarded

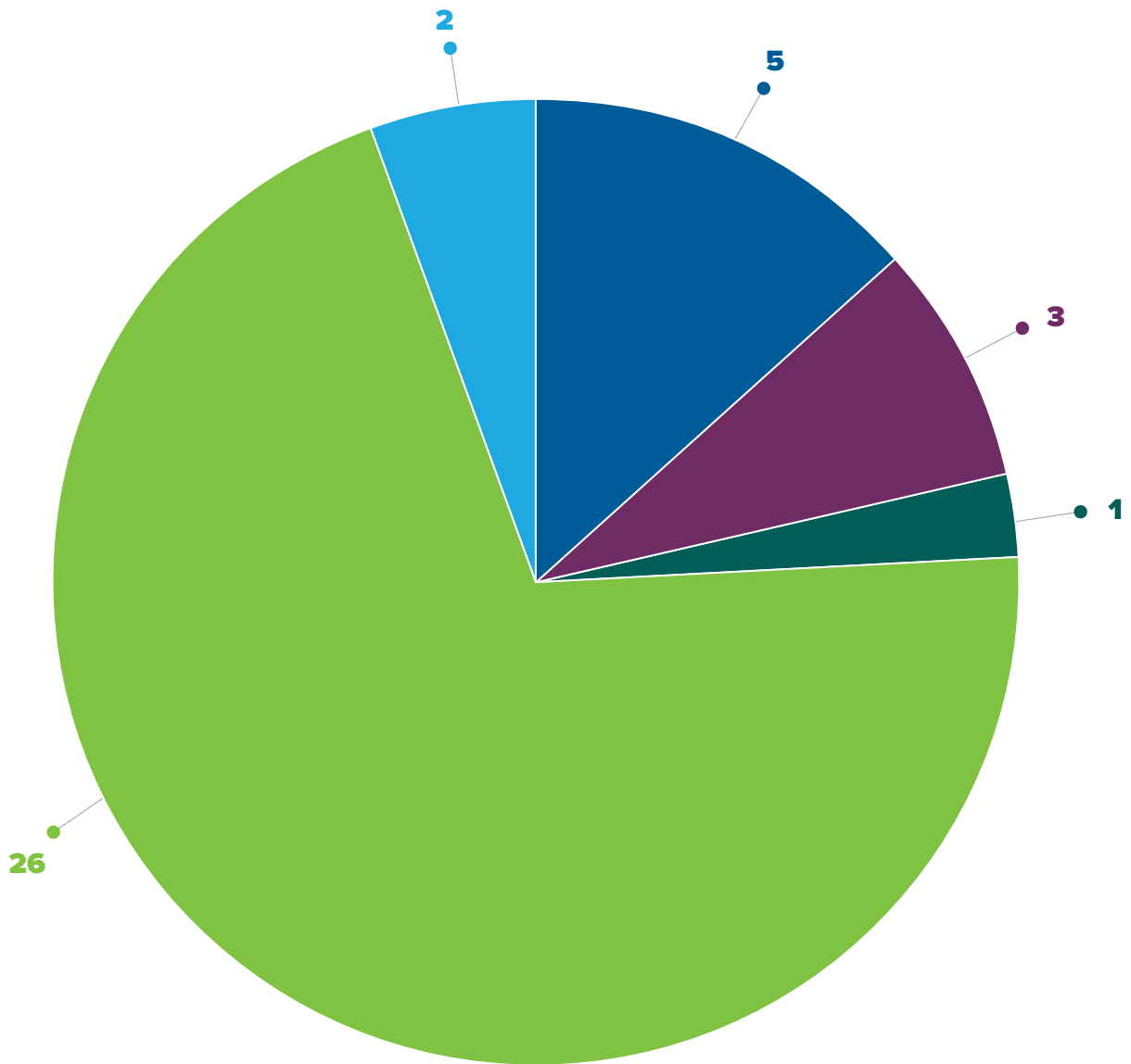
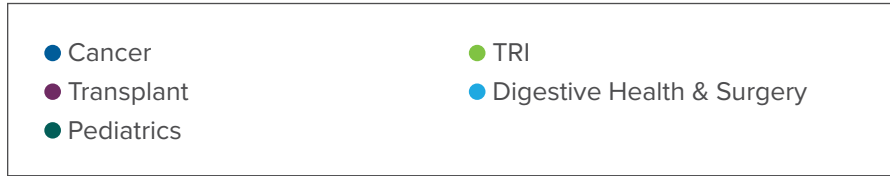


## Total Active Grants



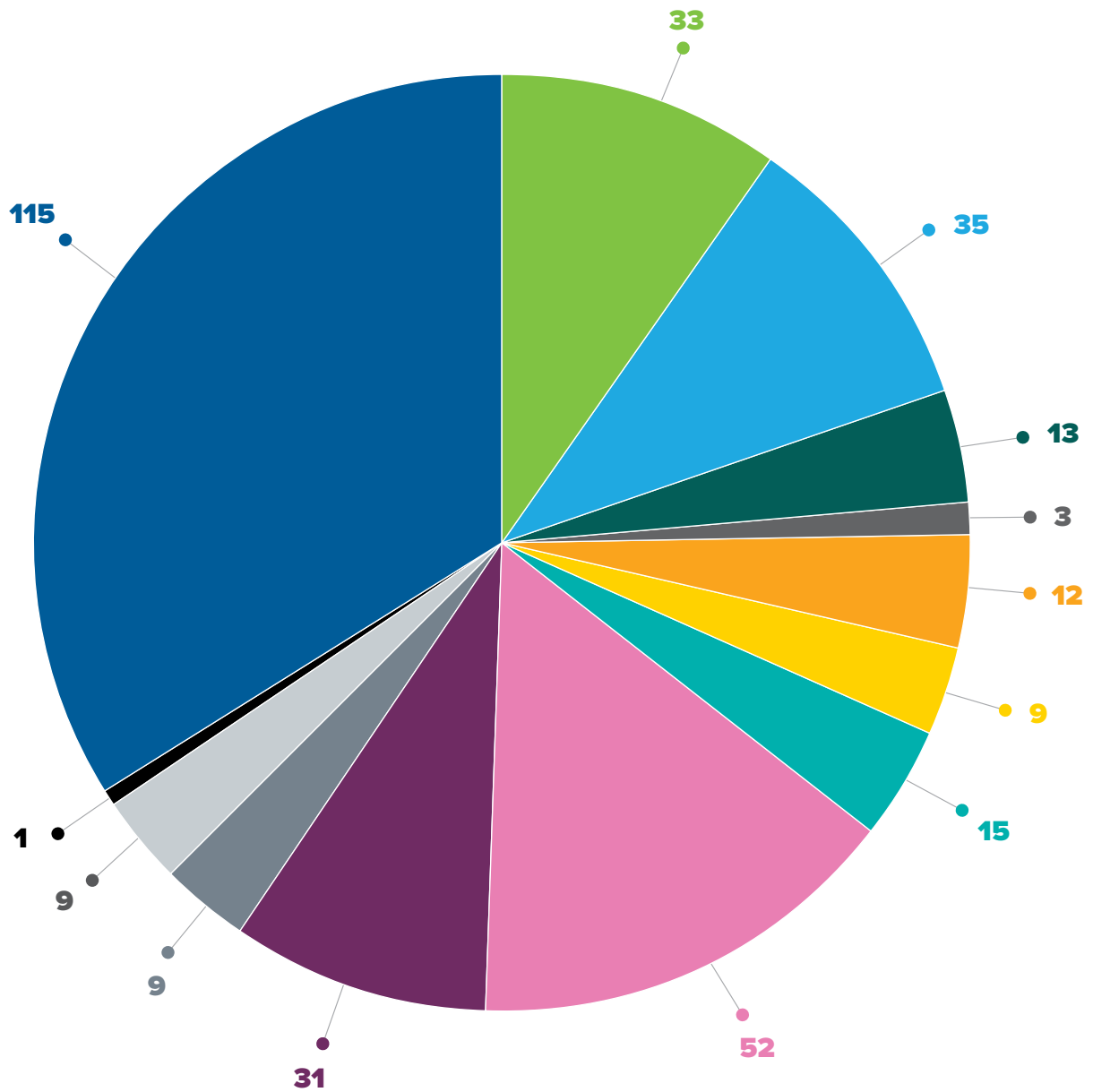
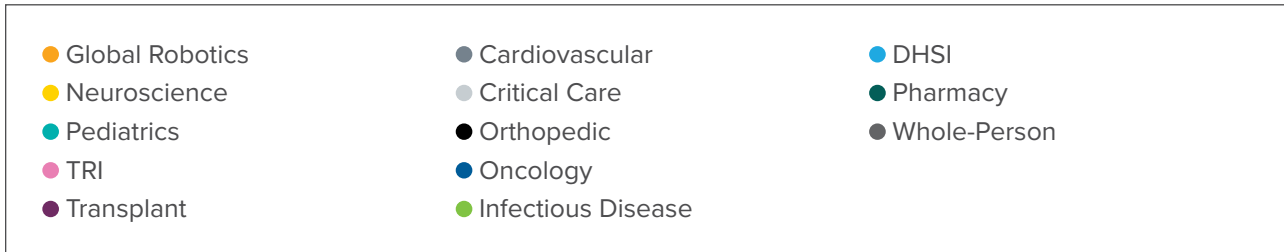
## Total Active NIH Awards - 21 NIH awards are R01

The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services, is the nation's premier medical research agency, making important discoveries that improve health and save lives. AdventHealth currently has 37 active NIH awards, 21 of which are R01.



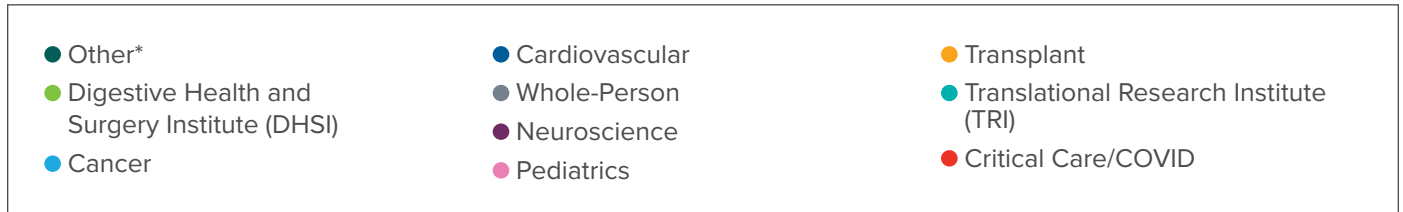
## AHRI Publications 2020 by Department

AdventHealth investigators publish in many of America's top journals, creating a high awareness among peers of the important work at AdventHealth. In 2020, our investigators published 337 publications.



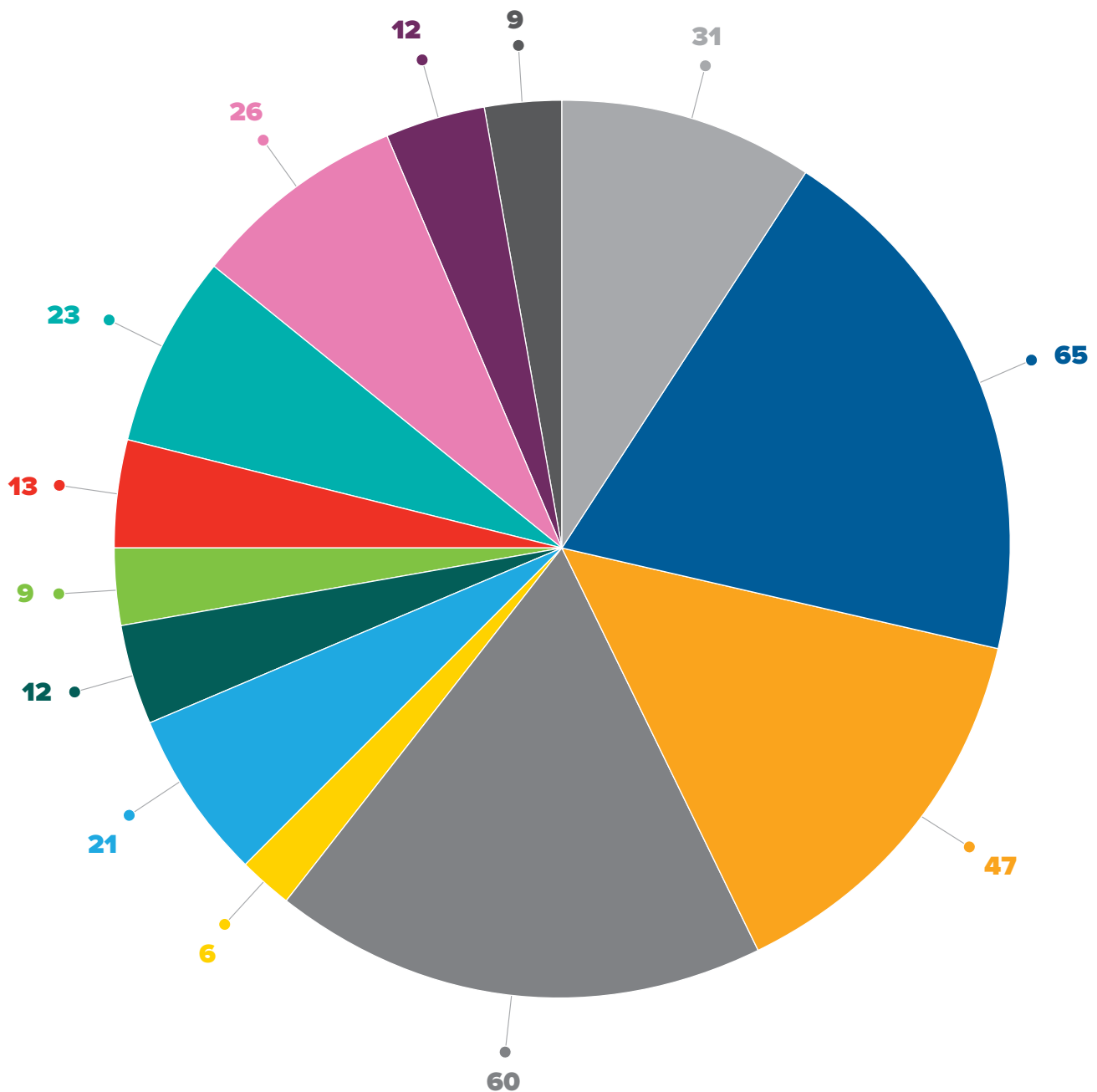
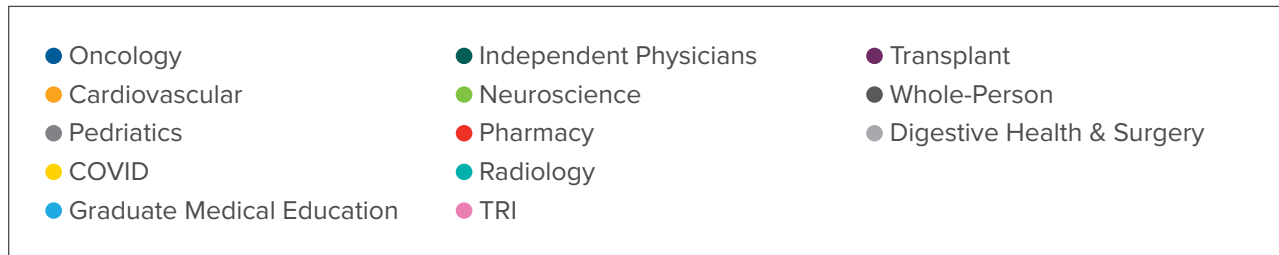
## Active Clinical Trials

The United States Food and Drug Administration (FDA) is the oldest comprehensive consumer protection agency in the U.S. federal government. The FDA's modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act, ensuring that food and drugs are properly tested and labeled. AdventHealth partners with sponsors to ensure that innovative new therapies and vaccines are properly tested according to scientific regulations for safety to "do no harm" and also effectiveness against target diseases. In 2020, AdventHealth engaged in 546 clinical trials.



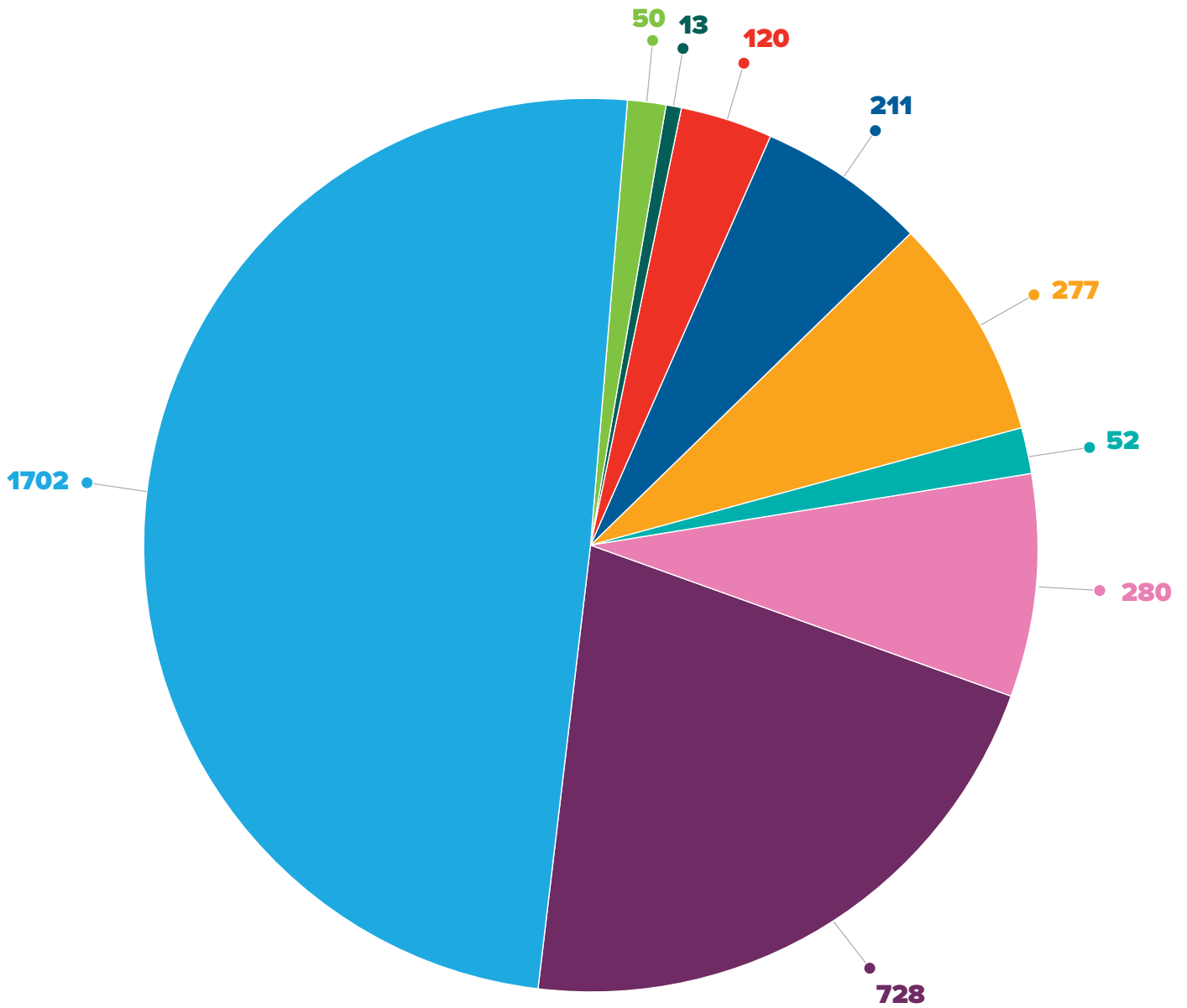
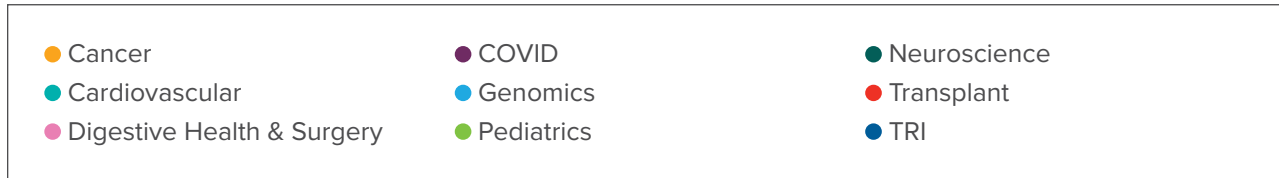
## Investigators by Department

In 2020, AdventHealth supported 334 investigators across a wide spectrum of departments.



## 2020 New Participant Enrollment

In 2020, AdventHealth enrolled 3,433 new participants in supported scientific studies.





# Whole-Person



The Center for Whole-Person Research is committed to exploring and assessing the evidence behind whole-person care. Our multidisciplinary team of researchers works to advance the AdventHealth Mission by improving patient experiences and outcomes while reducing healthcare costs in collaboration with our partners. Using whole-person care models and validated instrumentation, we focus on the science behind how the body, mind, and spirit contribute to wellness and lifelong flourishing. Using robust scientific methodologies, we guide patients, employees, clinicians, and entire communities to improved health and disease management. Through our study of mind-body-spirit models, we strive to help our community feel whole.

## Mission

To promote whole-person care by identifying, developing, and testing the scientific foundations of whole-person care.

## Vision

To transform health care delivery into our whole-person model of care, empowering our patients, employees, and communities to experience optimal wellness throughout their lives.

One model of whole-person care is the CREATION Life model, a wellness philosophy developed by AdventHealth. It consists of eight principles that guide overall mental, physical, social, and spiritual health: Choice, Rest, Environment, Activity, Trust, Interpersonal Relationships, Outlook, and Nutrition. Whole-Person Research supports the development and assessment of comprehensive and inclusive wellness initiatives to ensure the programs we offer to our patients, employees, clinicians, and communities are supported by scientific evidence.

## Areas of Focus

- Wellness of body, mind and spirit
- Transformative whole-person healthcare delivery
- Scientific foundation for CREATION principles™



8

Active Clinical Trials



3

2020 Publications



RESILIENCE · INSIGHT · SELF-COMPASSION · EMPOWERMENT

## Workforce Well-Being: The RISE<sup>®</sup> Story

Katherine had only been in nursing for nine months in a busy multisystem patient care unit when she saw a “burnout study” advertisement. Although still a novice, the challenges of caring for acutely ill patients were already taking a toll on her mental health. She knew she needed to do something, so she enrolled in RISE<sup>®</sup>, a randomized controlled study intended to help her invest in herself and regain the joy of the nursing profession.

Workforce well-being contributes to patient care quality and nurses’ job satisfaction. Unfortunately, nursing burnout rates had been rising even pre-pandemic, resulting in an RN shortage projected to impact health systems across the U.S. In response,

Principal Investigator **Amanda Sawyer, PhD**, and program developer and interventionist **Mandi Bailey, LMHC**, created RISE<sup>®</sup>, an evidence-based curriculum to help nurses flourish, remain at the bedside, and continue to provide excellent patient care.

RISE<sup>®</sup>, an acronym for **resilience, insight, self-compassion, and empowerment**, was developed to promote self-care, protect against burnout, and improve well-being indicators among nurses. RISE<sup>®</sup> was based on an integrative theoretical framework of mindfulness, acceptance and commitment therapy, and cognitive behavioral therapy. The study consisted of eight psychoeducational group sessions with topics related to the four RISE<sup>®</sup> themes, with the intent of furthering the understanding of effective interventions to mediate the detrimental effects of stress and burnout in nursing, in addition to improving nurses’ mental health and well-being amid the complex interplay of factors at the individual, unit, and organizational levels. As an approach that combined education with the therapeutic process and support to improve coping and well-being inside and outside the workplace, RISE<sup>®</sup> addressed the underlying causes and effects of high stress, burnout, and compassion fatigue. The intervention group’s results were compared to a control group who had to wait three months to start their sessions.

The RISE<sup>®</sup> intervention group showed improved insight, increased engagement in self-reflection, and reduced stress and burnout compared to the control group. The study participants also reported improved resilience, self-compassion, stress mindset, and perceived stress compared to the start of the study. This type of whole-person intervention can support nurses to improve their well-being and ability to cope with the stressors of a busy and challenging clinical environment. RISE<sup>®</sup> will continue to be studied in other high-impact target populations more subject to burnout, such as graduate nurses, ICU nurses, and nurse leaders.

Today, Katherine credits RISE<sup>®</sup> as a catalyst for her personal growth and reconnection with the joy of nursing. She is a role model, empowering nurses to impact patient care while cultivating a positive nursing culture and engaging in self-care. “My mental health impacts my patient care and the patient care of those I precept. RISE<sup>®</sup> empowered me to change my thinking and impacted how I spend my time. I realized others felt similarly; I was not alone.” As a new nurse educator with a pivotal role in nurturing nurses’ enthusiasm for direct patient care, she taps into her experience with RISE<sup>®</sup> to promote a nursing environment that will lead to the highest quality of patient care.

According to Katherine, “We need to focus on the nurses’ mind, body, and spirit - especially the spirit – and we need to take care of our staff the way we take care of patients.”

The health and well-being of our nurses are important for safe, quality patient care, positive relationships, high-functioning healthcare teams, and a healthy, engaged, and effective workforce. RISE<sup>®</sup> is an evidence-based strategy to address the whole-person health of our direct care nursing workforce.

*Sources: A Randomized Controlled Trial of the RISE Program for Nurses, featured on AdventHealth’s Whole Person Research Page, Spring 2020. Authored by Amanda T. Sawyer, Amanda K. Bailey, Jeanette F. Green, Jingwei Sun, and Patricia S. Robinson. doi:10.1177/10783903211033338.*

*Journal of the American Psychiatric Nurses Association, June 2021. Authored by Amanda K. Bailey, Amanda T. Sawyer, and Patricia S. Robinson. doi:10.1177/10783903211001116.*

“

“My mental health impacts my patient care and the patient care of those I precept. RISE<sup>®</sup> empowered me to change my thinking and how I spend my time. I realized others felt similarly; I was not alone.”

## Whole-Person Publications

### The CREATION Model: A Whole-Person Wellness Model to Facilitate Patient-Provider Partnerships for Health Promotion

With the rising prevalence of chronic disease, healthcare in the United States must move toward a wellness and preventive healthcare model that guides individuals to healthier behaviors. Primary care providers are uniquely positioned to help individuals recognize and implement needed health behavior changes. Previous wellness models are comprehensive and encompass mental, social, physical, and spiritual wellness; however, they do not provide a clear path to behavior change.

The whole-person wellness model, or the CREATION model, is based on eight whole-person elements: choice, rest, environment, activity, trust, interpersonal relationships, outlook, and nutrition. The model focuses on the relationship between individual choice and physical, psychological, social, and spiritual health.

The CREATION model posits that interventions that focus on an individual's mind, spirit, environment, and relationships will influence choices in a continuous cycle that reinforces positive, healthy behaviors, facilitating robust patient-provider partnerships that may help shift the healthcare delivery paradigm from an illness model to a wellness model.

Source: *Journal of Health and Social Sciences*, 2020. Authored by Gabriella A. Anderson, Amanda T. Sawyer, Stephanie L. Harris, and Patricia S. Robinson. doi:10.19204/2020/thcr8.



1. An intervention targets one or more of the mind/spirit elements.
2. A change in one or more of the mind/spirit elements influences choices.
3. Choices impact the body and/or mind/spirit elements.
4. Body and/or mind/spirit elements lead to mental, spiritual, and physical well-being.
5. Mental, spiritual, and/or physical well-being reinforces body and/or mind/spirit elements.
6. Mental, spiritual, and/or physical well-being influences choices.

## Evaluation of Neonatal Intensive Care (NICU) Healthcare Providers' Experience of Patient Ethics and Communication Excellence (PEACE) Rounds



Kim McManus, PhD



Patricia Robinson, PhD, ARNP

AdventHealth's **Kim McManus, PhD** Manager of Process Development, and **Patricia Robinson, PhD, ARNP**, Scientific Director of Research, sought to determine if Patient Ethics and Communications Excellence (PEACE) Rounds proved to significantly relieve distress by facilitating interdisciplinary discussions of clinically and ethically challenging issues associated with pediatric intensive care (PICU) patient care.

NICU healthcare providers face similar challenges and benefit from understanding the potential efficacy of PEACE Rounds in this setting. Therefore, researchers conducted interviews with 24 intervention participants, observed 12 interventions, facilitated a validation focus group, and performed a thorough analysis based on findings.

Our research showed that PEACE Rounds improved interdisciplinary communication and collaboration, relieved employee distress, and reduced ethics consultations. The application of PEACE Rounds in other clinical settings with qualified facilitators may improve interdisciplinary communication and reduce the need for ethics consultants.

Source: *Advances in Neonatal Care*, April 2020. Authored by Kim McManus, PhD and Patricia S. Robinson, PhD. doi:10.1097/ANC.0000000000000774.

## An Evaluation of Patient-led Care to Improve the “Whole-Person” Lifestyle

A group of AdventHealth officials examined the effects of a motivational interviewing intervention, or encouraging a patient's autonomy in decision-making, in improving the whole-person lifestyle and reducing the cardiovascular disease risk profile.

The study recruited a sample of 111 adults with type 2 diabetes and/or hypertension from a primary care physician practice to determine if this “whole-person lifestyle intervention” could improve health for patients with metabolic syndrome, a cluster of co-occurring conditions that increase the risk of heart disease, stroke, and diabetes.

The study evaluated multiple elements, including body mass index, cholesterol, blood pressure, and waist circumference. Wellness scores were also factored in via the WEL scale or the Wellness Evaluation of Lifestyle. WEL incorporates 20 scales, including sense of worth, sense of humor, exercise, love, and cultural identity.

Ultimately, body mass index and waist circumference changed between the intervention and control groups after six months; in the intervention group, the proportion of high wellness scores increased after the program. These findings reveal that efforts to improve the health of these patients may incorporate motivational interviewing to guide goal setting and address mental and spiritual health in addition to physical health.

Source: *Journal of Primary Care and Community Health*, May 2020. Authored by Amanda T. Sawyer, PhD, Jo Wheeler, Pamela Jennelle, Julie Pepe, PhD, and Patricia S. Robinson, PhD. <https://doi.org/10.1177/2150132720922714>.



# Translational Research Institute (TRI)



The Translational Research Institute (TRI) remains at the forefront of medical research, radically shifting our methods of conducting studies and trials.

In the following pages, you'll read how muscle cells from TRI study participants were sent to the International Space Station via a "lab-on-a-chip," evaluating the detrimental effects of microgravity on muscle health. Additionally, you'll learn how Central Floridians are helping researchers investigate the specific "why and how" of exercise benefits, as well as the effects of a drug meant to treat Type 2 diabetes on cardiovascular disease.

## Areas of Focus

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



58

Active Clinical Trials



52

2020 Publications

## Rocket Delivers Cell Samples to International Space Station to Study Effects of Microgravity on Muscles

Muscle cells from research study participants at AdventHealth's Translational Research Institute were flown to the International Space Station as part of an experiment intended to examine the effects of a weightless environment on muscle health. Launched in December 2020, the flight was a follow-up to a 2018 mission.

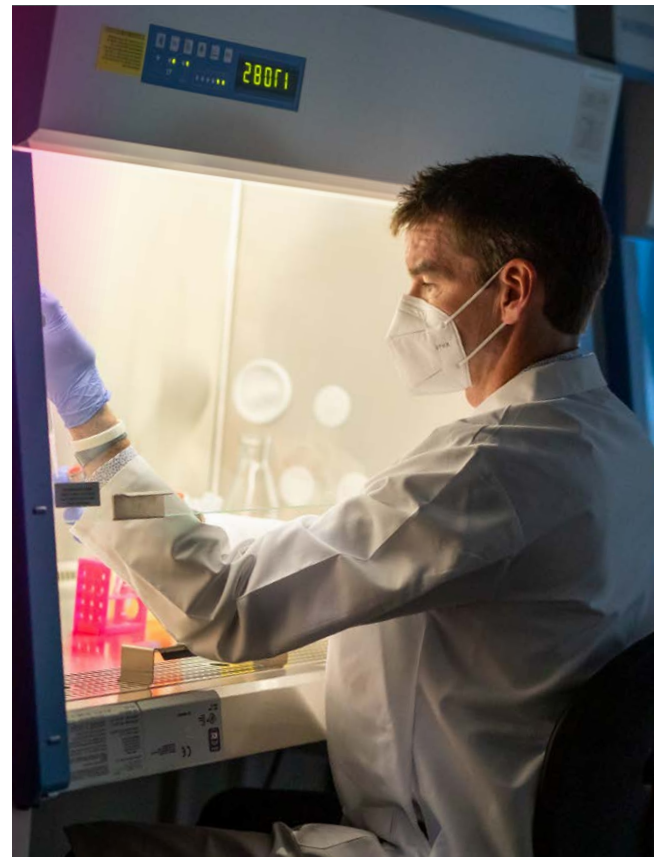
"We know microgravity has quite detrimental effects on skeletal muscle; after a long stay in space, astronauts come back in a very weak state and are often confined to wheelchairs until their muscle can recover," said **Paul Coen, PhD**, an investigator at the Translational Research Institute (TRI). "This experiment will allow us to study the effects of microgravity on muscle cell biology."

The samples were obtained from a study on aging and muscle loss conducted by Dr. Coen and supported by National Institute on Aging, an agency of National Institutes of Health. TRI researchers like Dr. Coen bridge the gap between the research laboratory and the patient's bedside to collaborate on clinical trials that tackle some of today's biggest health problems, such as obesity, diabetes, and cardiovascular disease. The findings from the flight will be important because the research can also be applied to find treatments for age-related muscle loss, known as sarcopenia.

The cells rode into orbit on a "lab on a chip" developed in part by Siobhan Malany, PhD, a scientist at Sanford Burnham Prebys and president of Micro-gRx. "Because the cells have a limited life span, there is only a brief window to study the effects of weightlessness," Malany said. "We hoped to get seven days of microgravity before the samples were preserved, frozen, and stored until they were brought back on a SpaceX Dragon capsule."

Each chip is slightly smaller than a business card, with four small squares. The entire "lab" was contained in a 10-by-30-centimeter box, including boards, electronics, pumps, fluidics, and a small microscope that took multiple images throughout the cells' trip in orbit.

Once returned, the team studied the gene expression changes in the cells sent to space compared to the cells remaining on earth.



### Diabetes Program Overview



**Richard Pratley, MD**

Diabetes affects more than 34 million people in the United States and more than 435 million globally, with numbers expected to grow significantly in the next 25 years. Diabetes is the leading cause of morbidity and the seventh leading cause of death in the U.S., costing the U.S. economy more than \$327 billion annually. In Central Florida alone, more than 10% of the population has diabetes, while approximately 28% of patients admitted to AdventHealth hospitals carry a diabetes diagnosis. Due to the magnitude and impact of the problem, diabetes has been a key area of focus within the Translational Research Institute (TRI) since its inception.

Led by **Richard Pratley, MD**, the Medical Director of the AdventHealth Diabetes Institute, the mission of the diabetes program is to advance diabetes prevention and treatment through research. The program's goal is to develop and grow a world-class, comprehensive clinical research program by recruiting top-tier clinical researchers in type 1 and type 2 diabetes and creating multi-disciplinary collaborative teams.

Dr. Pratley and investigators from the diabetes program have played key leadership roles in multicenter trials investigating new approaches to prevent type 2 diabetes and its complications in recent years; notably, the “D2d” study, which enrolled more than 75 patients at the TRI testing whether Vitamin D supplementation could delay the onset of diabetes. Dr. Pratley has also helped lead studies of new drugs for the treatment of type 2 diabetes and prevention of complications, including ertugliflozin, an SGLT-2 (transport protein) inhibitor which was shown to decrease the risk of heart failure by 30%, and efglenatide, a GLP-1 (hormone) receptor agonist which decreased the risk of cardiovascular events by 27%.

**Tina Thethi, MD**, the TRI’s Medical Director who recently joined the diabetes program, focuses on developing new diagnostic and treatment approaches for diabetic kidney disease (DKD), which disproportionately affects certain populations, including African American and indigenous people in the U.S. Dr. Thethi hopes her interest in health disparities will lead to new modalities to treat DKD in these high-risk populations.

“

This is a great opportunity for Central Floridians to play a role in major research that can shape how we understand and maximize the disease-fighting properties of exercise in the future.”

*Bret Goodpaster, PhD*

The prevention and treatment of type 1 diabetes is a major focus of diabetes program investigators, and work in this area has rapidly expanded under the direction of **Anna Casu, MD**, the von Weller Family Chair in Type 1 Diabetes Research. Dr. Casu was recruited to the TRI just over two years ago from Palermo, Italy, where she developed and led a successful islet transplant program to treat type 1 diabetes. The type 1 diabetes study portfolio includes a National Institutes of Health (NIH) study focused on the prevention of type 1 diabetes (TrialNet), a study funded by The Helmsley Charitable Trust that tests a

potential new treatment to prevent hypoglycemia (low blood sugar), and an NIH Research Project Grant study examining advanced insulin delivery in older individuals with type 1 diabetes. The latter study builds directly on research recently published by Dr. Pratley and his colleagues, demonstrating that continuous glucose monitoring could reduce the incidence of severe hypoglycemia by 90% in older adults with type 1 diabetes.

Drs. Pratley and Casu are also investigators on two NIH consortia. The first is the New-Onset Diabetes Study, which aims to build a cohort of 10,000 patients to study the relation of new-onset diabetes to pancreatic cancer; the second, called the Type 1 Diabetes Acute Pancreatitis Consortium, will study the risk for diabetes among patients who suffer an episode of acute pancreatitis. To further their research, Drs. Casu and Pratley, and Translational Research Institute Scientists Heather Cornell, PhD, Carley Glass, PhD, and Yury Nunez-Lopez, PhD, are developing and testing advanced methods to image the pancreas using the TRI’s MRI and novel biomarkers of pancreatic function called extracellular vesicles. The latter research has been funded by a grant from the Miller Foundation, which provided necessary equipment to characterize extracellular vesicles and conduct a pilot study in children with recent-onset type 1 diabetes.

Sources:

*The New England Journal of Medicine, August 2019. Authored in part by Richard Pratley, MD. doi: 10.1056/NEJMoa1900906.*

*The New England Journal of Medicine, October 2020. Authored in part by Richard Pratley, MD. doi:10.1056/NEJMoa2004967.*

*The New England Journal of Medicine, September 2021. Authored in part by Richard Pratley, MD. doi: 10.1056/NEJMoa2108269.*

*The Journal of the American Medical Association, June 2020. Authored in part by Richard Pratley, MD. doi: 10.1001/jama.2020.6928.*



**Tina Thethi, MD**



**Anna Casu, MD**

## Clinical Research Roundup

### Central Floridians are Helping Researchers Determine the Overall Benefits of Exercise in Study on Physical Activity



**Bret Goodpaster, PhD**

AdventHealth's Translational Research Institute (TRI) is one of 11 nationwide sites in a three-year NIH Common Fund study to discover why exercise helps the body's cells and organs at a molecular level. The study, Molecular Transducers of Physical Activity in Humans (MoTrPAC), evaluates sedentary to active individuals across Central Florida to determine the overall benefits of movement.

"Exercise can be very powerful. This is the first large-scale study to investigate why and how it works," said **Bret Goodpaster, PhD**, the TRI's Scientific Director. Goodpaster and his team are seeking 150 - 200 volunteers, classified into three groups: the sedentary, aerobic athletes (such as cyclists), and anaerobic athletes (such as bodybuilders). The sedentary group will be placed on a 12-week exercise program, with some subjects cycling and doing other aerobic activities and others focusing on weight training. Researchers will collect blood and tissue samples from all three groups before and after exercise, Goodpaster said. These volunteers will be among 1,500 - 2,000 participants nationwide. The blood and tissue samples will be sent for chemical analysis to sites including the Mayo Clinic and Stanford University. "MoTrPAC is here, and we're excited that Central Floridians will play a role in major research that can shape how we understand and maximize the disease-fighting properties of exercise in the future."

Source: Cell.com. Authored in part by Bret Goodpaster, PhD <https://doi.org/10.1016/j.cell.2020.06.004>.

### Bridging the Gap: Understanding Obesity in Samoa



**James DeLany, PhD**

AdventHealth TRI Senior Investigator **James DeLany, PhD**, identified a fundamental gap in our understanding of the high prevalence of obesity in Samoa, which is currently among the highest observed across the globe. Over 80% of Samoan adults are overweight or obese, with 21.5% having a Body Mass Index, or BMI, greater than 40 (anything over 30 is considered obese). Thus, Dr. DeLany initiated a longitudinal study in 2019 with the overarching objective of gaining insight into the metabolic differences responsible for this excess weight gain.

Dr. DeLany and his team identified a novel missense variant, or a genetic alteration, highly associated with BMI. Based on the team's observations gleaned from similar studies evaluating the relationship between RMR and energy requirements in African American and Caucasian women, and that the majority of genes known to contribute to human obesity do so primarily by influencing the central control of energy intake and/or expenditure, the team proposed to determine the role that energy expenditure and energy intake play in the increased obesity risk in the Samoan population associated with identified missense variant.



Dr. DeLany's team was ideally positioned to conduct these studies due to their long-term experience working with obesity and health risks in the Samoan population and their extensive experience assessing energy and substrate metabolism. They hypothesized that a lower resting metabolic rate (RMR), or the total number of calories burned when a body is completely at rest, is involved. Although the study is still underway, Dr. DeLany and his team believe it will provide novel and important insight into the metabolic differences responsible for the excess weight gain in those with the missense variant playing a significant role in the extreme prevalence of obesity in Samoa. This research will advance the understanding, prevention, and appropriate treatment of obesity and heart diseases in this high-risk population.



## AdventHealth Research Institute (AHRI) Completes a Study Aimed at Evaluating the Contribution of the Gut Microbiome to Human Metabolism



**Karen Corbin, PhD, RD**

Most of us have thought about our metabolism at some point in our lives and how we can change our lifestyle to optimize it. Then, about two decades ago, the entire paradigm of metabolism changed. We learned that trillions of bacteria and other microorganisms colonize the human body. The ones in the gut, called the gut microbiome, impact how efficiently we extract energy (calories) from food, the effectiveness of some medications, and multiple other aspects of human health.

**Karen Corbin, PhD, RD**, is an Investigator at the AdventHealth Translational Research Institute and the lead author of “Integrative and quantitative bioenergetics: Design of a study to assess the impact of the gut microbiome on host energy balance” published in Contemporary Clinical Trials Communications in August 2020. This paper expounded on the design employed during a study completed at the AdventHealth Translational Research Institute that evaluated the quantitative contribution of the gut microbiome to human metabolism (NCT02939703). The work was a collaboration with a large team from AHRI and Arizona State University led by Dr. Steven R. Smith and Dr. Rosy Krajmalnik-Brown, respectively.

Since the initial discovery of the profound impact of the gut microbiome on human physiology, many clinical studies have been conducted surrounding the topic. However, what is missing in the current literature is an approach that determines how the gut microbiome and its bioenergetics quantitatively change the absorption of nutrients, enteroendocrine secretions, or energy expenditure of the human host.

To address this important knowledge gap, AHRI researchers implemented an innovative and rigorous design to determine whether the gut microbiome and its bioenergetics quantitatively change host energy balance. The study’s primary objective was to determine differences in energy balance after consuming a Western Diet (control) versus a Microbiome Enhancer Diet intervention intended to optimize the gut microbiome for positive impacts on host energy balance.

The AdventHealth Translational Research Institute is a global leader in the assessment of human metabolism. The study’s central technological innovation involved measuring energy expenditure and the use of substrates (carbohydrates, proteins, and fats) in whole-room indirect calorimeters. Only 43 institutions worldwide have whole room calorimeters. The ones at AHRI are exceptionally precise and the only ones capable of measuring compounds produced by microbes, such as methane.

Large clinical trials are expensive. Increasing the precision of measurements and deeply understanding participant characteristics helps reduce the costs. AHRI accomplished this by using a prospective design with comprehensively evaluated participants, adequate dietary and environmental controls, and initial studies in healthy individuals to characterize expected responses.

The AHRI team completed the study utilizing this integrated approach in late 2019. The team generated high-quality data that is amenable to quantitative interrogation and is currently being analyzed. The data generated in the clinical study will support the development of a mathematical model that integrates human and microbial metabolism. Our entire understanding of the calorie content of foods does not currently account for how the gut microbiome impacts energy absorption and utilization by the human host. Therefore, the results of this work will help redefine our understanding of the impact of diet on weight regulation and overall health.

## AdventHealth and BERG Collaborate to Advance Aging, Metabolism, and Nash Research

AdventHealth's Translational Research Institute is working in conjunction with BERG. This clinical-stage biotech company employs patient biology and artificial intelligence (AI) to research diseases and develop innovative treatments to comprehensively study various age-related metabolic, neurological, and musculoskeletal disorders.

The study comprises several separate investigations that employ BERG's Interrogative® platform to examine potential biomarker signatures of age-related diseases, such as sarcopenia, or age-related loss of muscle tissue, and Non-Alcoholic Steatohepatitis (NASH), or liver inflammation and damage caused by a buildup of fat in the liver.

The research currently being conducted investigates five studies, including the use of AI to define signs of aging skeletal muscle and response to exercise and the integration of varying analysis types to predict declines in physical function in aging.

"BERG's AI platform will be invaluable for developing an optimal strategy to collect and monitor clinical data across a variety of age-related disorders and to understand the biological mechanisms underlying the aging process, along with the benefits of nutritional and exercise therapies," said **Bret Goodpaster, PhD**, Scientific Director of the Translational Research Institute at AdventHealth.

According to BERG's President and CEO, Dr. Niven R. Narain, the biopharma sector continues to dedicate resources to studying age-related diseases; however, progress has been slow.

"Partnerships like these with AdventHealth will be a game-changer," said Dr. Narain. "BERG and AdventHealth scientists will collaborate to enable the patient biology, functional phenotypes, and longitudinal studies to power unbiased hypotheses that can be readily validated within the AdventHealth ecosystem. As we go forward, we will seek to advance the field to drive biomarker, and therapeutic insights into novel disease mechanisms."

*Source: Cision, December 2020.*



# Cancer



AdventHealth Cancer Institute (AHCi), Central Florida's largest cancer center, is recognized worldwide for its comprehensive, state-of-the-art care and reputation as a destination cancer care facility. AHCi research initiatives span clinical and translational research and research in population health and value-based care, precision medicine, and pharmacogenomics.

In this section, we share highlights from studies of lung cancer, bladder cancer, and cervical cancer, in addition to sharing why AHCi's Executive Medical Director has been ranked one of the Top 10 Lung Cancer Specialists in the US. Additionally, one research participant shares how her involvement in a life-saving ovarian cancer treatment study encouraged her to fight on behalf of others.

Due to its commitment to improving the care of cancer patients through pivotal clinical trials, the AHCi was one of just 12 community oncology programs to be honored by the American Society of Clinical Oncology.

## Areas of Focus

- Brain and Spine Cancers
- Breast Cancer
- Digestive Tract Cancers
- Gynecologic Cancers
- Head, Neck, and Skin Cancers
- Leukemia, Lymphoma, Myeloma & Blood Cancers
- Lung & Esophageal Cancers
- Urologic Cancers



**256**

Active Clinical Trials



**115**

2020 Publications

## AdventHealth Cancer Institute (AHCI) Executive Medical Director Mark Socinski, MD Among Top 10 Lung Cancer Specialists in the US



**Mark A. Socinski, MD**

**Dr. Mark A. Socinski** was ranked fifth out of ten on the 2020 Top 10 Specialists in Lung Cancer list compiled by Expertscape, a platform used for discovering physicians excelling in the treatment and diagnosis of specific disease states. A specialist in all thoracic malignancies, Dr. Socinski is an internationally recognized expert in developing novel chemotherapy agents and treatment strategies for lung cancers. His research incorporates personalized medicine and molecular biomarkers in treatment.

Expertscape selected physicians based on their commitment to advancing the understanding and treatment of lung cancer through scientific publication. Most recently, Dr. Socinski published an article entitled “Atezolizumab in Combination With Carboplatin and Nab-Paclitaxel in Advanced Squamous NSCLC (IMpower131): Results From a Randomized Phase III Trial.”

The study, published in the *Journal of Thoracic Oncology*, sought to evaluate the effects of combining atezolizumab, a cancer drug, with chemotherapy in treating stage IV Non-Small Cell Lung Cancer. A total of 1021 patients were randomized, and it was determined that adding the drug to chemotherapy significantly improved progression-free survival in patients.

*Source: Journal of Thoracic Oncology, April 2020. Authored in part by Mark Socinski, MD. doi:10.1016/j.jtho.2020.03.028.*

## Clinical Research Roundup

### AdventHealth Cancer Institute Participates in Global Study for Bladder Cancer



**Carlos A. Alemany, MD**

The AdventHealth Cancer Institute (AHI) is supporting a clinical trial to determine if pembrolizumab, a cancer immunotherapy drug used in combination with chemotherapy and surgery, is more effective than a placebo used with chemotherapy and surgery for the treatment of muscle-invasive bladder cancer.

The current standard of care for muscle-invasive bladder cancer (MIBC) is chemotherapy alone, which acts as a bladder-preserving treatment option in select patients and works to keep the bladder intact while treating the cancer. This global study, sponsored by Merck Sharp & Dohme Corp, aims to determine if combining the drug with chemotherapy will help patients live longer in addition to experiencing an improved quality of life. There is a clinical need for improved therapies for patients with MIBC, and the evidence of clinical activity of pembrolizumab across disease states provides a strong rationale for the addition of the drug to chemotherapy. **Carlos A. Alemany, MD**, is the Principal Investigator for this study and acts as the Medical Director for AHCI's Clinical Research Department.

*Source: Clinicaltrials.gov, Clinical Trial Registry Number NCT04241185.*

## Study Aims to Compare the Results Between Open and Minimally Invasive Radical Hysterectomies in the Treatment of Cervical Cancer



**Robert Holloway, MD**

ACHI physician **Robert Holloway, MD**, participated in a retrospective review to compare the success rates of patients with cervical cancer treated with abdominal surgery versus those with minimally invasive radical hysterectomy.

This multi-institutional study evaluated a total of 815 patients, and it was determined that those who underwent minimally invasive hysterectomies had an increased likelihood of cervical cancer recurrence.

*Source: Journal of Clinical Oncology, April 2020. Authored in part by Robert Holloway, MD. doi:10.1200/JCO.19.03012.*

## Retired Teacher Enjoys Retirement Following Participation in Life-Saving Clinical Trial

In January 2012, Karen was diagnosed with ovarian cancer. She completed her first line of treatment in Pittsburg, where she and her husband Joe worked as longtime schoolteachers. With a family history of cancer and her own diagnosis, Karen was determined to fight this disease. Inspired by the Komen sisters, Karen became an active participant in 5k races and any other event she could find related to the cause.

Later, in January 2014, Karen was also diagnosed with breast cancer.

When Karen and Joe retired and moved to Florida, she found Robert Holloway, MD at AdventHealth. When her second round of chemotherapy wasn't successful, Dr. Holloway invited Karen to participate in a new research study for ovarian cancer treatment. This revolutionary immunotherapy treatment uses a variation of smallpox to defeat cancer. AdventHealth is the only hospital in the United States to participate in this life-saving clinical trial. In September 2016, Karen participated in the research study. In 2019, Karen and Joe were enjoying their retirement in the Florida sun.

Karen Bierer always knew she would leave a gift for charity in her will. Her appreciation for receiving expert, life-changing care led Karen to inquire about making a planned gift to AdventHealth Cancer Institute. As a result, Karen donated directly to the cause in addition to making provisions in her will.

According to Karen, "We give so other people who might not be as fortunate as us, have a chance to beat this disease. I am a dog in the fight. Dr. Holloway is an expert in the field, and he is dedicated and passionate about what he does."

Karen continues to donate and stay active in events benefiting AdventHealth Cancer Institute. When asked about the incredible personal legacy she has created, Karen explains the mantra behind it all - "We believe in helping each other. We've always felt fortunate."

# Cardiovascular



The Cardiovascular Institute conducts research that helps patients gain access to innovative and promising new treatments and technologies before they become the standard of care. The department offers the latest cutting-edge, patient-focused research while leveraging deep clinical and scientific expertise.

This section reviews how the current global crisis has placed cardiothoracic surgeons at the forefront of leadership and ingenuity due to the challenge of defining a new normalcy for an unprecedented era in health care. In addition, we share a story about a successful double lung transplant following participation in a clinical trial.

Finally, we discuss a clinical trial surrounding a device designed to combat cardiovascular disease, improving blood pressure, heart rate, and quality of health. The highest enrolling trial site in Florida, AdventHealth Orlando treats more cardiovascular surgery patients than any other hospital in the state.

To understand the future of cardiovascular medicine, we need to look to the researchers who have led us to where we are today – like the researchers at AdventHealth Cardiovascular Institute. With a world-renowned team of scientists and physicians and a close partnership with the cardiovascular team, our researchers use groundbreaking science to conduct lifesaving research, providing patients with early access to promising new treatments and technologies.

We treat nearly 80,000 patients each year, ranging from routine arrhythmia treatments and preventative cardiology to minimally invasive vascular surgery and heart and lung transplants. In addition, the Institute works to pair hundreds of patients, some facing life-threatening diagnoses, with cutting-edge research studies and clinical trials. Thus, the Institute creates a seamless research experience through our coast-to-coast network of hospitals and heart specialists to simplify the “bench-to-bedside” process and ensure that our patients receive the most effective care available.

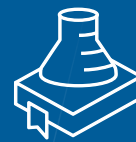
## Areas of Focus

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



39

Active Clinical Trials



20

2020 Publications



**Rohit Bhatheja, MD**

Award-winning **Rohit Bhatheja, MD** is the medical director at the AdventHealth Cardiovascular Institute, one of the top cardiac centers nationwide, which offers the latest in patient-focused, high quality, cutting-edge research partnering with the Cardiovascular Research Department. The department leverages deep clinical and scientific expertise to address important questions impacting the community's health. An experienced team of physicians and research nurses enroll participants in a broad range of randomized trials and registry-based research studies to help patients gain access to innovative and promising new treatments and technologies before they become the gold standard of care.

As a frontrunner in cardiac research, AdventHealth employs a multidisciplinary team of subspecialized cardiologists, like interventional cardiologist electrophysiologists, cardiac surgeons, and vascular surgeons, to ensure that each patient receives complete, end-to-end care.

Current cardiac research is forward-looking, so Dr. Bhatheja and his team are focused on rectifying a lack of evidence-based medicine in the field. "Our laser point focus is to collect evidence-based data with minimal to no harm to our patients, and then add that to a big bucket of FDA-approved studies," said Dr. Bhatheja. "We are a part of the future – if there is a new medicine, device, or procedure for cardiac care, we will be able to offer it to patients in our community. Since we are at the forefront of that research, there is no learning curve for our team. Any diagnosis isn't that far from cardiovascular care, and we have been directly involved or collaborated with other specialties to conduct this research."

Dr. Bhatheja has been an integral part of hundreds of local, national, and international studies over the past decade, acting as the Principal Investigator for many of them, including an Early Feasibility Study, or EFS, for a device that provides minimally invasive care for patients with acute pulmonary embolism or blood clots. The device, sponsored by Thrombolex, works to dissolve the clot through a concentrated micro-dose of blood thinners and "clot-busting" drugs. AdventHealth used this procedure to treat three of only nine U.S. patients. FDA approval was given for institutes nationwide to enroll patients in what is referred to as a pivotal study; trial enrollment is ongoing.

AdventHealth's Cardiovascular Research Department has housed many landmark clinical trials, including the study of the Diamondback 360 Coronary Orbital Atherectomy System (OAS), an adjunctive therapy used to remove calcified plaque by inserting a bullet-shaped, crystal-covered device into the arteries intended to "chisel off" this calcified plaque to facilitate optimal stent delivery in patients with coronary artery disease (CAD). The Cardiovascular Research Department has worked with the Diamondback 360 throughout its entire lifecycle, beginning with a clinical study and multiple iterations before receiving full FDA approval. As a result, AdventHealth's Cardiac Center is now one of the top ten U.S. users. Dr. Bhatheja is a National Proctor for the device and has trained interventional cardiologists across the country to utilize the device.

While Dr. Bhatheja has been associated with 22 major research areas, he is most passionate about preventative cardiology. "I don't like to see my patients on the procedure table – I try to keep them away," says Dr. Bhatheja. And with the Cardiovascular Research Department's commitment to advancing the future of medicine through innovation and education, the patients can do just that.

## Clinical Research Roundup

### AdventHealth at the Forefront of Groundbreaking Device for Heart Failure Patients



**Nirav Ravel, MD**

AdventHealth Orlando was one of Florida's highest enrolling trial sites for a new pacemaker-like device, the Barostim Neo, which treats heart failure by altering nerve activity and normalizing nervous tissue function.

Physicians at AdventHealth Orlando were among the earliest in the U.S. selected to use the Barostim Neo, which stimulates a group of cells, called baroreceptors, to balance the body's fight or flight response when the heart is overstimulated.

The device is the first of its kind to fight cardiovascular disease. A three-phase clinical trial revealed that patients implanted with the device reported improved blood pressure, heart rate, and overall quality of life. In addition, these patients were more likely to exercise, work, and participate in hobbies.

**Nirav Ravel, MD**, medical director of thoracic transplant at AdventHealth Transplant Institute, is the Principal Investigator for the study for AdventHealth. He was on the ground floor of the device's development, first getting involved in early 2012.

"Investments in research and novel technologies are improving lives in ways we've never seen before," Ravel said. "With a growing number of Americans suffering from heart failure, developing less invasive, cost-effective devices to extend lives has become increasingly important. The Barostim Neo is a step in that direction — improving heart failure to give patients the ability to enjoy a better quality of life for a longer period."

"The Barostim Neo gave me my life back," said Eric Berkowitz, a patient in the clinical trial at AdventHealth Orlando. "The device allows me to walk a two-mile track with my dog without panting and once again participate in the activities I've always enjoyed."

*Source: AdventHealth Research Institute, February 2020.*





# Neuroscience



The research being done at the Neuroscience Institute is advancing the science of medicine in disease-focused research, working to improve diagnosis, treatment, and functional outcomes to reduce disease severity for patients suffering from neurological disorders to enhance the quality of life.

In the pages that follow, you'll read about an AdventHealth physician working to incorporate augmented reality to perform spinal surgery, developing a different approach that focuses exclusively on a spine surgeon's needs.

Additionally, we'll provide you with an in-depth look into our research initiatives encompassing cutting-edge pharmaceutical and medical devices, clinical registries, and physician-initiated trials. Finally, we'll share information about our current research, including a study on aneurysms, a clinical trial for treating a devastating pediatric neurological condition, and explain how cutting-edge surgery is conducted through our Minimally Invasive Brain Surgery program.

## Areas of Focus

- Alzheimer's Disease
- Brain Tumor
- Epilepsy
- Healthy Brain
- Movement Disorders
- Neurodegenerative Disorders
- Pain Management
- Spine
- Stroke



**36**

Active Clinical Trials



**18**

2020 Publications



**Chetan K Patel, MD**

*Executive Medical Director,  
Spine, AdventHealth  
Neuroscience Institute*

*Section Chair, Robotics  
& Navigation, North  
American Spine Society*

## Is Augmenting Reality the Next Frontier in Spine Surgery?

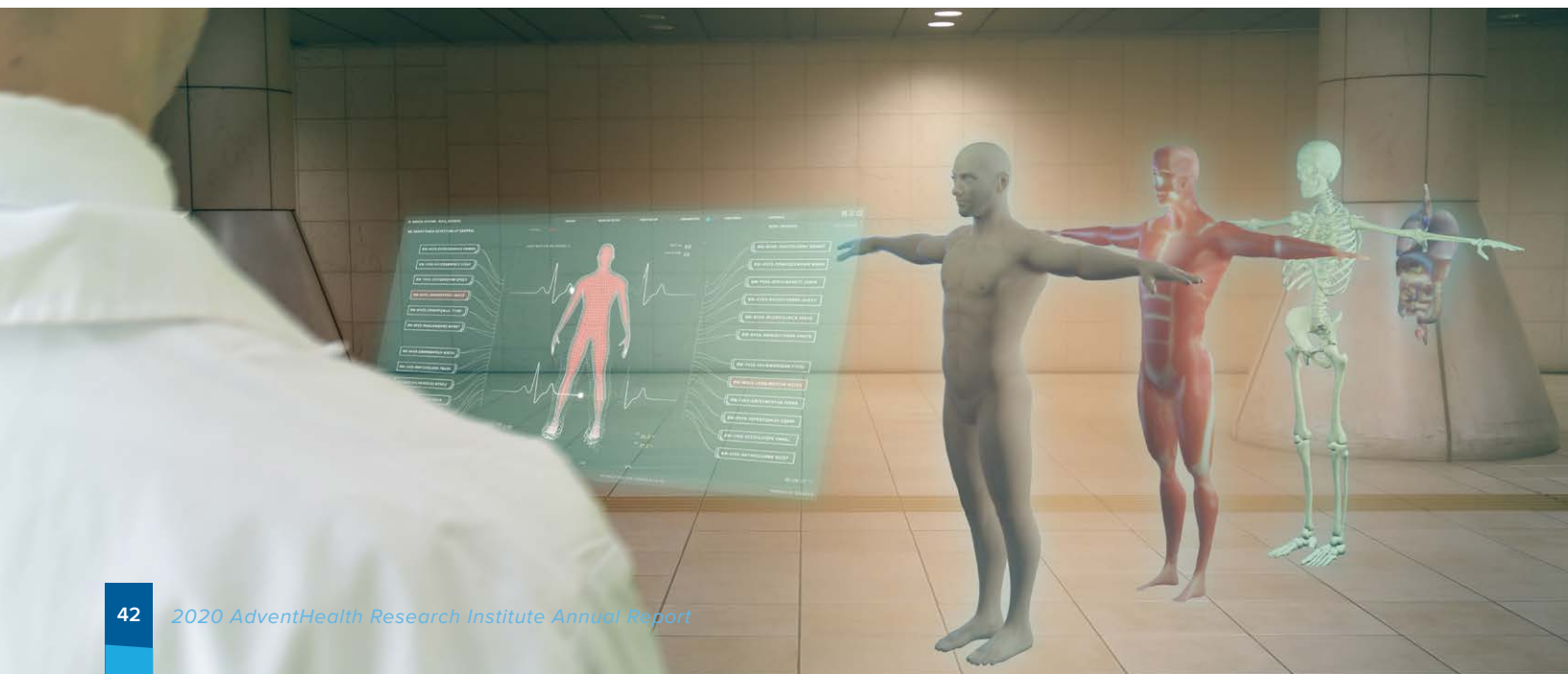
Each year, surgeons perform more than one million instrumented spinal procedures in the United States. While the rise in computer-assisted surgical navigation and robotics technology has improved outcomes, significant challenges remain. AdventHealth’s **Chetan Patel, MD**, is the Executive Medical Director, Spine, for the AdventHealth Neuroscience Institute and has been exploring various options for incorporating Augmented Reality (AR) into spine surgery since 2013.

Attention shift — the need for surgeons to look away from the patient during the surgical procedure to access information on a screen — remains the greatest challenge and can decrease the surgeon’s cognitive and motor task performance. AR could provide a solution that will improve both surgical efficiency and patient outcomes by superimposing contextually relevant patient information to be easily and readily available to the surgeon without ever looking away from the patient to a screen. In spine surgery, the aim is to improve patient safety and clinical outcomes while reducing overall procedure time.

Dr. Patel has worked extensively to evaluate different approaches as technology advances and is developing a different approach that focuses exclusively on a spine surgeon’s needs. These needs can be met with existing technology in a cost-efficient package called iSight™, which addresses the limitations of current technologies.

### Evolving the AR Approach to Benefit Patients and Surgeons

As anticipated, the iSight™ AR system, which has been in use since May of 2020, has mitigated the surgeon’s attention shift away from the patient, thus offering improved safety and efficiency. Preliminary data suggest a 25-55% improvement in the time required to place pedicle screws, less anesthetic time, potentially less blood loss, and improved clinical outcomes. The system also has a minimal learning curve and is cost-effective because it uses current technology and does not require the surgeon to acquire new skills.





## Clinical Research Roundup

### AdventHealth Neuroscience Research Institute Supports Aneurysm Study



Frank R. Hellinger, MD

AdventHealth's Neuroscience Research Department supported a preliminary clinical trial on the safety and efficacy of a pipeline embolization device (PED) to treat small/medium aneurysms.

A total of 141 patients were treated at multiple sites, and it was determined that 76.7% of patients treated achieved favorable results. Ultimately, the study determined that the PED was a safe and effective alternative to surgery and other conventional techniques. Neuroradiologist **Frank R. Hellinger, MD**, was the Principal Investigator at the AdventHealth site.

Source: *Journal of NeuroInterventional Surgery*, January 2020. Authored in part by Frank R. Hellinger, MD. Clinical Trial Registry Number NCT02186561. <http://dx.doi.org/10.1136/neurointsurg-2019-015091>.

### AdventHealth Pediatric Epilepsy Medical Director Dr. Ki Hyeong Lee Seeks Treatment for Devastating Pediatric Neurological Condition



Ki Hyeong Lee, MD

**Ki Hyeong Lee, MD**, Medical Director of the Comprehensive Pediatric Epilepsy Center at AdventHealth for Children, was part of an international cohort studying febrile infection-related epilepsy syndrome (FIRES), a devastating neurological condition characterized by a sudden onset of constant seizures.

With mounting evidence that innate immune dysfunction acts as an underlying cause for FIRES, Dr. Lee worked with a group of physicians to determine if Anakinra, a drug used to modify or modulate the immune system, would be an effective treatment for FIRES.

Ultimately, Dr. Lee and the team determined that children who received earlier treatment with Anakinra experienced a shorter duration of mechanical ventilation, shorter ICU length of stay, and decreased hospital length of stay.

This data serves to potentially lay the groundwork for the continued study or implementation of Anakinra for the treatment of FIRES.

Source: *Annals of Clinical and Translational Neurology*, December 2020. Authored in part by Dr. Ki Hyeong Lee, MD. doi:10.1002/acn3.51229.

# Digestive Health and Surgery



The AdventHealth Digestive Health and Surgery Institute 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).

In the following pages, we'll share 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
- Ear, Nose, and Throat
- Fatty Liver Disease
- Gastroenterology
- General Surgery
- Inflammatory Bowel Disease (IBD)
- Ophthalmology
- Plastic Reconstructive Surgery
- Urology



50

Active Clinical Trials



35

2020 Publications

# The AdventHealth Digestive Health and Surgery Institute Continues to Innovate and Expand

Over the years, the Digestive Health and Surgery Institute has become a destination hospital for digestive health, earning a reputation for high-quality care as the largest interventional endoscopy center in the U.S.

The Institute is one of two Nationally Accreditation Programs for Rectal Cancer (NAPRC) “Commission on Cancer” accredited Centers of Excellence for rectal cancer in Florida and the third center established in the U.S.

The Institute sees the largest volume of complex inflammatory bowel disease (IBD) surgery patients in Florida and is home to the inventors of the transanal minimally invasive surgery (TAMIS) technique, lauded as pioneers in colorectal robotic surgery and minimally invasive approaches.



## Clinical Research Roundup

### AdventHealth Team Defines the Learning Curve for New Excision Method for Rectal Cancer

Physicians from AdventHealth’s Center for Colon and Rectal Surgery determined the number of cases required to achieve proficiency in transanal total mesorectal excision for rectal adenocarcinoma (TA-TME), a new method for removing rectal cancer.

While the surgery is safe and feasible, it is technically challenging and requires a high level of expertise. The physicians, who included **Dr. John Monson**, the Executive Director for Colorectal Surgery at AdventHealth, concluded that the complex technique requires a minimum of 45 – 51 cases to become proficient.



**John Monson, MD**

Source: *Surgical Endoscopy*, April 2020. Authored by AdventHealth physicians Lawrence Lee, MD, Justin Kelly, MD, George J. Nassif, DO, Teresa C. deBeche-Adams, MD, Matthew R. Albert, MD, John Monson, MD. doi:10.1007/s00464-018-6360-4.

# Orthopedics



The orthopedic experts at AdventHealth Orlando strive to develop deeper knowledge through the advancement of research and education and is led by nationally renowned orthopedic traumatologists and surgeons.

In the following pages, you will learn about the future home of the Rothman Orthopaedic Institute and new developments in the diagnosis of patellar osteoarthritis.

Our Mission is to improve the quality of care and outcomes for patients with musculoskeletal diseases or trauma. We conduct studies to advance medical/surgical treatments and techniques to improve our patients' quality of life.

## AHRI Physician Proposes the Use of Stem Cells for the Non-Operative Treatment of Small Rotator Cuff Tears



**Tariq Awan, DO**

AdventHealth Research Institute physician **Tariq Awan, DO**, will act as the co-Principal Investigator on a study evaluating the use of Stromal Vascular Fraction (SVF) cells for the non-operative treatment of partial to small rotator cuff (RC) tears.

Currently, there is no “gold standard” treatment for partial and small rotator cuff tears, so this study, funded by an NIH/NIAMS R21 grant, aims to determine the clinical efficacy of SVF cell injection to augment conservative management. These tears have been shown to progress in size, and the progression is often accompanied by a deterioration in muscle quality and the redevelopment of symptoms. Investigators believe this may be attributed to conservative management, which does not facilitate structural healing of the tear and is associated with a heightened risk for future intervention.

### Areas of Focus

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

Adipose-derived stem and progenitor cells have shown extensive promise in the field of soft tissue regeneration, and due to the ease and relatively noninvasive nature of harvesting these cells with a small, percutaneous liposuction, they present an attractive biologic treatment able to augment standard conservative management of tears.

The trial will assess the efficacy of injecting SVF cells into partial and small RC tears by comparing patients injected with the cells to patients injected with saline. Study participants will be recruited from AdventHealth Orlando's sports medicine practice and the surrounding primary care physician network. The participants will undergo physical therapy in conjunction with the injection. The clinical outcome will be assessed using patient-reported outcomes and strength testing, while MRI will evaluate structural healing.

The team hypothesizes that patients treated with SVF cells will experience higher two-year RC healing rates and superior two-year clinical outcomes.

## AdventHealth Research Institute and Rothman Orthopaedic Institute – The Future of Orthopedic Research



**Daryl Osbahr, MD**

In 2020, AdventHealth and Philadelphia-based Rothman Orthopaedic Institute announced a long-term partnership to promote innovation in the orthopedic space, intended to provide high-quality care — both clinically and academically — in Central Florida. The initiative is headed by **Daryl Osbahr, MD**, an internationally renowned Orthopedic Sports Medicine Surgeon who serves as Managing Director

and Chief of Orthopedic Surgery at Rothman Florida.

Already a distinguished institute with true clinical leaders dedicated to value-based care as well as high-quality sub-specialty care, Rothman was identified as the ideal partner to help AdventHealth drive initiatives forward and become a national leader in orthopedic research.

“I’m motivated and excited about providing an orthopedic care model that will elevate the level of care that we are providing to the community, in addition to establishing ourselves as national leaders in orthopedics. In addition to providing quality care, we aim to provide a cultural environment that will help innovate in both research and education,” said Dr. Osbahr. “My goal here is to be able to provide a stirring pot of innovative excellence that will enable our team to reach high expectations in the academic world.”

The partnership will create and facilitate a positive, innovative research environment by promoting collaboration between the hospital system, the orthopedic group, and the community. “Fundamentally, a positive partnership and research initiatives come down to the people. We can build all the buildings we want, but the quality of who and what we are is what matters. So it is the people who will be inside of the buildings that count,” says Dr. Osbahr, whose own research as part of the AdventHealth and Rothman partnership has been surrounding biomechanical and motional analysis studies. “We’ll strive to look within the community to identify existing leaders but will also recruit physicians and researchers who display academic and clinical excellence across the country. By providing these physicians and researchers with important resources, we will be able to develop an environment that nurtures innovation.”

AdventHealth and Rothman are dedicated to utilizing evidence-based medicine to identify where experimental therapies have proven successful, as well as where they have proven to be unsuccessful. The team has been focused on how to create these resources on the ground, both immediately and in the future, to perform high-quality research on a national level.



## Research Spaces Identified

The AdventHealth and Rothman teams have targeted the primary research spaces they would like to bring to Central Florida: Clinical Research, Biomechanical Motion Analysis, Innovation, Lab Space, and Surgical Simulation.

As the primary focus, the Clinical Research space will help evaluate the quality of treatments in addition to helping inform the innovations required to generate potential new treatments. Biomechanical Motion Analysis will be crucial in supporting sports medicine research. At the same time, the team hopes that the development of cutting-edge Lab spaces will aid in the creation of new techniques and patents, further supporting the Innovation space.

The Surgical Simulation space will help define how technology is used to enhance surgical outcomes and education through the use of virtual reality, which will allow trainees to sharpen their skills prior to operating on patients.

## Virtual Reality and Artificial Intelligence: The Future of Orthopedics

As technology continues to develop in the virtual reality and artificial intelligence spaces, the AdventHealth and Rothman team is evaluating ways to leverage these new technologies in the educational space and the operating room to help optimize outcomes. The team has already begun bringing surgical simulation projects to AdventHealth, including a new study surrounding a non-operative treatment for ACL injuries.



“We need to continue advocating for the surgical simulation, virtual reality, and artificial intelligence spaces. The goal is to develop a program surrounding these exciting technologies, says Dr. Osbahr. “To truly conduct high-quality research, you need to be on the forefront of education. You need to continue to provide an environment conducive to learning to motivate people.”

## Clinical Research Roundup

### AdventHealth Physician Explores Lateral Kneecap Tilt and the Association With Cartilage Damage



Michael Hakky, MD

AdventHealth radiologist **Michael Hakky, MD** evaluated the association between increased lateral patellar tilt (LPT), or the angle of the tilt in the kneecap, and osteoarthritis-related structural damage.

The study was based on the recorded clinical and imaging data of 600 participants, in which osteoarthritis-related features, including cartilage and bone marrow lesions and knee cartilage volume, were evaluated at baseline and a two-year follow-up.

The study uncovered that an increase in LPT might be associated with the progression of osteoarthritis in the knee.

Source: *Knee*, December 2020. Authored in part by Michael Hakky, MD. doi:10.1016/j.knee.2020.11.002.





# Pediatrics



AdventHealth's Center for Pediatric Research strives to create the future of pediatric health care through research and data analysis to improve clinical performance and quality of care.

The research department provides full-service research support for all investigator-initiated, grant-funded, and sponsored research at AdventHealth for Children, with a research portfolio that crosses many pediatric areas. Comprehensive sub-specialty care includes a Level IV Comprehensive Pediatric Epilepsy Center, Level III Neonatal Intensive Care Unit (NICU), Cancer and Blood Disorder specialty with a pediatric bone marrow transplant program, a Pediatric Liver Transplant Program, and a Complex Care Clinic for patients with complex diagnoses.

Further in this section, you'll learn about a teenager whose Hepatitis C is cured in time for college, as well as how the research performed at AHC informs how we care for premature babies.

Finally, you'll learn why AdventHealth for Children, which currently has more than 135 specialists covering more than 35 pediatric sub-specialties, has been recognized by U.S. News & World Report as the Best Children's Hospital for newborn care in Florida the third year in a row.

## Areas of Focus

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



**46**

Active Clinical Trials



**15**

2020 Publications

## Hepatitis C in Children



**Regino Gonzalez-Peralta, MD**

AdventHealth pediatric gastroenterologist **Regino Gonzalez-Peralta, MD**, looks forward to days when he can share great news with his patients. Recently, he had one such day — he was able to tell 17-year-old Caroline and her parents that her Hepatitis C was cured.

“Our goal as a family was for Caroline to be cleared through treatment by the time she went to college, and guess what? Caroline is 17, and she will be heading to college in a couple of years as a fully healthy girl. We are so, so glad about it,” shares Caroline’s mother.

Caroline’s dad also was joyful about his daughter’s recovery, stating, “We feel relieved that Caroline is cured and that she played a role in hopefully making this treatment available to others. I feel very proud of her for going through this process and being just incredible the entire time. Now we know that our family is healthy, and we feel whole and hopeful.”

Source: <https://vimeo.com/316614841/128f6a8f18>



## Clinical Research Roundup

### AdventHealth Among Sites Evaluating the Impact of Hormone Treatment on Neurodevelopment in Premature Infants



**Rajan Wadhawan, MD**

AdventHealth was chosen as one of 19 sites to determine if high-dose erythropoietin, a hormone that stimulates red blood cell production, would aid in the prevention of neonatal brain injury in premature infants. While Phase 2 trials had suggested possible efficacy, the benefits and safety of the therapy had not yet been established.

The study evaluated 741 infants born between 24 weeks and 27 weeks 6-days to receive either the hormone or a placebo within 24 hours of birth.

AdventHealth’s involvement in the study helped determine that ultimately, no significant differences were detected between infants receiving the hormone versus those who did not, as hormone administration did not result in a lower risk of severe neurodevelopmental impairment or death at two years of age.

Rajan Wadhawan, MD, neonatal physician and Senior Executive Officer for AdventHealth for Children and AdventHealth for Women, was the Principal Investigator for this trial.

Source: *The New England Journal of Medicine*, January 2020. Authored in part by Rajan Wadhawan, MD. doi:10.1056/NEJMOA1907423.

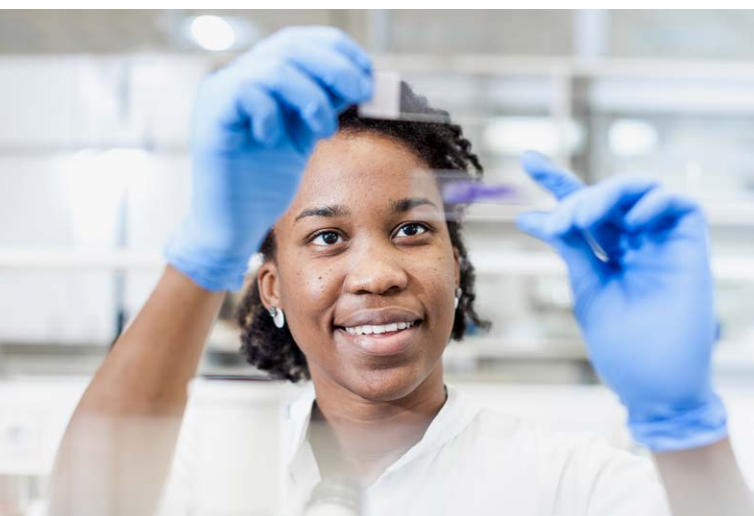


# Genomics



The more you know about your health, the more empowered you are to take charge of your wellness. A first-of-its-kind genomics research study in Florida, WholeMe screens for hereditary heart conditions and cancer — and reveals 22 fascinating insights about one’s health and heritage. Genomics will be an essential component of health care, not just for the individual but for our greater community as we focus on wellness and preventive care. The implications of genomics programs are significant for today’s patients, and importantly, the future of Florida’s health. WholeMe is an important first step in our genomics program; it performs advanced screening for heart disease (beginning with familial hypercholesterolemia) by engaging the community to increase their awareness of genetics and genomics in their health and encouraging them in their healthcare-related decision-making as a result of receiving genomic findings.

In the following pages, you’ll learn how AdventHealth is working with partners to accelerate the delivery of precision medicine through a learning network and discover how clinicians are helping Floridians learn more about the role genetic traits play in health. We will also share real-world examples of how AdventHealth patients are leveraging these genomic studies to impact their lives positively, today and for the future.



## AdventHealth and Syapse® Partner to Advance Cancer Care

In October 2020, AdventHealth and Syapse®, a real-world evidence company accelerating the delivery of precision medicine through the Syapse Learning Health Network™, partnered to ensure that the right therapies are available to patients using clinical and genomic data.

The Syapse Learning Health Network™ allows AdventHealth to access cancer data from patients worldwide. Syapse™ enables improved cancer care by sharing real-world treatment data to support clinical decisions and foster collaborations among participants. This investment in building real-world evidence also accelerates our commitment to advancing cancer research.

Through the partnership, a secure data platform integrates clinical and genomic data to deliver actionable insights to AdventHealth’s clinical, operational, and research teams across all Central Florida cancer institutes, enabling cancer patients to access novel targeted therapies through the first Phase 1 Clinical Trial Unit in Central Florida. The partnership will also allow for the acceleration of breakthrough research in cancer care and personalized medicine.

AdventHealth is a key collaborator for Syapse because it offers a connected system of individualized, holistic care for every stage of life and health, a rich array of research resources, and a culture of discovery.



## Clinical Research Roundup

### Can We Crack the Code to a Healthier Life?

AdventHealth Researchers are giving consumers potentially lifesaving information about their heart health with a first-of-its-kind DNA study in Florida – “WholeMe.”

Approximately 6,955 people have had the opportunity to join the WholeMe study. Helix, a personal genomics company, sequenced DNA using proprietary next-generation technology called Exome+. Study participants were screened for the genes linked to familial hypercholesterolemia, known as “FH,” a life-threatening genetic condition that causes high cholesterol. If left untreated, it can lead to cardiovascular disease, including heart attacks, even in young adults.

WholeMe will do more than help Floridians learn about genetic conditions that impact their health - researchers will also gain insight into how consumers respond to knowing their genomic information.

“Genomics stands to have as great an impact on medicine as penicillin and radiology in earlier decades,” said **Steven R. Smith, MD**, the AdventHealth Research Institute’s chief scientific officer. “These genomic insights will be essential to how people live and the decisions we make. As a result, we are not only learning important information from participants, but we are also empowering them to change their behaviors and hopefully mitigate their risks for disease.”

Earlier this year, AdventHealth Orlando began laying the foundation for its comprehensive genomics program — AdventHealth Genomics and Personalized Health — which will ultimately provide comprehensive genomics testing, analysis, interpretation, and genetic counseling services.

“

“Everyone benefits from knowing more about their genetics, with actionable insights that can lead to people living healthier lives,” said James Lu, co-founder and senior vice president of Applied Genomics at Helix, which is based in California.

“Our partnership with AdventHealth, and in particular the WholeMe study, empowers individuals with information about how their genetics could impact their heart health. AdventHealth is at the leading edge of offering these insights to the community. By leveraging Helix’s population health solutions together, we are providing individuals with insights about how their DNA impacts their overall well-being.”

## WholeMe Success Stories

### Multigenerational patients and families benefit from Cardiovascular Genomics

Gerry, his sister Sandra, and their mother Joselyn tested positive for a gene associated with a predisposition for high cholesterol and requested a consultation as a family with Cardiovascular Genomics program cardiologist Puxiao Cen, MD. They also determined that Sandra’s daughter and ten-month-old granddaughter should be tested so they could be proactively treated for heart disease.

# Transplant



The researchers at the AdventHealth Transplant Institute strategically selects research protocols that offer new or improved treatments that would not otherwise be available for our patients. The department is committed to offering patients the opportunity to access the most current treatments, even as they are being developed.

On the pages that follow, read how the AdventHealth Transplant Institute's Cardiothoracic program performed a heart transplant using a donor heart that was no longer beating, giving hope to the nation's organ shortage. Additionally, we'll share how one AdventHealth physician is working to determine the clinical significance of left ventricular assist device implantation.

Home to one of the nation's oldest and largest kidney transplant programs, the institute is also home to the Living Donor Program and has successfully transplanted more than 800 kidneys from living donors.

## Areas of Focus

- Abdominal Organ Transplants (Kidney, Liver, Pancreas)
- Thoracic Organ Transplants (Heart, Lung)
- Mechanical Circulatory Support (MCS)
- Advanced Liver Disease
- Advanced Heart Failure
- Advanced Lung Disease



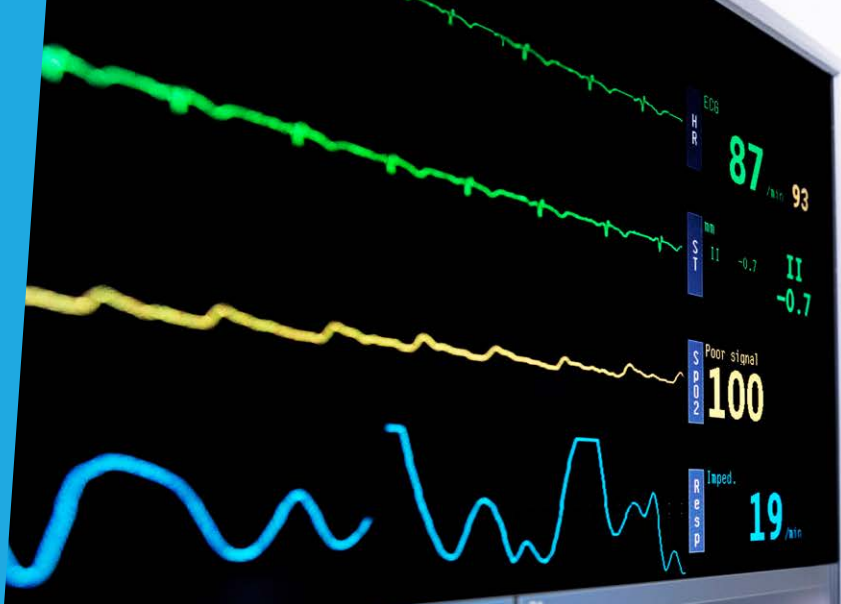
17

Active Clinical Trials



31

2020 Publications



## Heart in a Box: Can dead hearts be transplanted?



**Scott Silvestry, MD**

The AdventHealth Transplant Institute Cardiothoracic program performed the first heart transplant in Florida through a process known as Donation after Circulatory Death (DCD). The team utilized a donor heart that was no longer beating and was evaluated via a groundbreaking process under a clinical FDA investigation.

DCD heart transplantation gives hope to patients and physicians faced with a growing organ shortage across America. These heart transplants are made possible by a clinical trial using the Transmedics Organ Care System, a machine that keeps a heart which was stopped prior to donation viable for hours. AdventHealth is one of 12 transplant centers in the country participating in a clinical trial for the process.

The transplant was a team effort in partnership with AdventHealth Translational Research Institute and the organ procurement agency OurLegacy.

“There are far more people in this country who need heart transplants than there are heart donors,” said **Scott Silvestry, MD**, Principal Investigator for this program at AdventHealth. “We’re excited to have another tool in our arsenal that can help us save lives. These kinds of transplants also could expand the donor pool by thousands.”

George Martin, 46, had been awaiting a transplant since 2018 when a severe case of influenza attacked his heart muscle. The Belleview resident had twice before been told a donor’s heart was available only to learn later that the organ was not viable. In mid-June, the AHTI team traveled out of state to the donor’s location, procured the heart for Mr. Martin after the donor was removed from the ventilator, and connected it to the machine to support it with blood from the donor. The team returned to Orlando with the heart, where it was transplanted into Martin. “The next day, I was up walking,” Martin, a Navy veteran and an engineer for Lockheed Martin, said. “From an engineering standpoint, the technology was something that appealed to me. It’s just a blessing.”

Nearly 110,000 people are on the national transplant waiting list, and according to the U.S. Health Resources and Services Administration, more than 3,000 of those are waiting for a heart. Twenty people die each day waiting for an organ transplant. “The hearts that will be transplanted as a result of this technology would have been buried before,” said Dr. Silvestry. “Instead, they’ll save lives of people like George Martin and hopefully many more Central Florida residents.”

“Organ donors are heroes who deserve our gratitude and respect,” said Ginny McBride, executive director of OurLegacy, Central Florida’s organ procurement organization. “This new technology will allow donors and their families to touch even more lives through their generosity. We are humbled to be stewards of these life-saving gifts.” NCT03835754; NCT03831048; NCT04615182

Source: AdventHealth TV – Episode 64

## Clinical Research Roundup

### AdventHealth Works to Determine the Impact of Left Ventricular Assist Device Implantation on the Outcomes of Advanced Heart Failure

AdventHealth's Transplant Institute participated in a trial to determine the impact of a left ventricular assist device (LVAD) on mitral regurgitation, or the flow of blood backward into the heart, as part of a study on advanced heart failure.

Patients were implanted with either a HeartMate 2 or HeartMate 3 as part of the study, called the MOMENTUM 3 trial. The trial ultimately established the superiority of the Heartmate 3, which utilized a fully magnetically levitated centrifugal-flow pump.

AdventHealth physician and Surgical Director of Thoracic Transplant, Scott Silvestry, MD, was the Principal Investigator on this study.

Source: *The Journal of Heart and Lung Transplant*, March 2020. Authored in part by Scott Silvestry, MD. <https://doi.org/10.1016/j.healun.2020.03.003>.

## The Office of the Vice President of Research



**Rob Herzog**  
Vice President Research

The Research Institute has responded to organic clinical institute growth opportunities, developing AdventHealth as a thought leader in whole-person research. Scientific growth continues to increase the integration of Research Institute discoveries into clinical workstreams, enhancing how healthcare can be delivered to our patients, community, researchers, and scientists. Additionally, the Research Institute leverages

academic partnerships with AdventHealth University to connect clinical research learners to research teams.

A vibrant research enterprise benefits AdventHealth's overall brand and reputation as a leader in healthcare. The Research Institute's activation and support of more than 550 active clinical studies places AdventHealth at the forefront of providing novel treatment options for current and future patients, opening doors for the acceleration of destination programs and development of 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 for recruiting clinical thought leaders from nationally prominent academic medical centers, which is necessary to establish national centers of excellence. 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 continuing to support our promises to support our passage to world-class clinical research and shape the future standards of care. For patients, this means more treatment options at every stage of disease. For clinical investigators and teams, this means an engine for discovery and growth. For sponsors and collaborators, this means partners in prevention and cure, plus a reduced cycle time for discovery.

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

### The Research Institute:

- Participates in more than 550 clinical studies annually
- Supports more than 300 Principal Investigators
- Won 61 active grant awards as of June 30, 2020, compared to 35 active grant awards in 2015 (34 of the 61 current active grants are federal or federal flow down)

## Research Services

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

### Areas of Focus:

- Grant Submission and Management
- Clinical Trial Agreements & Budgeting
- Study Auditing and Monitoring
- Clinical Trials Management System
- Conflict of Interest
- Research Related Agreements
- Technology Transfer
- Competency Training and Professional Development
- Protocol Review and Monitoring System
- Institutional Review Board
- Research Oversight Committee
- Regulatory Services
- Research Billing Compliance

### The Office of Research Integrity (ORI)

The ORI helps ensure that AdventHealth Orlando researchers and staff maintain compliance with the numerous regulatory requirements governing research. ORI collaborates within the many interdepartmental research offices across the institution to foster communication and align policies and procedures that build a more integrated and robust research compliance program, in addition to administering the AdventHealth Conflict of Interest review process.

The ORI includes the AdventHealth Institutional Review Board (IRB), the entity responsible for reviewing all research conducted at AdventHealth Orlando or by AdventHealth Orlando employees/agents; areas of focus include ethical standards, scientific merit, and regulatory compliance. Additionally, the IRB works to protect the rights and welfare of those who participate in human subjects research.

### The Office of Sponsored Programs (OSP)

The OSP helps researchers manage funding, data, and biospecimens for their studies by offering research-related agreements, budget support, and system support and assuring the appropriate processing of grant proposals and research agreements to ensure compliance. The OSP also works to help determine the appropriate payors for items and services provided to a subject participating in a research study, ensuring all costs associated with conducting the project are requested and compliant with the funding agency's guidelines, institutional policies, and procedures, and applicable regulations.

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

AdventHealth employees and physicians often create new inventions and discoveries. The Office of Intellectual Property and Development (OIPD) provides a full range of technology transfer support, including intellectual property assessment and protection, marketing, development and prototyping, startup support, licensing, and agreement management.





## Research Operations

Our clinical Research Operations teams provide the structure to evaluate and execute clinical trial and research study opportunities at AHRI. Built with subject matter expertise in the therapeutic areas they serve, Research Operations works closely with other investigators, departments, and teams to select research opportunities for operational and financial feasibility. The department also works to foster and develop trial and study portfolios targeted to address the barriers to the health and wholeness of the communities we serve.

Our experienced research teams interrogate breakthrough compounds, trial life-saving surgical techniques, and develop whole-person care treatment methods to improve the quality of life for the entire lifespan, from NICU babies to mature adults. Our physician-led research team ensures participant safety and clinical advancement receive the highest priority.

## Centralized Core Services

The Centralized Core provides services to all AdventHealth Research Institute departments for internally and externally sponsored projects.

## Central Processing Laboratory

The laboratory is equipped with molecular biology analysis instruments for cancer biomarker analysis and tumor tissue processing and review. These highly advanced research instruments and systems provide researchers with the valuable resources needed to conduct advanced trials and studies. The laboratory also offers resources intended to support the characterization of molecular classes and provides a biorepository, data analysis workstations and software, an isolation room with biosafety cabinets, a robotic liquid handler, and a microscopy suite for multi-color fluorescence analysis of samples.

## Centralized Core Highlights

- Biorepository
- Research Laboratory
- Metabolomics Core
- Clinical Research Unit
- Imaging Core
- Nutrition Core
- Energy, Metabolism, and Calorimetry Core
- Exercise and Bioenergetic Laboratory

## Institute Development Office (IDO)

Our leaders are engaged in a transformational journey to meet standards that will achieve industry-leading results. The Institute Development Office (IDO) offers programs that promote individual, team, and interdepartmental readiness and performance, fostering relationships with research industry sponsors and partners to advance innovative treatments for our patients.

Our collaborations range from established biopharmaceutical and medical device organizations to early-stage startups that may yield important benefits to patients, representing truly groundbreaking scientific discoveries and medical advances.

Together with the AdventHealth Research Institute, Cancer Institute, and Moffitt Cancer Center Partnership leaders and interdisciplinary stakeholders, our subject matter experts consult in oncology, infusion services, and clinical research to optimize outcomes for priority research and clinical programs. This year, these collaborations focused on opening the Moffitt Cancer Center and AdventHealth Early-Phase Clinical Research Unit at the AdventHealth Celebration campus and building program infrastructure, processes, and governance to support leadership, research, and clinical teams.

### Institute Development Office Attributes

- Creates long-term value for our organization through high-impact relationships with our customers
- Serves as the formalized, professional department to fuel AHRI growth
- Prepares stakeholders to move farther and faster by honing their planning, reporting, and communication skills while removing obstacles

### Business Development

The IDO fosters business development (BD) by establishing and supporting relationships with research sponsors and partners. The BD team helps identify, initiate, develop, implement, and support growth opportunities, partnering with AdventHealth physicians and scientists to advance innovative treatments for our patients. These experimental therapies often provide hope to patients with limited standard care options. Collaborations provide access to innovative experimental biopharmaceutical therapies and medical devices yielding benefits to patients. The BD team offers a strategic and operational mindset and follow-through to launch new projects with clinical and institutional partners.

### Consultative Delivery Office

Our IDO team provides consultative delivery services, delivering value to AdventHealth clients. Our team of Program Managers, Coordinators, and Specialists provides tailored, practical strategies to the AHRI departments and our business partners, utilizing a collaborative approach to provide support at all stages of programs and projects. Using a combination of technology, data analytics, process architecture, and change management, the IDO team provides hands-on orchestration to provide strategic alignment, measurable ROI, stronger governance, effective collaboration, consistent process, improved quality, and more effective management of project time and cost.

### Research Leadership Development

The IDO supports the Research Institute teams and leadership by providing education, coaching, and team development. Research Institute leaders and team members participate in workshops to develop courageous leadership and strengthen intra- and interpersonal skills. In addition, IDO strategizes, develops, and delivers leadership support and fosters cultural influences that support our passage to world-class clinical research and future standards of care.

# Investigator Support: Center for Academic Research Excellence (CARE)

CARE features a team of data and nurse scientists, biostatisticians, health economists, medical editors, and research professionals conducting data-driven research to meet some of the biggest challenges in healthcare. The ability to collaborate and develop protocols and analysis plans with fellow data scientists provides an exciting opportunity for problem-solving.

## Areas of Focus:

- Biostatistics
- Health Economics
- Centralized Laboratory
- Medical Editing
- Research Methodology
- Education for Clinicians

Partnering with faculty, fellows, residents, doctoral, and medical students allows us to support quality research projects within our academic group, with projects focused on enriching patient care, as well as nurse and physician wellness. These efforts also include exploring data sources to create more actionable provider encounters.

CARE provides statistical support services for all AdventHealth Orlando-aligned research departments. Biostatistical or Health Economist (HEOR) support provides preliminary and advanced study design and implementation services, completed study analysis and reporting, and publication development support services to researchers.

## Medical Editing

The medical editor serves as a bridge between researchers who create ideas and the audiences who use them, employing a didactic approach to support Principal Investigators and their research teams in submitting successful journal manuscripts and competitive grant proposals seeking funding.

## The CARE Team:

- Addresses evolving needs of healthcare research
- Conducts data-driven research to meet challenges
- Collaborates with fellow data scientists
- Partners with industry for mutually beneficial projects
- Supports academic research by faculty and students
- Standardizes and centralizes the research volunteer process
- Brings together statisticians to form a stronger core



## Pharmacy: Investigational Drug Services (IDS)

Pharmacy Research at AdventHealth Orlando is committed to improving the lives of individuals through research into medication and disease states that affect our patients who are participating in clinical research studies intended to improve the use of medication. The IDS is also used to support the Pharmacy Department and is a fully equipped, stand-alone pharmacy able to compound sterile investigational medications and work with nucleic acid molecules, as outlined by the National Institutes of Health.

In 2020, IDS managed investigational medication for approximately 200 active studies across all AdventHealth clinical research areas. The pharmacy also supported the new Critical Care Research Program's development during the recent pandemic, managing remdesivir, an antiviral used to treat COVID-19, and other investigational medications for COVID-19 studies.

### The Investigational Drug Service (IDS) manages:

- The receipt and storage of investigational medications
- The dispensing of investigational medications
- The accountabilities of investigational medications

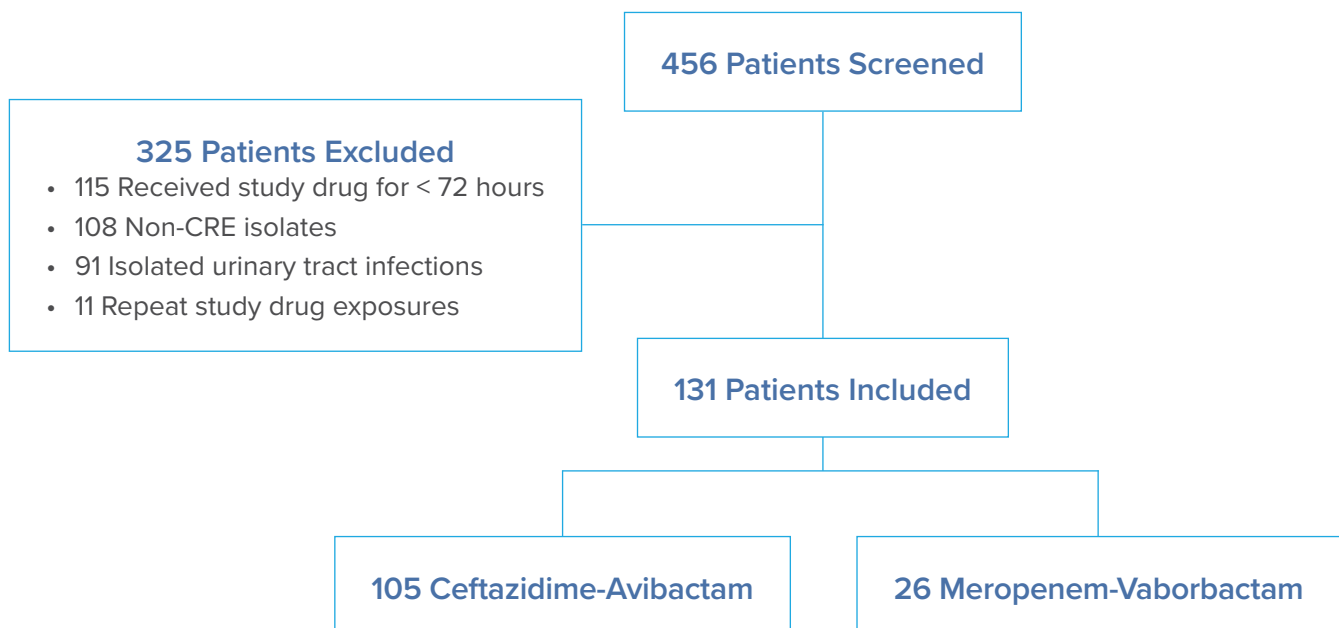
## Clinical Research Roundup

### AdventHealth Participates in a Clinical Trial Comparing Two Drugs Used in Treating Complicated Infections and Pneumonia

AdventHealth Clinical Coordinator Sara Minor and colleagues collaborated in the Antimicrobial Stewardship Learning Experience: Infectious Diseases to determine the efficacy of meropenem-vaborbactam versus ceftazidime-avibactam, two drugs intended to treat complicated abdominal infections, urinary tract infections, and pneumonia. The trial compared the effectiveness of the medications in treating carbapenem-resistant Enterobacteriaceae (CRE), or an antibiotic-resistance bacteria.

This retrospective study included 131 patients and ultimately found no significant difference in clinical success between the two groups.

Source: *The American Society for Microbiology Journals, April 2020. Authored*



## Donate to Research

Your support keeps us on the cutting edge of care. Contributions empower us to help more people live their best, most vibrant lives. Your donations help us build new facilities, attract expert physicians and researchers, and develop groundbreaking ways of treating illness and disease.

Expanding research capabilities across Florida will increase access to clinical trials and support translational studies aimed at making vital health discoveries that lead to cures. As one of the largest providers of health care in the state of Florida and nationwide, AdventHealth is committed to excellence that's shown through our clinical outcomes and the 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 research, whether you make an annual contribution, help purchase the latest equipment and technology, or establish a legacy gift in honor of a loved one or as a family through planned gifts such as a bequest, gift annuity, or IRA rollover. 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 provider or researcher in the country and provides a permanent, stable program and research funding source. They can be named after the donor or a loved one and exist in perpetuity as testaments to the appreciation of world-class care while honoring a family's legacy of generosity and commitment to making health discoveries.

Join us today in extending the healing ministry of Christ by helping more people experience a life of whole health. Contact AdventHealth Foundation Central Florida at **407-303-2784** or **ResearchGive@AdventHealth.com** to learn more.

## Looking Forward

It has been quite a year, but the best is yet to come! The AdventHealth Research Institute is poised to grow next year, and we are excited about the opportunities and breakthroughs this will bring to our communities.

It is important to remember that every cutting-edge treatment that we use at AdventHealth today started as an idea in the mind of a scientist somewhere in the past. These ideas were tested in clinical studies and adopted by our clinical teams. The treatments of today were research studies last year.

As we launch new research initiatives in neurology, cancer, aging, outcomes research, and whole-person care, we ask that you join us. How? By volunteering for a research study, making a contribution to the AdventHealth Foundation to support our brightest and most creative scientists, and most of all, helping us to raise awareness of how research changes lives every day.

**Steven R. Smith, MD**

Senior Vice President & Chief Scientific Officer