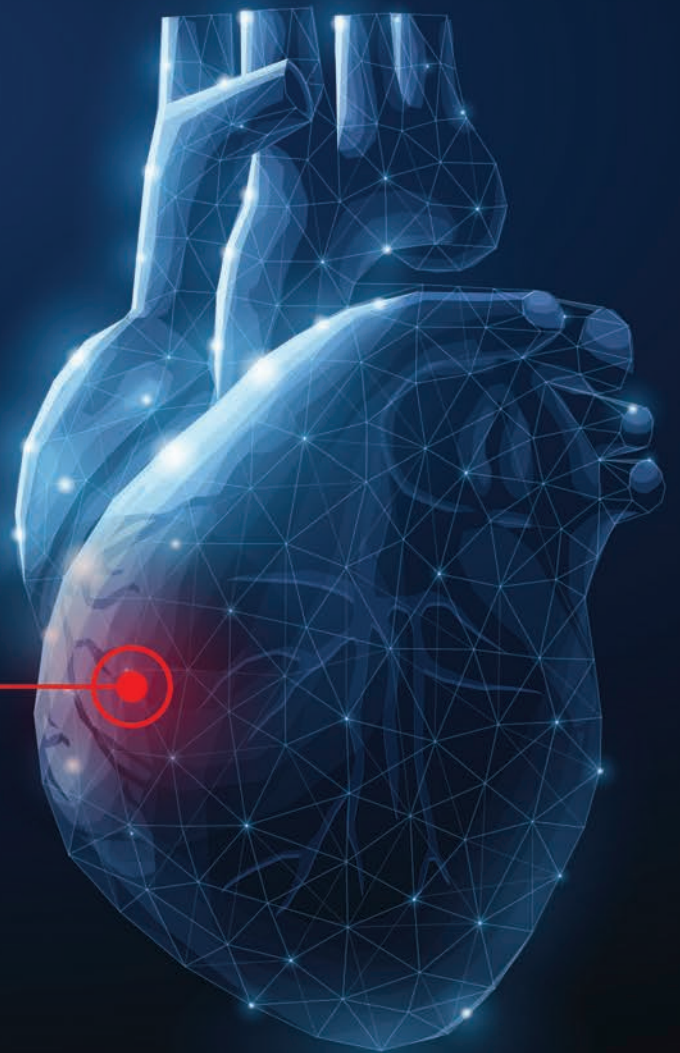


Enhancing Patient Outcomes Through a Culture of Research

Inova Heart and Vascular Institute



INOVA[®]

Heart and Vascular Institute

OUR MISSION



Inova is fully committed to providing the highest quality cardiovascular care in the safest possible environment. Under the leadership of Christopher M. O'Connor, MD, a world-renowned authority on heart failure, Inova Heart and Vascular Institute (IHVI) has aggressively expanded its focus on academic excellence and discovery, including cutting-edge research designed by members of the IHVI team. The internal culture values innovation and quality, and this translates into excellence in patient care.

We are proud of IHVI's contributions to our health system and its scientific contributions on a national and international level to identify and test novel therapies to enhance the treatment of cardiovascular and lung disease. We look forward to even greater accomplishments in the coming years.

J. Stephen Jones, MD, MBA, FACS
President and CEO, Inova



INOVA HEART AND VASCULAR INSTITUTE



Clinical research drives advances in patient care, and Inova Health System's commitment to provide world-class, compassionate care drives our participation in cutting-edge clinical research to raise the standard of care for patients suffering from cardiovascular and lung disease in the Washington, DC, region and around the world. Consistent with Inova's research vision, IHVI focuses on clinical and late translational research with the potential for application to patient care within five to seven years.

Our research covers a broad range of cardiovascular, vascular and advanced lung conditions, and our faculty present at major national and international meetings, serve on editorial boards, and consistently publish in high-impact journals. We are awarded competitive grants from the federal government, foundations and industry and collaborate with academic centers throughout the country.

IHVI was at the forefront of research to diagnose, treat and mitigate the impact of the COVID-19 pandemic. We engaged in clinical trials to test the feasibility and efficacy of new treatment options and are continuing to conduct widespread serological testing to help us understand the rate of asymptomatic exposure and the prevalence of the virus in the Washington, DC, region. Our highly diverse patient population is representative of the nation as a whole and makes IHVI an ideal site for population-based protocols.

Conducting clinical research in the context of the uncertainties of the COVID-19 era presents challenges and creates opportunities as well. We continue to develop creative solutions to minimize direct contact and keep our vulnerable patients safe while satisfying the needs of all constituents in the clinical trial ecosystem. These innovative approaches are serving us well as we refocus and reinvigorate our research efforts in other areas.

State-of-the-art research, academic excellence and the highest standards of clinical care in a safe environment are, and will continue to be, the major priorities for IHVI. We are proud to play a role in developing and testing novel therapies to improve patient care.

Christopher M. O'Connor, MD, MACC, FESC, FHFS, FHFA
President, Inova Heart and Vascular Institute

ABOUT IHVI – 2021



219,477

Patient Visits

7

Cardiovascular and Hybrid ORs

23

Catheterization EP/IR Labs

H

5

Hospitals



209

Dedicated Cardiac Beds



41

Inova Cardiology, Arrhythmia, Vascular and Cardiac Surgery outpatient practice locations providing more than 125,194 appointments



26

Noninvasive Cardiac and Vascular Imaging and Diagnostic Service Sites



Patients treated from **48** states and **5** territories, countries or armed forces locations worldwide



For a complete list of IHVI's awards and recognition, visit [inova.org/heartawards](https://www.inova.org/heartawards).

IHVI's clinical capabilities cover the full spectrum of complex cardiovascular and pulmonary care, from medical evaluation and diagnostic testing through the most innovative minimally invasive surgical techniques and complex open surgeries, including heart and lung transplantation.



Inova Heart and Vascular Institute –
Inova Fairfax Medical Campus
3300 Gallows Rd.
Falls Church, VA 22042

Located just outside of Washington, DC, in Falls Church, VA, Inova Fairfax Medical Campus is home to IHVI's dedicated heart hospital, which serves as the hub of the system's cardiac, vascular and advanced lung disease services.

Centers for Medicare and Medicaid Services
4-Star Rated Hospital

U.S. News and World Report 2020 – 2021

#1 in both the Washington, DC Metro Area and Virginia
High Performing in Abdominal Aortic Aneurysm Repair
High Performing in Aortic Valve Surgery
High Performing in Heart Attack Care
High Performing in Heart Bypass Surgery
High Performing in Heart Failure
High Performing in Transcatheter Aortic Valve Replacement (TAVR)



The Leapfrog Group

"A" Hospital Safety Grade –
7 consecutive reporting periods



American Nurses Credentialing Center

Magnet Recognition® for Nursing Excellence



Healthgrades

America's 50 Best Cardiac Surgery Award™ (2021, 2020)
America's 100 Best for Cardiac Care Award™ (2022, 2021, 2020)
America's 100 Best Hospitals Award™ (2021, 2020)
Outstanding Patient Experience Award™ (2021, 2020, 2019)
Pulmonary Care Excellence Award™ (2022, 2021, 2020)

IHVI HOSPITAL SERVICE SITES



**Inova Heart and Vascular Institute –
Inova Alexandria Hospital**
4320 Seminary Rd.
Alexandria, VA 22304

Centers for Medicare and Medicaid Services
4-Star Rated Hospital

U.S. News & World Report 2021 – 2022
#7 in Washington, DC Metro Area
#13 in Virginia
High Performing in Heart Failure



The Leapfrog Group
“A” Hospital Safety Grade –
7 consecutive reporting periods



Healthgrades
America’s 100 Best Hospitals for Critical Care Award™
(2022, 2021, 2020)
America’s 250 Best Hospitals Award™ (2021, 2020)
Patient Safety Excellence Award™ (2021, 2020)
Pulmonary Care Excellence Award™ (2022, 2021, 2020)



**Inova Heart and Vascular Institute –
Inova Fair Oaks Hospital**
3600 Joseph Siewick Dr.
Fairfax, VA 22033

Centers for Medicare and Medicaid Services
5-Star Rated Hospital



U.S. News & World Report 2021 – 2022
#4 in Washington, DC Metro Area
#10 in Virginia
High Performing in Heart Failure



The Leapfrog Group
“A” Hospital Safety Grade –
19 consecutive reporting periods
Top Hospital



American Nurses Credentialing Center
Magnet Recognition® for Nursing Excellence



Healthgrades
Outstanding Patient Experience Award™ (2021, 2020, 2019)
Patient Safety Excellence Award™ (2021, 2020, 2019)
Pulmonary Care Excellence Award™ (2022, 2021, 2020)
Vascular Surgery Excellence Award™ (2021)



**Inova Heart and Vascular Institute –
Inova Loudoun Hospital**
Schaufeld Family Heart Center
44045 Riverside Pkwy.
Leesburg, VA 20176

Centers for Medicare and Medicaid Services
5-Star Rated Hospital



U.S. News & World Report 2021 – 2022
#7 in Washington, DC Metro Area
#13 in Virginia
High Performing in Heart Failure



The Leapfrog Group
“A” Hospital Safety Grade –
19 consecutive reporting periods
Top Hospital



American Nurses Credentialing Center
Magnet Recognition® for Nursing Excellence



Healthgrades
America’s 250 Best Hospitals Award™ (2021, 2020, 2019)
Critical Care Excellence Award™ (2022, 2020)
Patient Safety Excellence Award™ (2021, 2020, 2019)
Pulmonary Care Excellence Award™ (2021, 2020)



**Inova Heart and Vascular Institute –
Inova Mount Vernon Hospital**
2501 Parkers Ln.
Alexandria, VA 22306

Centers for Medicare and Medicaid Services
5-Star Rated Hospital



The Leapfrog Group
“A” Hospital Safety Grade –
15 consecutive reporting periods



Healthgrades
Outstanding Patient Experience Award™ (2021, 2020, 2019)

IHVI'S LEADERSHIP TEAM



Christopher M. O'Connor, MD, MACC, FESC, FHFA



Christopher deFilippi, MD, FACC

Christopher M. O'Connor, MD, MACC, FESC, FHFA, FHFA

President, IHVI

Dr. Christopher M. O'Connor came to IHVI in 2015, having previously served as Director of the Duke Heart Center and Chief of the Divisions of Cardiology and Clinical Pharmacology at Duke University Medical Center. He is highly regarded internationally for leadership in clinical trials addressing therapeutics for the treatment of acute and chronic heart failure. He has obtained well over \$100 million in private research grants and has secured multiple R01 and U01 grants from the National Heart, Lung and Blood Institute as principal and co-principal investigator.

Dr. O'Connor is Professor of Medicine, Duke University and Editor in Chief of JACC: Heart Failure. He serves on the editorial boards of various top-tier medical and cardiovascular journals and has authored more than 900 publications, 3 textbooks and 15 textbook chapters. He has consistently been an invited speaker and moderator at the annual scientific meetings of national and international societies, has served in leadership roles in major professional societies, is a Past President of the Heart Failure Society of America, and is the 2021 recipient of the American College of Cardiology's Distinguished Clinical Scientist Award.

During his tenure at IHVI, Dr. O'Connor has applied the scientific rigor of a clinical investigator to promote a culture of excellence in research and bring about outstanding clinical outcomes.

Christopher deFilippi, MD, FACC

Vice Chair, Academic Affairs

Director, Cardiovascular Disease Fellowship Training Program Director, Inova BioCore Laboratory

Prior to his arrival at Inova in 2016, Dr. Christopher deFilippi was Associate Professor of Medicine at the University of Maryland. His research has centered around in vitro diagnostics, and he has served as the principal investigator and adjudication chair for several multicenter cardiac biomarker approval studies.

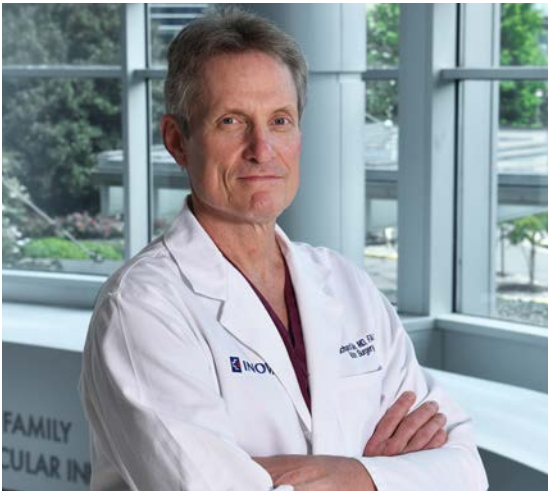
He is a Senior Consulting Editor for JACC: Heart Failure, an Associate Editor of the Journal of Applied Laboratory Medicine, and an editorial board member for Circulation and the Journal of the American College of Cardiology. He has introduced innovative methods for clinical trial recruitment across the Northern Virginia region to encourage participation at both the investigator and participant levels to take advantage of the diversity of the region and the spectrum of patients cared for in the health system, from the critical care setting to the primary care ambulatory setting.



Alan M. Speir, MD

**Director, Cardiac Surgery, Inova Health System
Senior Associate Director, IHVI**

Dr. Alan Speir has been a practicing cardiothoracic surgeon in the Washington, DC, region for 40 years. His clinical interests include valvular heart disease and surgery of the aorta and great vessels. He also has expertise and interest in quality improvement and cost containment in healthcare as well as experience in alternative payment methodologies and healthcare policy.



Richard F. Neville, MD, FACS, DFSVS

**Chair, Department of Surgery
Associate Director, IHVI
System Director, Vascular Services
Professor of Medical Education, University of Virginia**

Dr. Richard Neville joined Inova with more than 25 years of clinical experience. Most recently, Dr. Neville served as a Professor in the Department of Surgery and as the Ludwig Chief of Vascular Surgery at George Washington University. Prior to that position, he was Chief of Vascular Surgery at Georgetown University. His clinical interests include lower extremity revascularization, wound healing, amputation prevention, carotid artery treatment for stroke prevention and hemodialysis access.



Wayne Batchelor, MD, MHS, FACC, FSCAI

**System Director, Interventional Cardiology and Interventional Heart
Disease Research, Education, and Innovation
Associate Director, IHVI**

Dr. Wayne Batchelor's primary research interests are clinical trials, structural heart disease innovations, complex percutaneous coronary intervention, and racial and ethnic healthcare disparities within interventional cardiology. He has published more than 130 peer-reviewed abstracts/manuscripts and multiple book chapters. He is incoming Chair of the American College of Cardiology (ACC) Interventional Section Leadership Council and serves on the Society for Cardiovascular Angiography and Interventions (SCAI) Vascular Disease Council, SCAI Diversity and Inclusion Council and the Society of Thoracic Surgeons/ACC TVT Registry Steering Committee.

RESEARCH

Leading the Way with Cutting-Edge Research to Improve Patient Care



Research Staff

IHVI is committed to research to enhance early detection, provide optimum treatment and substantially improve outcomes for patients with cardiovascular and lung disease. Studies to evaluate new technologies and explore new treatments for advanced heart failure, advanced lung disease, coronary artery disease, structural heart disease, arrhythmias and critical limb ischemia are currently underway, and we are proud of our ability to offer our patients research options that harmonize with clinical care.

IHVI's dedication to engaging in clinical research has been demonstrated through the tremendous growth in the number of studies initiated by IHVI investigators. Faculty participation in national and international medical conferences and publication in high-impact journals including the *New England Journal of Medicine*, *JACC*, *Circulation*, the *Journal of Vascular Surgery*, *Chest* and others are

further evidence of academic excellence, as is the fact that the *Circulation* paper "Cell-Free DNA to Detect Heart Allograft Acute Rejection," co-authored by Palak Shah, MD, was selected as the winner of the **2021 James T. Willerson Award in Clinical Science**.

We are the top enroller in several major national and international clinical trials and were the recipients of four prestigious competitive National Institutes of Health (NIH) awards in 2020 with Inova as the prime contractor.

Demographics

Our Northern Virginia location provides access to a highly diverse urban, suburban and rural patient population. The 21-county region of Northern Virginia, Southern Maryland, Washington, DC, and its suburbs served by Inova includes considerable ethnic, racial, socioeconomic and age diversity, thereby making

data from our patients particularly useful and extrapolatable to the United States population at large. The socioeconomic diversity with its implications for nutrition, lifestyle, and overall health and health-care further enriches IHVI's patient pool, and our ambulatory sites across Northern Virginia provide good opportunities for outpatient recruitment.

Collaborating to Enhance Capabilities

IHVI researchers conduct both inpatient and ambulatory clinical trials that are either Inova investigator-led or performed in collaboration with organizations and research institutions such as NIH, George Mason University, the Virginia Department of Health, the University of Virginia (UVA), Carilion Clinic and the American Heart Association (AHA). Our staff also collaborates with researchers at Johns

Hopkins University and the University of Maryland. These partnerships, in addition to the resources and personnel at all five Inova hospitals and affiliated physician offices, allow IHVI to deliver the critical components of a successful research enterprise: a well-trained, knowledgeable and facile team of researchers; biobanking capabilities; and a diverse patient population to facilitate high enrollment.

Our robust clinical research structure has made IHVI the premier go-to site for clinical research in the Washington, DC, region. IHVI is a highly valued research partner and collaborates with academic medical centers, the U.S. Food and Drug Administration (FDA), AHA, NIH, and the pharmaceutical and device industry, including partnerships with Abbott, Medtronic and Amgen, among others. Our team has taken the lead on the



The Integrated Translational Health Research Institute of Virginia (iTHRIV) is a transformational cross-Commonwealth collaboration.

Integrated Translational Health Research Institute of Virginia (iTHRIV) Clinical and Translational Science Award (CTSA)/UVA/Virginia Tech consortium, and a collaboration with George Mason University's statistics department augments our capabilities and supports higher-level statistical analyses in "omics" and machine learning. IHVI is included in the Cardiothoracic Surgical Trials Network as an independent site. This provides a new source of cardiovascular surgery studies and adds significant prestige for recruitment and retention.

An Independent Academic Medical Center: Investing in the Leaders of Tomorrow

IHVI is committed to training the clinical and research leaders of the future. Our fellowship training program, accredited by the Accreditation Council for Graduate Medical Education, attracts applicants from a wide range of prestigious programs across the nation and around the world. Under the leadership of Program Director Dr. Christopher deFilippi and Associate Program Director Nasrien Ibrahim, MD, the program emphasizes research, engagement in clinical trials and academic excellence. We are proud of our trainees and their many accomplishments.



IHVI Cardiology Fellows. **Front Row:** Leonard Genovese, MD; Hooman Bakhshi, MD; Andrei Minciunescu, MD; **Back Row:** Rafael Arias, MD; Moemen Eltelbany, MD; Xiaoxiao Qian, MD; Raghav Gattani, MD; **Missing from photo:** Araba Ofosu-Somuah, MD

BIOCORE LABORATORY:

Providing a Full Range of Immunochemistry Services



Our state-of-the-art equipment, highly trained staff and experienced faculty provide diagnostic clinical testing, specimen processing and research testing including normal reference range studies, validation studies, clinical endpoint for FDA approval and interference studies.

We offer a broad portfolio of immunoassay and general chemistry tests using several commercial platforms and can perform research-based enzyme-linked (ELISA) immunoassays in multiple domains including, but not limited to, cardiac, diabetes, hepatic, inflammatory,

infectious disease, respiratory, therapeutic drug monitoring and thyroid/metabolism.

In addition to providing clinical and research testing services for faculty within Inova, BioCore is a valuable resource for researchers in the in vitro diagnostic industry, the pharmaceutical device industry and academia, and provides serology testing for the Commonwealth of Virginia. The laboratory supported multiple manufacturers in their development of COVID-19 immunoassays as well as providing ongoing academic contributions in this domain.



Sheena Villagomez, Director, Inova BioCore Laboratory

Selected Publications

- Haymond A, deFilippi CR, et al. Viral Neutralization is Durable in Asymptomatic COVID-19 for at least 60 Days. *J Infect Dis.* 2021 Mar 15
- Damluji AA, deFilippi C, et al. Serological Testing for COVID-19 Disease: Moving the Field of Serologic Surveillance Forward. *J Appl Lab Med.* 2021 Mar 10
- Damluji AA, deFilippi C, et al. Clinical Application of Serologic Testing for Coronavirus Disease 2019 in Contemporary Cardiovascular Practice. *J Am Heart Assoc.* 2021 Feb 23
- Stevenson LG, deFilippi CR. Swab-Free Transport as an Optimized Preanalytical Workflow for SARS-CoV-2 Molecular Testing. *J Appl Lab Med.* 2021 Feb 14
- Shah P, deFilippi CR, et al. Navigating COVID-19 Testing, Special Considerations for the Cardiovascular Clinician. *Circulation.* 2020 Oct 16
- deFilippi C, Grinspoon SK, et al. Differential Plasma Protein Regulation and Statin Effects in HIV-infected and Non-HIV-infected Patients Utilizing a Proteomics Approach Protein Regulation and Statin Effects in HIV. *J Infect Dis.* 2020 Apr 20

OMICS

Information at the Cellular Level Informing Clinical Research

The BioCore laboratory has played a key role in analyzing blood samples and contributing academically to the understanding of the mechanisms and efficacy of the new heart failure medication, vericiguat.

In addition, several ancillary studies with novel biomarkers, proteomics and genomics are underway to better understand the underlying mechanisms of heart failure and atherosclerotic disease and the role of comorbidities. The results of these studies will help guide both pharma and device therapy as well as develop prevention strategies.



Grants/Clinical Trials/Research Activities

- NIH K23 Mentored Patient-Oriented Research Career Development Grant – MicroRNA Biomarkers of Allograft Rejection and Cardiac Allograft Vasculopathy in Cardiac Transplantation
- AHA and Enduring Heart Foundation Grant – MicroRNA Biomarkers of Allograft Rejection in Cardiac Transplantation
- Heart Failure Biobank
- DCM – Genetic Testing for Dilated Cardiomyopathy
- TRANSFORM RO 1 Advanced HF Ancillary Biomarker Study

Selected Publications

- deFilippi CR, Mills NL. Rapid Cardiac Troponin Release After Transient Ischemia: Implications for the Diagnosis of Myocardial Infarction. *Circulation*. 2021 Mar 16
- Nowak RM, deFilippi CR, et al, Outpatient versus observation/inpatient management of emergency department patients rapidly ruled-out for acute myocardial infarction: Findings from the HIGH-US study. *Am Heart J*. 2021 Jan
- Shah P, Agbor-Enoh S. et al, Transcriptomics in transplantation: More than just biomarkers of allograft rejection. *Am J Transplant*. 2020 Dec 5



- Armstrong PW, O'Connor CM, et al. VICTORIA Study Group. Vericiguat in Patients with Heart Failure and Reduced Ejection Fraction. *N Engl J Med*. 2020 Mar 28
- Nowak RM, deFilippi CR, et al. Performance of Novel High-Sensitivity Cardiac Troponin I Assays for 0/1-Hour and 0/2- to 3-Hour Evaluations for Acute Myocardial Infarction: Results From the HIGH-US Study. *Ann Emerg Med*. 2020 Feb 8

IMPROVING THE CONDUCT OF CLINICAL RESEARCH:

Heart Failure Collaboratory

The Heart Failure Collaboratory (HFC), a public-private partnership between IHVI and the FDA developed under the leadership of IHVI President Dr. Christopher O'Connor, continues to improve and modernize heart failure clinical trials through meetings and innovative working group projects with diverse stakeholders. This unique forum brings together patients, investigators, academic leaders, pharmaceutical and device industry representatives, society representatives, third-party payers, and government representatives from the FDA, NIH and the Centers for Medicare and Medicaid Services to discuss challenges and identify actionable opportunities. The collaboration has resulted in strategies and tactics to enhance the efficiency of clinical trials and to support the development of safe and effective treatment options for patients. Importantly, the HFC continues to provide structured recommendations and tools for the conduct of clinical trials during the COVID-19 pandemic.



Top: Mitchell Psotka, MD, PhD; Bottom: Nasrien E. Ibrahim, MD, HFC Faculty

Grant

- R18 FDA – The Heart Failure Collaboratory Public-Private Partnership Between the FDA, IHVI and the Heart Failure Community

Selected Publications

- DeFilippis EM, Psotka MA, Ibrahim NE. Promoting Health Equity in Heart Failure Amid a Pandemic. *JACC Heart Fail.* 2021 Jan;9(1):74-76.
- Zeitler EP, O'Connor CM, Abraham W, Lindenfeld J. How Is Medical Device Innovation Currently Supported in the U.S.? From the Heart Failure Collaboratory. *JACC Heart Fail.* 2021 Nov;9(11)
- Lindenfeld J, O'Connor C, et al. Promoting Diversity in Clinical Trial Leadership: A Call to Action. *JACC Heart Fail.* 2021 May
- Psotka MA, O'Connor CM, et al. Conduct of Clinical Trials in the Era of COVID-19: JACC Scientific Expert Panel. *J Am Coll Cardiol.* 2020 Nov 17
- Abraham WT, Psotka MA, O'Connor CM, et al. Standardized Definitions for Evaluation of Heart Failure Therapies: Scientific Expert Panel from the Heart Failure Collaboratory and Academic Research Consortium. *JACC Heart Fail.* 2020 Nov 10
- Abraham WT, O'Connor CM, et al. Heart Failure Collaboratory Statement on Remote Monitoring and Social Distancing in the Landscape of COVID-19. *JACC Heart Fail.* 2020 Aug
- Abraham WT, O'Connor CM, et al. Heart Failure Collaboratory Statement on Clinical Trials in the Landscape of COVID-19. *JACC Heart Fail.* 2020 May

AMBULATORY

IHVI's ambulatory research team actively recruits patients to enter multicenter, randomized studies investigating new therapeutic agents or new indications. The ambulatory team also participates in clinical trials of new diagnostics typically applied in an acute care setting such as the emergency department. These include several studies to evaluate more sensitive versions of cardiac troponin testing for the diagnosis of acute myocardial infarction and developing new algorithms to diagnose these patients in as little as an hour.



Henry Tran, MD



Tariq Haddad, MD

Conducting Clinical Research in the Era of COVID-19

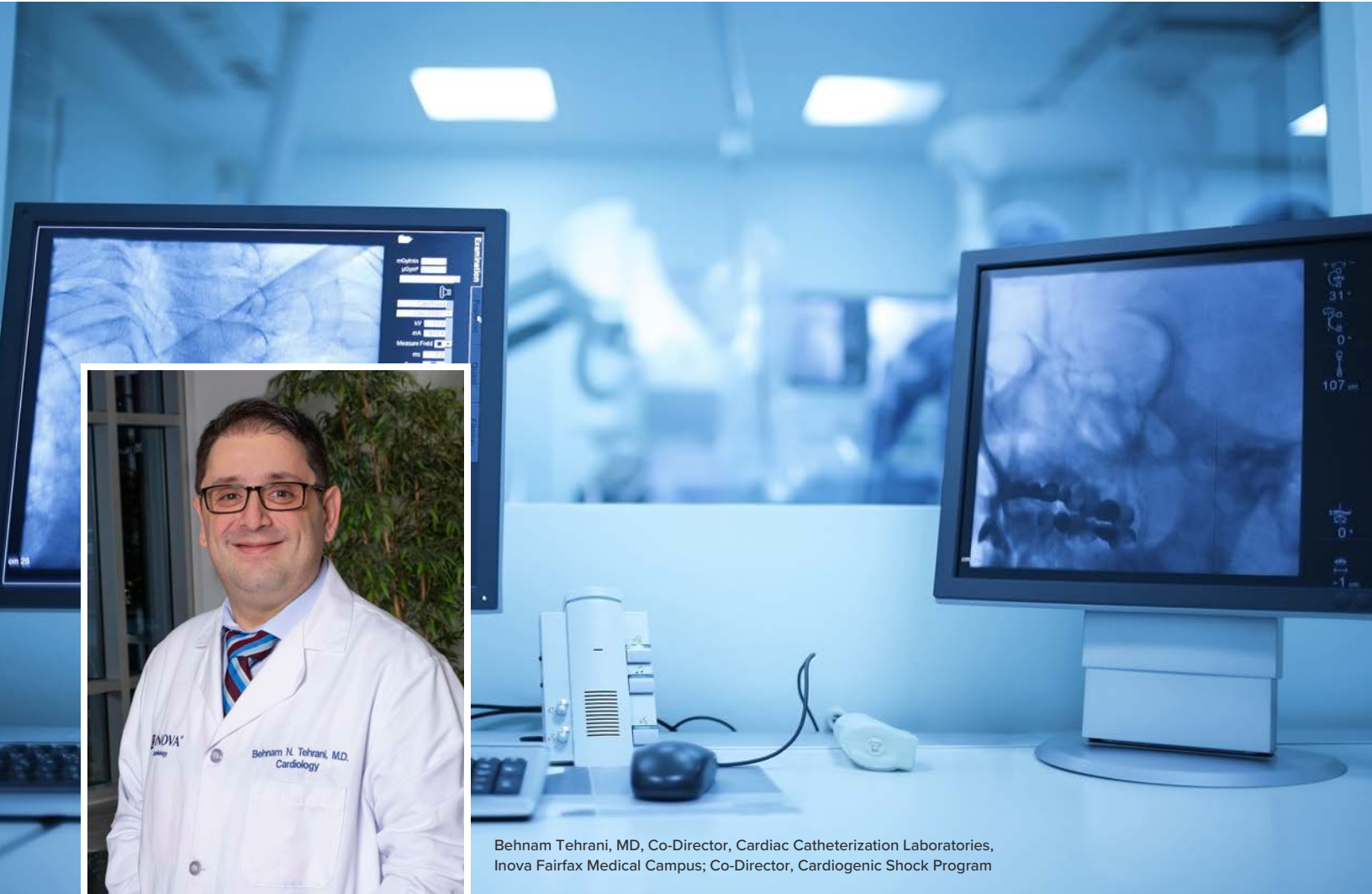
The clinical research ecosystem has been profoundly changed by COVID-19. Adapting to these changes was critical to ensuring continued advances in patient care. IHVI's researchers have been at the forefront of efforts to develop recommendations for best practices for conducting clinical trials while maintaining patient safety, and many of these changes have important benefits for future research. The lessons learned from the conduct of clinical research in an extreme environment have already informed new efficiencies and furthered a patient-centered focus to implement innovative studies that can minimize burden and maximize potential participation benefit.



Grants/Clinical Trials

- SELECT: Semaglutide Effects on Heart Disease and Stroke in Patients with Overweight or Obesity
- FINEARTS-HF: Study to Evaluate the Efficacy and Safety of Finerenone on Morbidity and Mortality in Participants with Heart Failure and Left Ventricular Ejection Fraction Greater Than or Equal to 40 Percent
- PARAGLIDE-HF: Changes in NT-proBNP and Outcomes, Safety and Tolerability in HFpEF Patients with Acute Decompensated Heart Failure Who Have Been Stabilized During Hospitalization and Initiated In-Hospital or Within 30 Days Post-Discharge

CARDIOGENIC SHOCK



Behnam Tehrani, MD, Co-Director, Cardiac Catheterization Laboratories, Inova Fairfax Medical Campus; Co-Director, Cardiogenic Shock Program



Alexander Truesdell, MD, Co-Director, Cardiogenic Shock Program

Our multidisciplinary cardiogenic shock (CS) program continues to lead the nation in outcomes and serve as a model for clinical excellence in the management of patients with CS and those with end-stage heart failure. Our standardized team-based treatment algorithm, which focuses on rapid triage, assessment and tailored mechanical circulatory support, has been associated with durable improved survival, gaining IHVI national and international recognition.

We also have a complex high risk and indicated PCI program for the management of patients with advanced and highly

complex coronary artery disease, including those with chronic total occlusion. Our multidisciplinary team consists of interventional cardiologists, cardiac surgeons, advanced heart failure specialists, cardiac intensivists and advanced practice providers (APPs) who deploy the full spectrum of care, from cutting-edge catheter-based and surgical revascularization therapies to multiorgan system critical care in our cardiac intensive care unit (CICU).



Shashank Sinha, MD, MSc, Co-Medical Director, Cardiac Intensive Care Unit; Director, Cardiovascular Critical Care Research Program



Carolyn Rosner, RN, MSN, NP-C, MBA, Director, Innovative Programs

Grants/Clinical Trials/Research Activities

- Inova Shock Single-Center Prospective Registry
- Inova High Risk PCI Prospective Registry
- National Cardiogenic Shock Initiative
- Cardiogenic Shock Working Group
- Critical Care Cardiology Trials Network
- FDA Cardiac Safety Research Consortium Shock Think Tank – First Clinical Question and Network Working Groups

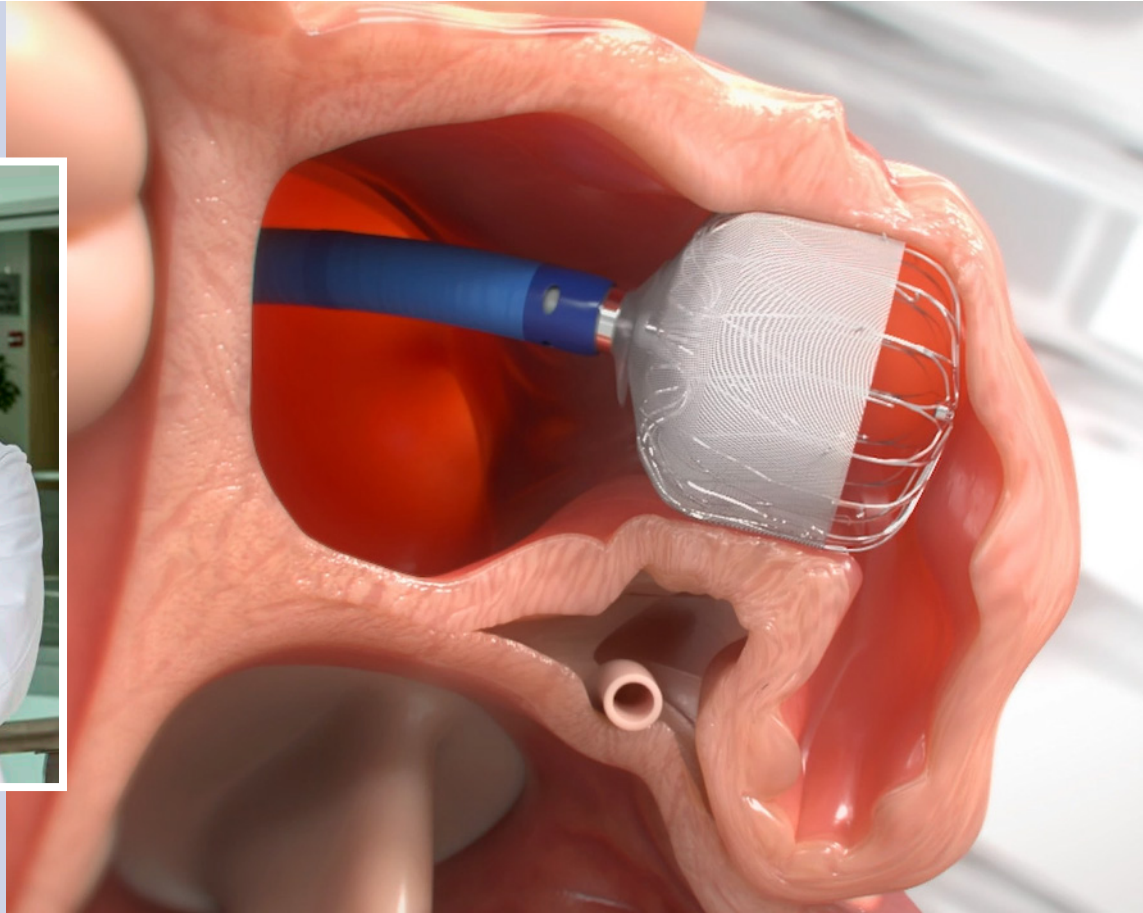
Selected Publications

- Rosner CM, Batchelor WB, et al. Management of Cardiogenic Shock During COVID-19: The IHVI Experience. *Research Letter J Am Coll Cardiol.* 2021 Jan
- Tehrani BN, Batchelor WB, et al. A Standardized and Comprehensive Approach to the Management of Cardiogenic Shock. *JACC Heart Fail.* 2020 Nov
- Tehrani BN, Kapur NK, et al. Acute myocardial infarction and cardiogenic shock: Should we unload the ventricle before percutaneous coronary intervention? *Prog Cardiovasc Dis.* 2020 Sep 10
- Tehrani BN, Batchelor WB, et al. A Standardized and Comprehensive Approach to the Management of Cardiogenic Shock. *JACC Heart Fail.* 2020 Nov
- Tehrani BN, O'Connor CM, et al. Standardized Team-Based Care for Cardiogenic Shock. *J Am Coll Cardiol.* 2019 Apr 9

INTERVENTIONAL AND STRUCTURAL HEART DISEASE



Wayne Batchelor, MD, MHS, Associate Director, IHVI; System Director, Interventional Cardiology and Interventional Heart Disease Research, Education and Innovation



Matthew Sherwood, MD, MHS, Director, LAAC/WATCHMAN Program, IHVI; Co-Director, Structural Heart Program and Cardiac Catheterization Laboratories, IFMC



Eric L. Sarin, MD, Section Chief, Adult Cardiac Surgery; Co-Director, Structural Heart Program; Co-Director, Cardiothoracic Surgery Research

Our interventional cardiology and structural heart disease programs are on a tremendous growth curve. We are participating in 18 major clinical trials, and this broad array of clinical research allows our patients to have access to the most promising state-of-the-art investigational therapies. Our portfolio is expanding substantially as we work toward breakthroughs and further develop innovative diagnostic and therapeutic strategies.

Novel Devices and Therapies for Structural Heart Disease

With the rapid technological advances in structural heart disease procedures and devices, there is a great need for clinical research to better evaluate these new therapies. Our program spans the range from “first-in-human” to better established devices with novel interventions.

Collaborations with biomedical engineering and technology companies expand IHVI's existing capabilities and present new opportunities. We continue to explore innovative treatments for patients for whom traditional approaches are technically challenging or limited in safety or efficacy.

Interventional Therapies and Algorithms for Heart Failure

We are researching the best way to treat patients who have heart failure and valvular heart disease through the development and validation of a treatment algorithm aimed at employing the safest and most efficacious state-of-the-art structural heart disease interventions and medical therapies to improve outcomes and long-term quality of life. IHVI is also a site in the RELIEVE-HF study to evaluate the V-Wave Interatrial Shunt System as a means of treating heart failure.

Novel Approaches to Radial Artery Access for Percutaneous Coronary Intervention

Using ultra-high-definition ultrasound techniques, our team is investigating healing the radial artery following access for heart catheterization procedures and comparing various novel techniques, including more distal radial artery access, to identify ways to optimize patient comfort and preserve radial artery patency and access for future procedures.

Mechanical Complications of Acute Myocardial Infarction

We are examining different management strategies for mechanical complication of acute myocardial infarction, including incorporating a multidisciplinary team approach to aid in prioritization. Abdulla Damluji, MD, PhD, was first author on an AHA Scientific Statement on this topic published in June 2021.



Abdulla Damluji, MD, PhD



Kelly Epps, MD, Medical Director, Women's Cardiovascular Health Center

Grants/Clinical Trials

- SUMMIT Clinical Trial to Evaluate the Safety and Effectiveness of Using the Tendyne Mitral Valve System for the Treatment of Symptomatic Mitral Regurgitation
- APOLLO Trial to evaluate the Safety and Effectiveness of the Intrepid™ Transcatheter Mitral Valve Replacement System – a New Therapeutic Option for Patients with Severe Mitral Regurgitation
- Abbott ICAIRE Best Practices for Patients with Heart Failure and Secondary MR: An Evaluation of the Inova Heart Failure Treatment Algorithm for Mitral Regurgitation
- RELIEVE-HF Trial: REDucing Lung congestion Symptoms Using the v-wavEShunt in adVancEd Heart Failure
- PRESERVE Radial Trial: A Single-Center and Investigator-Initiated Prospective Randomized Clinical Study Comparing Radial Artery Intimal Hyperplasia Following Distal vs. Forearm Transradial Arterial Access for Percutaneous Coronary Intervention
- CHAMPION-AF Trial: A Prospective Multicenter Randomized Trial to Evaluate the Safety and Efficacy of the WATCHMAN FLX LAAC Device vs. Direct Acting Oral Anticoagulants for First-Line Therapy in the Prevention of Stroke in Patients with Nonvalvular Atrial Fibrillation
- SMART – TAVR Trial: A Prospective Multicenter Randomized Trial to Evaluate the Hemodynamics and Valve Deterioration/Durability of Medtronic Corevalve vs. Edwards Sapien Valve in Patients with Small Aortic Annular Size

Selected Publications

- Damluji AA, Chikwe J, et al. American Heart Association Council on Clinical Cardiology; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular Surgery and Anesthesia; and Council on Cardiovascular and Stroke Nursing. Mechanical Complications of Acute Myocardial Infarction: A Scientific Statement from the American Heart Association. *Circulation*. 2021 Jun 15
- Sherwood MW, Vora AN. Is Transcatheter Aortic Valve Replacement Worth the Wait? *Circ Cardiovasc Interv*. 2020 Nov 10
- Sherwood M, Gurbel PA, et al. Detailed thrombogenicity phenotyping and 1 year outcomes in patients undergoing WATCHMAN implantation: (TARGET-WATCHMAN) a case-control study. *J Thromb Thrombolysis*. 2020 Jun 29
- Sherwood MW, Rao SV, et al. Outcomes of Cardiac Catheterization in Patients with Atrial Fibrillation on Anticoagulation in Contemporary in Practice: An Analysis of the ORBIT II Registry. *Circ Cardiovasc Interv*. 2020 May
- Sherwood MW, Rao SV, et al. Incidence, Temporal Trends, and Associated Outcomes of Vascular and Bleeding Complications in Patients Undergoing Transfemoral Transcatheter Aortic Valve Replacement: Insights from the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapies Registry. *Circ Cardiovasc Interv*. 2020 Jan

INTERVENTIONAL AND STRUCTURAL HEART DISEASE



Suture-Mediated Patent Foramen Ovale Closure

IHVI is one of only a handful of centers across the globe experienced in the NobleStitch™ EL technique, a simple, minimally invasive, suture-mediated method of closing a patent foramen ovale. We are currently participating in the only investigational device exemption trial comparing this novel technique to existing permanent implants.

New Minimally Invasive Treatment for Tricuspid Disease

The TRILUMINATE Pivotal Trial is evaluating a new, minimally invasive and promising treatment for severe tricuspid regurgitation (TR). We were selected to participate in this study because of our strong multidisciplinary team consisting of experts in interventional cardiology, heart failure, cardiac imaging, cardiothoracic surgery, skilled nursing and APPs. As one of only three hospitals in Virginia to offer this innovative approach, we are excited to provide this treatment to a broad range of patients with TR across the state and beyond.

Advanced Cardiac Imaging

State-of-the-art imaging is a critical component of our structural heart program.

In connection with the TRILUMINATE trial, we are prospectively screening all patients with TR to define the most accurate way to quantify this underrecognized and undertreated valvular disease by advanced cardiac imaging, and thereby allow a wider range of patients with TR to benefit from transcatheter therapies.

Advanced cardiac imaging also plays a key role in the assessment of mitral regurgitation (MR) following transcatheter edge-to-edge repair, and we are developing optimal methods to assess and quantify residual postprocedural MR using transthoracic echocardiography and cardiac MRI.

In addition, using pyrophosphate (PYP) nuclear scintigraphy, we are working with Virginia Heart to screen patients with severe aortic stenosis (AS) who are undergoing surgical or transcatheter valve replacement and generate a comprehensive registry to support earlier treatment for patients with AS/amyloidosis.



Abbas Emaminia, MD, Medical Director, Nuclear Medicine

Clinical Trials

- **NobleStitch EL STITCH Trial:** A Prospective Multicenter Comparative Parallel Concurrent Study of the NobleStitch EL Compared to the FDA-Approved Amplatzer Occluder Device for Closure of Patent Foramen Ovale to prevent Recurrent Ischemic Stroke
- **TRILUMINATE Pivotal Trial** to Demonstrate the Safety and Effectiveness of the Triclip Device in Improving Clinical Outcomes in Symptomatic Patients with Severe TR, Who are at Intermediate or Greater Estimated Risk for Mortality or Morbidity with Tricuspid Valve Surgery

IMPACT OF GERIATRIC SYNDROMES

Frailty, multimorbidity, polypharmacy, physical and cognitive dysfunction, malnutrition, quality of life, and other associated risks for older adults undergoing cardiovascular interventions is an important focus of research. The IHVI team led the development of an AHA Scientific Statement on the influence of geriatric syndromes on cardiovascular health and is contributing to an ACC/AHA position statement on the management of acute coronary syndromes in older adults.

Cardiovascular Procedural Risk Stratification in Older Frail Adults

Work supported by an NIH K23 Grant awarded to Abdulla Damluji, MD, PhD, is underway to develop a scoring system to help risk stratify older frail adults who need high-risk cardiovascular procedures. Candidate patients undergo a comprehensive geriatric evaluation, including testing for frailty, physical and cognitive function, nutritional status, and other clinical, hemodynamic and biochemical markers. This affords clinicians and patients information that can lead to improved patient selection and optimize outcomes.



Abdulla Damluji, MD, PhD, Director, Inova Center for Outcomes Research

Grants/Clinical Trials

- NIH K23 – Frailty and Resiliency in Older Adults with Acute Myocardial Infarction
- NIA P30-A021334 – Pepper Scholars Program
- Inova seed grant 152082-U20-03-3976D

Selected Publications

- Damluji AA, Gerstenblith G, et al. Frailty and cardiovascular outcomes in the National Health and Aging Trends Study. *Eur Heart J*. 2021 Jul 29
- Damluji AA, Gerstenblith G, et al. Physical Frailty Phenotype and the Development of Geriatric Syndromes in Older Adults with Coronary Heart Disease. *Am J Med*. 2021 May;134(5)
- Damluji AA, Batchelor W, et al. Transcatheter Aortic Valve Replacement in Low-Population Density Areas: Assessing Healthcare Access for Older Adults with Severe Aortic Stenosis. *Circ Cardiovasc Qual Outcomes*. 2020 Aug;13(8)
- Damluji AA, Gerstenblith G, Segal JB. Frailty Measurement Using Administrative Data in Older Patients with Cardiovascular Disease. *JAMA Cardiol*. 2020 May 20
- Damluji AA, Batchelor W. Sarcopenia and Health-Related Quality Of Life In Older Adults After Transcatheter Aortic Valve Replacement. *Am Heart J*. 2020 Apr 4
- Damluji AA, Cohen MG, et al. Older Adults in the Cardiac Intensive Care Unit: Factoring Geriatric Syndromes in the Management, Prognosis, and Process of Care: A Scientific Statement from the American Heart Association. *Circulation*. 2020 Jan 14

CARDIOVASCULAR HEALTHCARE DISPARITIES

We are engaged in efforts on multiple fronts to evaluate and reduce cardiovascular healthcare disparities in research and clinical care. Our research includes analysis of pooled data from major clinical trials and registries to evaluate outcomes of patients undergoing cardiovascular and structural interventions based on age, ethnicity, race, gender and urban/rural location. Our team is also working directly with the FDA to examine data from several pivotal trials to understand the influence of age, race and ethnicity on clinical trial enrollment and outcomes.



Wayne Batchelor, MD, MHS



Nasrien Ibrahim, MD



Kelly Epps, MD

Selected Publications

- Batchelor WB, Damluji AA, Mehran R, et al. Does Study Subject Diversity Influence Cardiology Research Site Performance? Insights From 2 U.S. National Coronary Stent Registries. *Am Heart J.* 2021 Feb 23
- Lindenfeld J, Fiuzat M, O'Connor C. Promoting Diversity in Clinical Trial Leadership: A Call to Action. *JACC Heart Fail.* 2021 May;9(5):401-402
- Ibrahim NE, O'Connor CM, Januzzi JL Jr. From Clinical Trials to Communities: The 5 C's of Ensuring Equitable Delivery of Heart Failure Therapies. *JACC Heart Fail.* 2021 Sep;9(9):694-696.
- Batchelor W, Yong C. et al. Optimal Clinical Research Performance Includes Diversity: insights from 2 U.S. National Coronary Stent Registries. *J Am Coll Cardiol* 2021 (in press)
- Ibrahim NE, Januzzi JL Jr, et al.; Prospective Study of Biomarkers, Symptom Improvement and Ventricular Remodeling During Entresto Therapy for Heart Failure (PROVE-HF) Study Investigators. Sex-Based Differences in Biomarkers, Health Status, and Reverse Cardiac Remodeling in Patients with Heart Failure with Reduced Ejection Fraction Treated with Sacubitril/Valsartan. *Eur J Heart Fail.* 2020 Nov;22(11)
- Ibrahim NE, Januzzi JL Jr, et al. Prospective Study of Biomarkers, Symptom Improvement and Ventricular Remodeling During Entresto Therapy for Heart Failure (PROVE-HF) Study Investigators. Racial and Ethnic Differences in Biomarkers, Health Status, and Cardiac Remodeling in Patients with Heart Failure with Reduced Ejection Fraction Treated with Sacubitril/Valsartan. *Circ Heart Fail.* 2020 Nov;13(11)
- Batchelor WB, Mehran R., et al. Aortic Valve Stenosis Treatment Disparities in the Underserved: JACC Council Perspectives. *J Am Coll Cardiol.* 2019 Nov 5;74(18)

CARDIOTHORACIC SURGERY

Since its inception, IHVI's Division of Cardiothoracic Surgery has been at the forefront of pioneering new technologies and techniques and has maintained robust participation in clinical research through the Virginia Cardiac Surgery Quality Initiative as well as the NIH-sponsored Cardiothoracic Surgical Trials Network.

As the first program in the region to perform a heart transplant nearly 35 years ago and the only active lung transplant program for the Washington, DC, region, IHVI is a leader in thoracic transplantation.

Extensive experience with minimally invasive valve surgery is the foundation of our nationally recognized, multidisciplinary structural heart program, with a volume among the top 10 percent in the country and outstanding outcomes.

Our nationally recognized expertise in complex aortic disease and in open reconstruction of the thoracic aorta has been augmented with the latest endovascular approaches. IHVI is an active participant in stent graft clinical trials, applying a truly multidisciplinary approach involving vascular surgery and interventional radiology.

Grants/Clinical Trials

- PACeS: Network for Cardiothoracic Surgical Investigations in Cardiovascular Medicine: Anticoagulation for New-Onset Post-Operative Atrial Fibrillation After Coronary Artery Bypass Graft (CABG)
- Phase 2 Proof of Concept, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy of ASP1128 (MA-0217) in Subjects at Risk for Acute Kidney Injury Following CABG and/or Valve Surgery

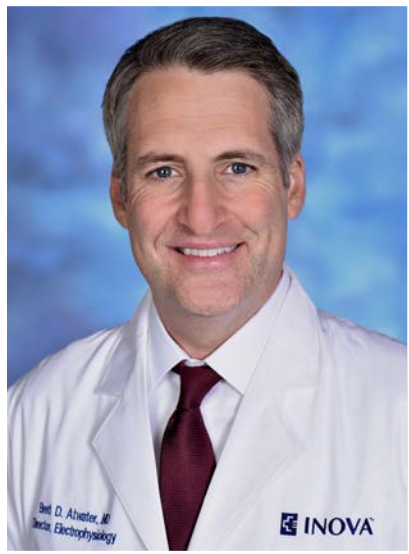


Alan Speir, MD, Senior Associate Director, IHVI; Director, Cardiac Surgery



Eric L. Sarin, MD, Section Chief, Adult Cardiac Surgery; Co-Director, Structural Heart Program; Co-Director, Cardiothoracic Surgery Research

CARDIAC ELECTROPHYSIOLOGY

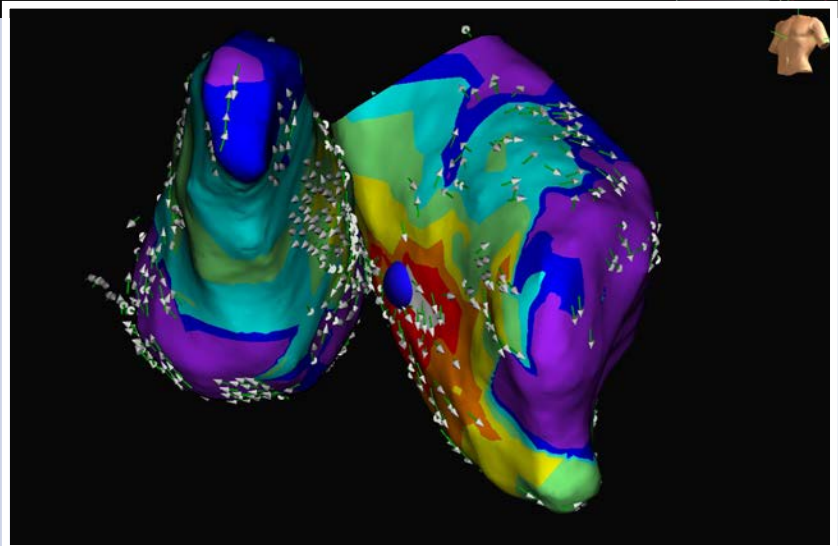
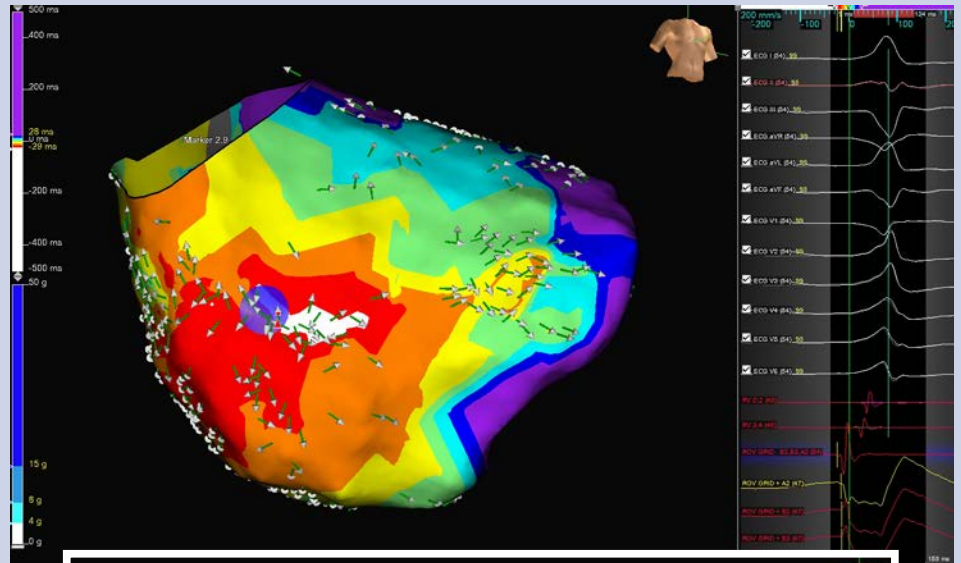


Brett Atwater, MD, System Director, Cardiac Electrophysiology and Electrophysiology Research

The scope and breadth of electrophysiology research is expanding rapidly with the recent addition of Brett Atwater, MD, as System Director of Cardiac Electrophysiology and Electrophysiology Research.

Plans are underway to leverage our excellent clinical procedural volumes to develop a comprehensive registry that will support the creation of a “learning health system” approach to the care of patients with heart rhythm disorders and facilitate future research.

We continue to participate in industry-funded trials of breakthrough technologies to treat atrial fibrillation (AFib), heart failure and bradycardia and to help prevent stroke. Current studies include the LEADLESS II trial to evaluate a novel



miniature pacemaker that can be implanted completely within the heart, and the STELLAR trial, led by Haroon Rashid, MD, that is evaluating a multielectrode radio-frequency ablation balloon to reduce AFib ablation procedural time and complications.

Investigator initiated projects are underway as well. Vineet Kumar, MD, is leading a study to explore the value of a battery of biomarkers in predicting the likelihood

of success of ablation for AFib by predicting the level of left atrial scarring.

Our portfolio of industry-funded research trials for the coming year includes investigational device exemption studies to test novel devices and therapies, and we look forward to being able to offer these innovative treatment options to our patients while advancing our field.



Brett Atwater, MD

Below: (L to R): Vineet Kumar, MD, Co-Director, Electrophysiology Research; Stephen Gaeta, MD, Associate Director, Electrophysiology Lab; Haroon Rashid, MD, Director, Atrial Fibrillation Ablation and Research; Aysha Arshad, MD



Grants/Clinical Trials

- LEADLESS II: Study of Clinical Safety and Effectiveness of Leadless Pacemaker System in Patients Who Are Indicated for a VVIR Pacemaker
- STELLAR Atrial Fibrillation IDE Study Investigating Safety and Effectiveness of Heliostar Multi-Electrode RF Balloon Ablation Catheter for Intermittent AFib

Selected Publications

- Atwater BD, Hammill BG, et al. Early Increased Physical Activity, Cardiac Rehabilitation, and Survival After Implantable Cardioverter-Defibrillator Implantation. *Circ Cardiovasc Qual Outcomes*. 2021 Jul 21
- Polcwiartek C, Atwater BD, et al. Clinical Heart Failure Among Patients with and Without Severe Mental Illness and the Association with Long-Term Outcomes. *Circ Heart Fail*. 2021 Sep 30.

- Gaeta S, Henriquez C, et al. High-Resolution Measurement of Local Activation Time Differences from Bipolar Electrogram Amplitude. *Front Physiol*. 2021 Apr 22
- Friedman DJ, Atwater BD, et al. Left Bundle-Branch Block is Associated With a Similar Dyssynchronous Phenotype in Heart Failure Patients with Normal and Reduced Ejection Fractions. *Am Heart J*. 2021 Jan; 231:45-55
- Atwater BD, Friedman DJ, et al. Predicting the Development of Reduced Left Ventricular Ejection Fraction in Patients with Left Bundle Branch Block. *Am J Cardiol*. 2020 Dec 15; 137: 39-44
- Gaeta S, Henriquez C, et al. Mechanism and Magnitude of Bipolar Electrogram Directional Sensitivity: Characterizing Underlying Determinants of Bipolar Amplitude. *Heart Rhythm*. 2019 Dec 13

ADVANCED HEART FAILURE AND HEART TRANSPLANTATION



Palak Shah, MD, MS, Medical Director, Cardiovascular Genomics Center; Director, Heart Failure, Mechanical Circulatory Support and Transplant



Mitchell Psotka, MD, PhD, Section Chief, Heart Failure and Transplant Program

The advanced heart failure research team combines high-quality clinical care with cutting-edge research to optimize patient outcomes. Our physicians lead and participate in national and international clinical trials in heart failure, thereby providing access to novel medical and device therapeutics from both government and industry and ensuring that our patients have access to the highest quality and most innovative care.

Research to better distinguish the genetic etiology of cardiomyopathy/heart failure and provide targeted therapeutics for diseases like amyloidosis is an important area of focus, as is the development of new biomarkers that can be used to manage patients with left ventricular assist devices and patients after heart transplant. The advanced heart failure

team has also led important advances in critical care cardiology and has been instrumental in the development of protocols and algorithms for the CICU.

Advanced Cardiac Imaging to Screen for Cardiac Amyloidosis

Identifying and treating those in the early stages of ATTR cardiac amyloidosis, before irreversible cardiac damage has occurred, is vital. Our dedicated cardiac amyloidosis imaging program is screening family members of patients with mutant ATTR cardiac amyloidosis using echocardiography with strain, cardiac MRI and PYP imaging to determine the most effective imaging modalities to monitor asymptomatic carriers of pathogenic genes.

Genomics and Personalized Medicine

Developing and validating genomic biomarkers that can inform the development of management strategies and newer therapeutics to improve long-term outcomes for patients with advanced heart failure is an active area of research for IHVI. In our translational lab, we perform essential genomic techniques for genetic analyses: DNA and RNA isolation from blood and myocardial tissue, spectrophotometry, electrophoresis, polymerase chain reaction, and next-generation sequencing.

Early analyses through an ongoing collaboration with the National Heart, Lung and Blood Institute (NHLBI), the Genomic Research Alliance for Transplantation (GRAFT), show that donor-derived, cell-free DNA can predict early allograft injury after cardiac transplantation. This offers the potential to noninvasively diagnose acute cellular and antibody-mediated rejection and relieve the morbidity associated with repetitive invasive assessments of graft function through endomyocardial biopsy. In addition to the detection of rejection, we are also identifying the long-term consequences of such allograft injury.

Our work using a novel genomic biomarker, microRNAs, shows that these markers are present in the circulation and appear to be differentially expressed based on the subtype of rejection. Further, they track with immune system activity and could be used as a marker of immune quiescence. This line of research holds great promise for developing strategies to reduce the complications of immunosuppression including infection, renal failure and malignancy.



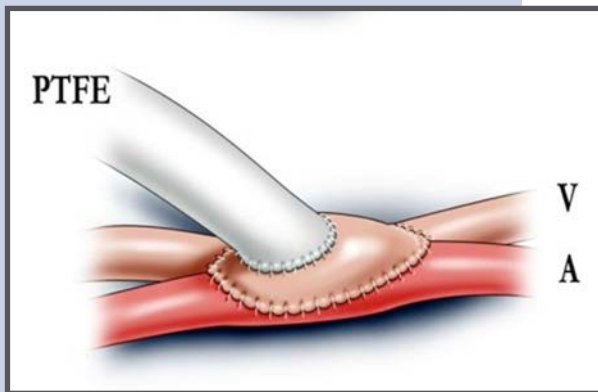
Nasrien E. Ibrahim, MD, Director, Heart Failure Clinical Research; Associate Program Director, Cardiovascular Disease Fellowship Training Program

Grants/Clinical Trials/Research Activities

- K23 NIH – MicroRNA Biomarkers of Allograft Rejection and Cardiac Allograft Vasculopathy in Cardiac Transplantation
- R01 NIH – The Optimal Loop Diuretic: Mechanistic Insights from Longitudinal Changes in Blood and Urine Proteins to Explain Efficacy and Safety of Torsemide vs. Furosemide After a Heart Failure Hospitalization
- AHA and Enduring Hearts Foundation Grant – MicroRNA Biomarkers of Allograft Rejection in Cardiac Transplantation
- RO1 TRANSFORM Advanced HF Ancillary Biomarker Study Victoria
- Donor-Derived Cell-Free DNA to DETect REjection in Cardiac Transplantation (DETECT)
- Dilated Cardiomyopathy Precision Medicine Study
- HF-eVOLUTION Study to Investigate Whether Digital Medical Technology Data, Including Data from Wearable Devices, Can Help Doctors Better Care for Patients by Prompting Earlier Interventions to Improve Symptoms, Function and Quality of Life
- Heart Failure Biobank

Selected Publications

- Cooper LB, deFilippi C, et al. Efficacy of Nephilysin Inhibition in Women with HFpEF: Beyond Phenotypes and Natriuretic Peptides. *Circulation*. 2021 Feb 16
- Gerhard EF, Shah P, et al. LVAD Decommissioning for Myocardial Recovery: Long-Term Ventricular Remodeling and Adverse Events. *J Heart Lung Transplant*. 2021 Aug 11
- Agbor-Enoh S, Shah P, et al. GRAFT Investigators. Cell-Free DNA to Detect Heart Allograft Acute Rejection. *Circulation*. 2021 Jan 13
- Eitelbany M, Shah P., et al. Delayed Presentation of Thrombophilia After Left Ventricular Assist Device Deactivation for Reverse Cardiac Remodeling. *Circ Heart Fail*. 2020 Jul 16
- Cowger JA, Shah P et al. Avoiding the “Set It and Forget It Mentality”: A Need to Regularly Reassess Left Ventricular Assist Device Patients for Optimal Support *J Thorac Cardiovasc Surg*. 2020 Apr



Richard Neville, MD, Chair, Department of Surgery; Associate Director, IHVI; System Director, Vascular Services

Our vascular program is internationally recognized for cutting-edge research involving diagnostic and treatment strategies for aortic aneurysms, stroke prevention, critical limb ischemia and amputation prevention with wound healing. Current research includes participation in national trials such as CREST 2 and CREST H to evaluate the results of carotid endarterectomy vs. carotid stenting vs. best medical therapy for asymptomatic high-grade carotid stenosis, BEST-CLI to evaluate the results of PCI vs. surgical bypass for critical limb ischemia, and multiple device trials for the treatment of aortic aneurysm disease both in the thoracic and abdominal spaces.

We are investigating near infrared spectroscopy imaging for lower extremity perfusion, working with Kent Imaging. We are

also participating in remote monitoring studies of dialysis access fistulas including physiologic data such as heart rate, blood pressure and hemoglobin levels through Alio, and we have been selected as a center to investigate a Humacyte biologic graft for dialysis access.

Clinical research includes TransCarotid Artery Revascularization, a novel therapy to treat carotid disease in patients at higher risk for standard surgery, and a technique described by Dr. Richard Neville to combine deep venous arterIALIZATION with distal vein patch bypass to allow revascularization when standard options are not available.



(L to R): Vickie R. Driver, MD, Medical Director, Inova Wound Care and Hyperbaric Centers; Dipankar Mukherjee, MD, Chief, Vascular Surgery; Anthony Comerota, MD, Medical Director, Eastern Region



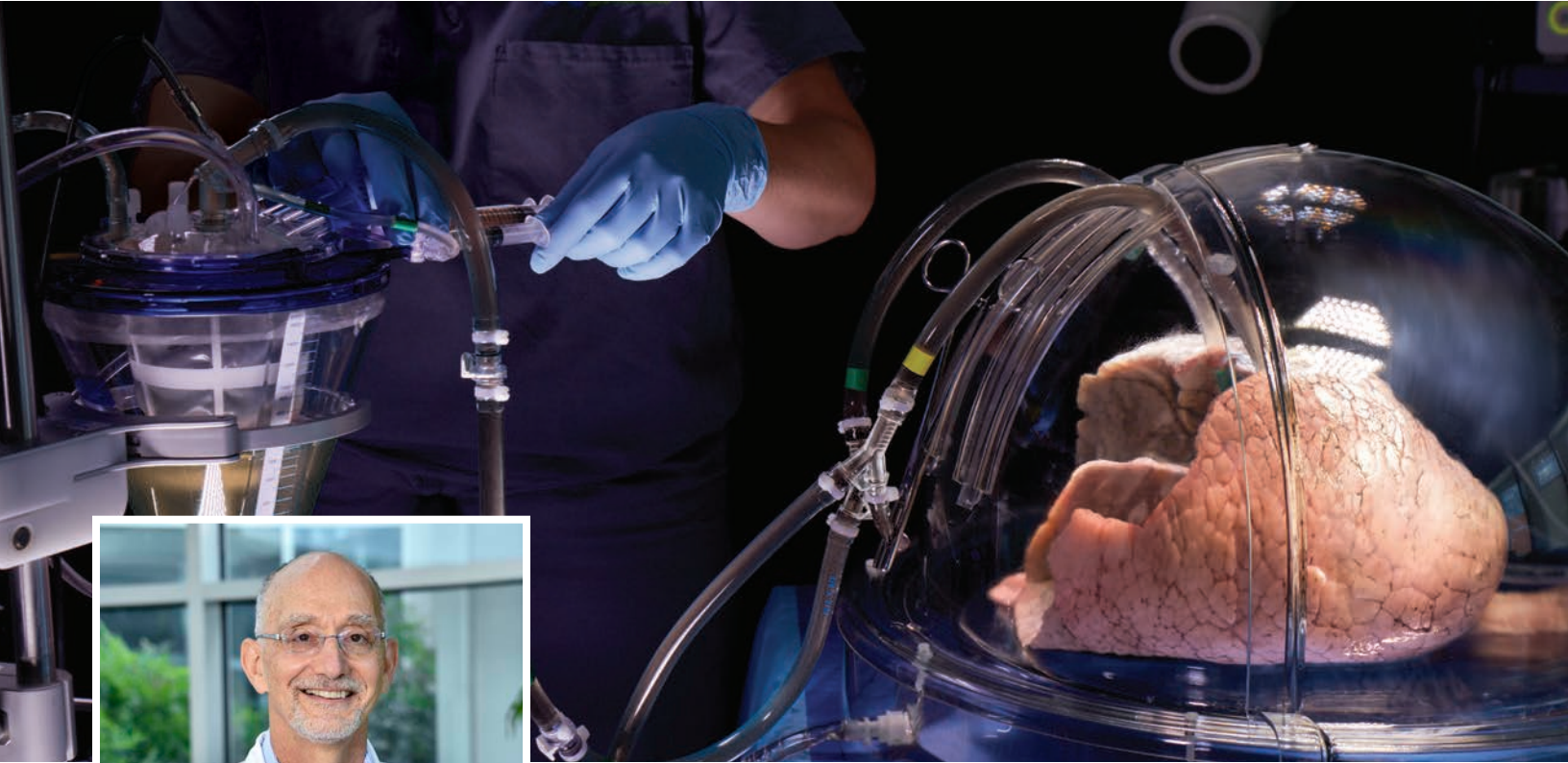
Grants/Clinical Trials

- CREST 2: Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial
- CREST H: Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial – Hemodynamics
- BEST-CLI: Best Endovascular vs. Best Surgical Therapy in Patients with Critical Limb Ischemia

Selected Publications

- Mukherjee D, Ryan L., et al. Retrograde Carotid Stenting Using Newly Released Venous Stent for Cerebral Malperfusion in Type A Aortic Dissection. *J Endovasc Ther.* 2021 Oct 8
- Ayalew D, Neville RF, Comerota AJ, et al. Common Femoral Vein Obstruction Secondary to Femoral Sheath Lipoma. *Ann Vasc Surg.* 2021 Aug 23
- Neville RF, Kuraguntla D. et al. Wearable Device for Continuous, Non-invasive Monitoring of Vascular Access Health and Fluid Status in Hemodialysis Patients. *J Vasc Surg* 2021;71(3):40.
- Parker M, Neville RF. A Novel Technique Utilizing Long Segment Patch Angioplasty Maturation (PAM) to Increase the Maturation Rate of Arteriovenous Fistulae. *J Vasc Surg* 2021
- Mukherjee D, Neville RF, et al. Effects of Peripheral Arterial Disease Interventions on Survival: A Propensity-Score Matched Analysis Using VQI Data. *Ann Vasc Surg* 2021

ADVANCED LUNG DISEASE AND TRANSPLANTATION



Steven Nathan, MD, Medical Director, Advanced Lung Disease and Lung Transplantation

IHVI's advanced lung disease research program was established in 1996 and covers a broad spectrum of lung diseases.

Our team is committed to exploring early therapeutic interventions in lung disease to prevent disease progression. We completed enrollment in a series of phase 2 studies of two small molecule agents that could potentiate the release of intrinsically produced alpha-1 antitrypsin. Looking forward, we are aiming to initiate a phase 2 trial investigating the potential for inhalational delivery of alpha-1 antitrypsin beginning in mid-2022.

Cystic Fibrosis

Our adult cystic fibrosis (CF) program delivers innovative and individualized care in collaboration with patients and their families. Our CF pulmonary rehabilitation program has achieved national recognition and we have been selected as a phase 3 clinical trial site for an alternative triple CFTR modulator candidate with enrollment starting at the end of 2021.

Interstitial Lung Disease

We are proud to participate in pivotal trials that are leading to groundbreaking developments in the rapidly evolving landscape of interstitial lung disease (ILD) and idiopathic pulmonary fibrosis treatment. Current research includes studies of novel antifibrotic therapies and inhaled nitric oxide for pulmonary hypertension (PH) in patients with ILD.

Lung Transplantation

Pulmonary sarcoidosis is an important indication for lung transplantation. Our multidisciplinary team includes

representation from cardiology, dermatology, neurology and ophthalmology as well as pulmonology to ensure comprehensive care for patients with this multisystem disorder. We offer multiple studies for sarcoid patients including studies for complicating PH and a registry for sarcoidosis-associated PH.

We have successfully transplanted three patients with COVID-19-related lung fibrosis, and we continue to receive referrals from regional and international centers. Post-COVID pulmonary fibrosis is an emerging cause of ILD as well as a growing indication for lung transplantation, and this has been an important area of research focus. We offer multiple studies for our lung transplant recipients including ex-vivo lung perfusion, genome transplant dynamics (in association with NIH), cell-free DNA registry, novel prophylactic antifungal therapy and extracorporeal photopheresis for chronic lung allograft dysfunction.



Top row (L to R): Christopher King, MD, Associate Medical Director, Advanced Lung Disease and Transplant Program; A. Whitney Brown, MD, Director, Adult Cystic Fibrosis Program

Bottom row (L to R): Kareem Ahmad, MD; Shambhu Aryal, MD, Associate Medical Director, Advanced Lung Disease and Transplant Program; Medical Director, Sarcoidosis Clinic; Vicramjit Khangoora, MD, Advanced Lung Disease and Transplant Critical Care Medicine



Grants/Clinical Trials/Research Activities

- Ex Vivo Lung Perfusion System Clinical Trial for Lung Transplantation
- Cystic Fibrosis Registry
- Extracorporeal Photopheresis for the Management of Progressive Bronchiolitis Obliterans Syndrome in Medicare-Eligible Recipients of Lung Allograft
- Genome Transplant Dynamics (GRAFT)
- Collection and Storage of Blood/Biospecimens for Research in Patients Referred to the Advanced Lung Disease Program
- NIH grant for the NIH-Inova Pulmonary Vascular Program
- Cystic Fibrosis Foundation Grant

Selected Publications

- Baughman RP, Nathan SD et al. Riociguat for Sarcoidosis Associated Pulmonary Hypertension: Results of a One Year Double Blind, Placebo Controlled Trial. *Chest*. 2021 Aug 4
- King CS, Nathan SD, et al. A Phase-2 Exploratory Randomized Controlled Trial of INOpulse in Patients with Fibrotic Interstitial Lung Disease Requiring Oxygen. *Ann Am Thorac Soc*. 2021 Oct 22.

- Nathan SD, Wells AU, et al. Impact of Lung Morphology on Clinical Outcomes with Riociguat in Patients with Pulmonary Hypertension and Idiopathic Interstitial Pneumonia: A Post Hoc Subgroup Analysis of the RISE-IIP Study. *J Heart Lung Transplant*. 2021 Feb 19
- Waxman A, Nathan SD, et al. Inhaled Treprostinil in Pulmonary Hypertension Due to Interstitial Lung Disease. *N Engl J Med*. 2021 Jan 13
- Pastre J, Nathan SD, et al. Idiopathic Pulmonary Fibrosis Patients with Severe Physiologic Impairment: Characteristics and Outcomes. *Respir Res*. 2021 Jan 6;22(1):5
- Nathan SD, Lancaster L. et al. A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of Pulsed, Inhaled Nitric Oxide (Ino) at a Dose of 30 Mcg/Kg-IBW/Hr (Ino 30) in Subjects at Risk of Pulmonary Hypertension Associated with Pulmonary Fibrosis (PH-PF) Receiving Oxygen Therapy. *Chest*. 2020 Feb 21



Oksana Shlobin, MD, Medical Director,
Pulmonary Hypertension Program

Pulmonary Hypertension

Inova's PH program is the only Comprehensive PH Care Center in the region and remains very active in internally initiated research, registries and industry-sponsored studies. Our group has led the way in studies of PH associated with ILD (PH-ILD), which culminated with the approval of the first drug to treat PH-ILD in April 2021. In addition to three actively recruiting trials, there are three upcoming studies targeting various groups of PH, including Group 1 PAH, HFpEF-PH, CTEPH, sarcoidosis PH, PH-ILD and PH-COPD.



Edwinia T. Battle, RN, Interim Director, Research, IHVI

Grants/Clinical Trials

- Pulmonary Hypertension Association Registry
- Study to Evaluate the Safety and Efficacy of Inhaled Treprostinil in Patients with Pulmonary Hypertension due to Chronic Obstructive Pulmonary Disease

FULL HEART AND LUNG SUPPORT IN PATIENTS WITH SEVERE SHOCK



Heidi Dalton, MD, Director, Adult and Pediatric Extracorporeal Life Support

Extracorporeal membrane oxygenation (ECMO) is a modified form of cardiopulmonary bypass that can support heart and lung function in patients with severe disease. We care for the sickest, most complex patients through our high-volume and highly ranked critical care/ECMO center. Our clinical research in this area includes a study to assess functional and psychological outcomes in ECMO survivors and research on methods to optimize anticoagulation monitoring, neuroprognostication, and reduction in bleeding and thrombotic complications.

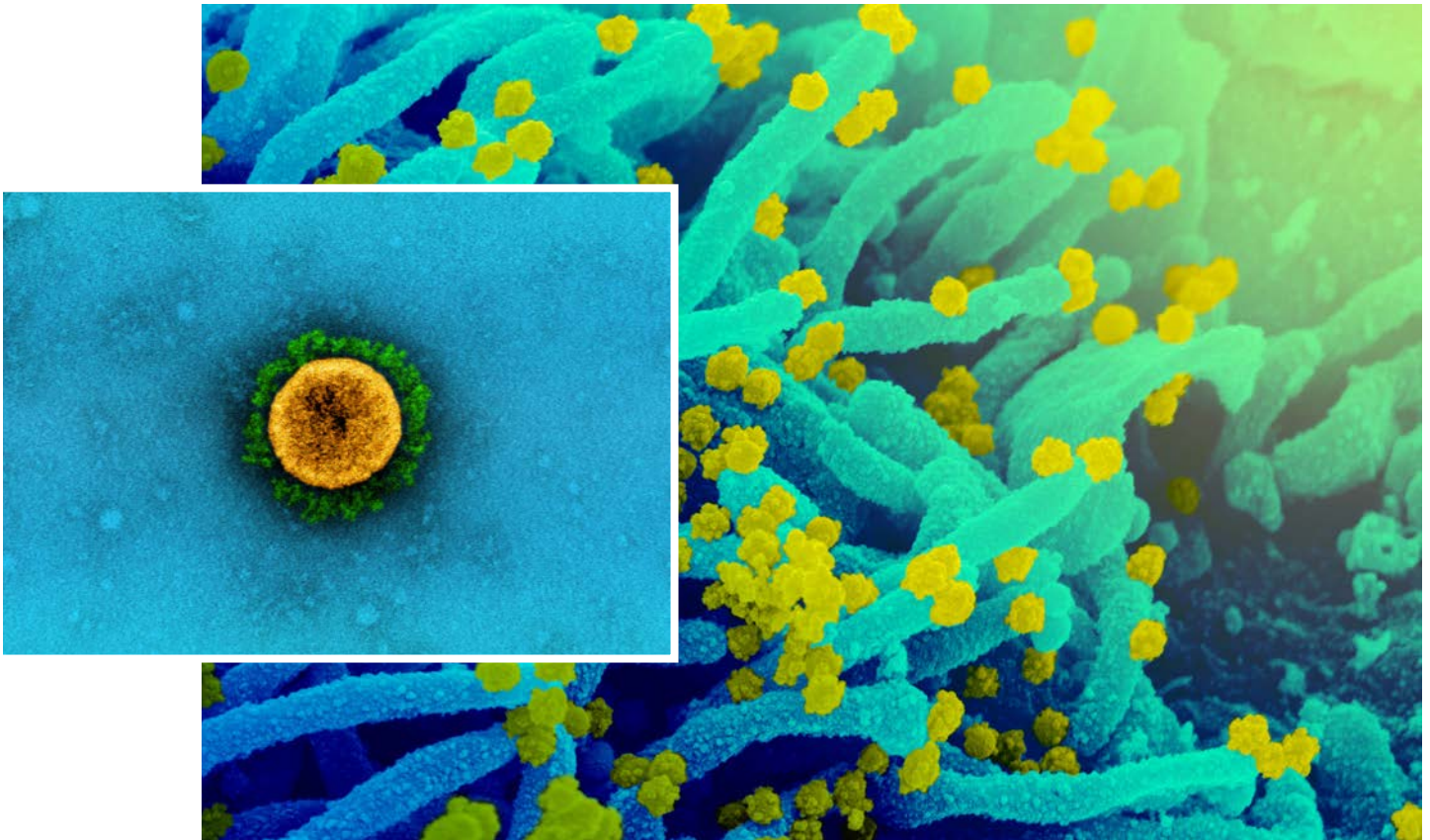
Grants/Clinical Trials

- Inova Seed Grant to Evaluate the Viscoelastic Monitor (VCM) In COVID-19 Patients
- Transonic Grant To Evaluate Cardiac Output In Venovenous ECMO Patients
- DOD Grant to Augment Ability to Download Data Directly from Epic into Research Databases and Evaluate the VCM in ECMO Patients
- Entegion Inc Grant to Validate the VCM Monitor Using Bedside Personnel: 18 Devices Tested

Selected Publications

- Mazzeffi MA, Dalton H, et al. Bivalirudin Superior to Heparin for Extracorporeal Membrane Oxygenation: Not So Fast. *Crit Care Med.* 2021 Oct 1;49(10):e1057-e1058
- Dalton HJ, Bartlett RH, et al. Cardiopulmonary Resuscitation and Rescue Therapies. *Crit Care Med.* 2021 Jul 14
- Dalton HJ, Buttram S. Identifying Injury to Improve Care in Infant Extracorporeal Membrane Oxygenation: Why Autopsy Is Important. *Pediatr Crit Care Med.* 2021 Mar 1;22(3):334-336
- Raman L, Dalton HJ. Surveying the Scene: Timing Is Everything. *Pediatr Crit Care Med.* 2020 Oct;21(10):902-903
- Gillespie AH, Dalton HJ. The Status of Pediatric Extracorporeal Life Support According to the National Inpatient Sample. *Pediatrics.* 2020 Aug 14

COVID-19 RESEARCH AT IHVI: Well Positioned to Respond to the Challenge



Steven Nathan, MD



Christopher deFilippi, MD

Under the leadership of Steven Nathan, MD, for inpatient trials and Dr. Christopher deFilippi for ambulatory research, IHVI moved quickly to initiate projects to evaluate new therapies, expand access and treatment protocols, and participate in clinical trials, registries, biobanking and testing for COVID-19. We diagnosed and treated some of the most acute cases but remain focused on exploring the long-term implications of COVID-19 on the cardiovascular and pulmonary systems.

Our COVID-19 research portfolio includes clinical trials for patients at all stages, from prevention and surveillance to “long haulers.” Our participation in cutting-edge research allows our patients to benefit from the newest investigational therapeutics before they became widely available.

We furthered our existing collaboration with the NHLBI and harmonized NIH's unique research capabilities with our robust COVID-19 clinical volumes, and we received the 2021 NHLBI Director's COVID-19 Response Award in recognition of our outstanding achievements. An exciting two-center phase 2 trial allowed us to demonstrate that fostamatinib, a novel splenic tyrosine kinase inhibitor, was safe and well tolerated in COVID-19 patients. There were multiple signals of improved clinical outcomes which, together with supportive biomarker data, suggest that this agent has potential therapeutic benefit, particularly in the sickest patients. We also worked on a drug-repurposing study with the virology department at George Mason University, one of the few BSL-3 labs in the country to have the SARS CoV-2 virus.

On the ambulatory side, in the early stages of the pandemic, we initiated serology surveillance of Inova's health-care workers and in collaboration with basic science researchers from George Mason and have published the results.

We are proud of our team's many contributions during all phases of the pandemic and their determination to remain focused and embrace innovative approaches to deliver the highest quality care in the safest possible environment.



Selected Publications

- Strich JR, Nathan SD, et al. Fostamatinib for the Treatment of Hospitalized Adults with COVID-19 A Randomized Trial. *Clin Infect Dis*. 2021 Sep 1
- King CS, Nathan SD, et al. How I Do It: Considering Lung Transplantation for Patients with COVID-19. *Chest*. 2021 Aug 18
- Damluji AA, deFilippi C. et al. Seropositivity of COVID-19 among Asymptomatic Healthcare Workers: A Multi-Site Prospective Cohort Study. *The Lancet Regional Health – Americas* Available online 29 July 2021
- Rosner CM, deFilippi CR, et al. Myocarditis Temporally Associated with COVID-19 Vaccination. *Circulation*. 2021 Jun 16
- King CS, Nathan S, et al. Outcomes of Mechanically Ventilated Patients with COVID-19 Associated Respiratory Failure. *PLoS One*. 2020 Nov 23;15

DONOR ACKNOWLEDGEMENT

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William and Marty Dudley and Family



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The Ludwig Family Foundation

The Norton Family

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For a complete list of recent publications by IHVI Faculty, go to:
[inoa.org/ihvipublications](https://www.inova.org/ihvipublications)

For more information about research at IHVI and opportunities for collaboration, email: Research.IHVI@inoa.org

View our most recent Outcomes Report at [inoa.org/heartoutcomes](https://www.inova.org/heartoutcomes)

