



Capital Region Research (CAPRES)

ROLE OF OFFICE

CAPRES is part of the Johns Hopkins Institute for Clinical and Translational Research, which is under the leadership of Dr. Daniel Ford, Vice Dean for Clinical Investigation. The Office of Capital Region Research is led by Dr. Mark Sulkowski, Associate Dean for CAPRES and Jackie Lobien, BSN, CCRP-CP, Director of CAPRES.

The Office of Capital Region Research was established:

1. To foster medical discovery within the Johns Hopkins Medicine (JHM) community in the Washington capital region including Sibley Memorial Hospital, Suburban Hospital, and Howard County General Hospital;
2. To nurture research collaborations within the Johns Hopkins University School of Medicine and the Johns Hopkins Health System.
3. Enhance the care and experience of patients by providing opportunities to participate in clinical research at or close to the Johns Hopkins facility in which they receive care.

CAPRES provides a dynamic interface for researchers in the Capital Region with several key Johns Hopkins Medicine research entities including the Institutional Review Board (IRB), Office of Research Administration (ORA), and Johns Hopkins Clinical Research Network (JHCRN). At each of the CAPRES institutions, CAPRES serves as a central resource for all areas of research oversight and administration including IRB/compliance, contracting, study budgets, research training, recruitment, clinical operations, marketing and finance. CAPRES has been integral in working with ORA to coordinate agreements and budgets for community physicians in private practice to open research studies within the walls of the community hospitals.

CAPRES is responsible for the Research Review Committees (RRC) at Sibley Memorial Hospital, Suburban Hospital, and Howard County General Hospital. The RRCs meet regularly to review all research protocols proposed for patients at the specific institution. They provide the local context review to support the work of the JHM IRB.

CAPRES manages and supports the long-standing research collaborations between elements of the National Institutes of Health (NIH) and Suburban Hospital, which are both located in Bethesda, Maryland. These research programs include the NIH Stroke Center at Suburban Hospital, National Heart, Lung, and Blood Institute (NHLBI) Advanced Cardiovascular Imaging and Transfusion-related Infections Prospectively Studied (TRIPS).

PERFORMANCE IN THE PAST YEAR

In November 2018, Mark Sulkowski was appointed as the Associate Dean for CAPRES. He brings extensive experience as a leader in clinical trials for hepatitis C. Under the leadership of Jackie Lobien, CAPRES has experienced clinical research teams located at the three hospitals, Sibley Memorial, Suburban and Howard County General. These teams directly support investigators for the conduct of a wide range of clinical research studies, including investigator-initiated and industry-sponsored protocols. Ms. Lobien and her team facilitate each of the steps of the research process, including hands-on patient care and coordination of the regulatory and financial aspects of the studies. CAPRES also coordinates research training for investigators at our community locations to ensure compliance with University and regulatory requirements. Training sessions for investigators offered at the community hospitals include in-person ReWards training, PI recertification and Good Clinical Practice training.

In the past year, CAPRES has supported the clinical research of more than 30 investigators through training and study coordination. The Research Review Committees led by Ms. Lobien reviewed more than 161 research studies conducted at the capital region hospitals as well as research conducted using patient data spanning the entire Johns Hopkins Health Systems. CAPRES research teams managed more than 30 protocols with more than 345 research participants across the hospitals. CAPRES also supported collaborative research with the NIH and Suburban Hospital related to stroke, traumatic brain injury, cardiac MRI and transfusion medicine. With Ms. Lobien's leadership, CAPRES provided valuable guidance to the hospital nursing teams who have expanded research as part of the American Nurses Credentialing Center's (ANCC) Magnet Model. The Model provides a framework for nursing practice, research and measurement of outcomes. In 2019, Suburban Hospital achieved Magnet designation in recognition of its nursing excellence.

Highlights of the CAPRES research activities include:

Suburban Hospital, Bethesda, Maryland

- Chair, Research Review Committee: Dr. Gary Roggin, Gastroenterology
<https://www.hopkinsmedicine.org/profiles/results/directory/profile/8049426/gary-roggin>
- The highly successful, ongoing collaboration between cardiologist Drs. Henry Halperin and Edward Healy demonstrated the safety of MRI in persons with implanted pacemaker or defibrillator was featured in Johns Hopkins Best Practice News (<https://www.hopkinsmedicine.org/office-of-johns-hopkins-physicians/best-practice-news/new-leadership-focus-for-capital-region-research-support>). Dr. Healy is Chief of Cardiology at Suburban Hospital and a member the Johns Hopkins Community Physicians (JHCP). MRI exams for the study are coordinated by the CAPRES team at Suburban and Sibley Memorial Hospitals.
- Cardiologist Dr. Greg Kumkumian initiated a new clinical trial to evaluate the use of stem cells in patients with congestive heart failure (the CardiAMP™ Heart Failure Trial). Dr. Kumkumian is also collaborating with Dr. Jon Resar, Director of the Johns Hopkins Adult

Cardiac Catheterization Laboratory, in the Medtronic Evolut Transcatheter Aortic Valve Replacement in Low-Risk Patients study. Dr. Kumkumian is a highly experienced investigator who directs an active clinical research program along with his colleagues in the JHCP cardiology clinical practice in Bethesda and Washington.

- The Johns Hopkins Cardiothoracic Surgery team Suburban Hospital (Drs. Thomas Matthew, Michael Siegenthaler and Philip Corcoran) are members of the Cardiothoracic Surgical Trials Network (CTSN), which is supported by the NIH and the Canadian Institutes of Health Research (CIHR). They work with CAPRES and the Department of Transfusion Medicine at NIH (Dr. Harvey Alter) on the TRIPS study, which evaluates transfusion-transmitted infections, providing critical surveillance of the blood supply. In addition to his role as Director of Cardiothoracic Surgery at Suburban, Dr. Matthew is an Assistant Professor of Surgery in the Johns Hopkins University School of Medicine.
- Under the direction of NHLBI Senior Investigator Dr. Andrew Arai, the team at Suburban Hospital performed cardiac MRIs on patients with heart disease, contributing significantly to the FDA-approval for gadobutrol injection in cardiac MR to assess myocardial perfusion in adults with known or suspected coronary artery disease.

Sibley Memorial Hospital, Washington, DC

- Chair, Research Review Committee: Dr. Matthew Ammerman, Neurosurgery <https://www.hopkinsmedicine.org/profiles/results/directory/profile/10000274/matthew-ammerman>
- The neurosurgery team at Sibley Memorial Hospital led by Drs. Joshua Ammerman, Joshua Wind and Matthew Ammerman is one of only 30 sites in the US to evaluate a novel alternative to spinal fusion surgery, the Premia Spine TOPS™ System. Dr. Wind is the principal investigator for the TOPS™ trial at Sibley. Dr. Joshua Ammerman also serves as Chairman of the Department of Surgery at Sibley Memorial Hospital.
- Investigators in the Division of Gastroenterology and Hepatology at Sibley direct important work on the management of obesity and its complications; their research is supported by CAPRES. Dr. Vivek Kumbhari, Director of Bariatric Endoscopy and Associate Professor of Medicine investigates innovative strategies for weight loss and Dr. Jacqueline Laurin, Assistant Professor of Medicine, is leading clinical trials of novel agents for the treatment of non-alcoholic fatty liver disease.
- CAPRES has worked to establish the research framework for the Joseph and Alma Gildenhorn Institute of Bone & Joint Health at Sibley Memorial Hospital. With the generous support of the Ambassador and his wife, the Institute was dedicated in October 2018 with the mission of excellence in orthopaedic research and care under the leadership of Medical Director, Dr. Anthony Unger. Dr. Unger and his team are collaborating with CAPRES to implement his research program.

Howard County General Hospital, Columbia, Maryland

- Chair, Research Review Committee: Dr. Uma Srikumaran, Orthopaedic Surgery
<https://www.hopkinsmedicine.org/profiles/results/directory/profile/3582168/umasuthan-srikumaran>
- Drs. Keith Friedman and Michael Silverman direct an active clinical research unit at the Cardiovascular Specialists of Central Maryland, which is part of Johns Hopkins Regional Physicians. The CAPRES team is located in the CSCM office in Columbia, Maryland on the HCGH campus. Recent research has focused on the intersection of cardiovascular disease and diabetes, leading to a unique collaboration with endocrinologist Dr Andrew Demidowich, who practices full-time at Howard County General Hospital.
- The CAPRES team also helped to launch the Investigational Drug Service at HCGH, which greatly expanded the research capability at the hospital. CAPRES is working with the IDS and cardiologist, Dr. Keith Friedman on the phase 3 clinical trial of a novel selective cardiac myosin activator, omecamtiv mecarbil, for the treatment of patients with chronic heart failure and low ejection fraction (GALACTIC-HF).
- Dr. Uma Srikumaran, the Chair of Johns Hopkins Orthopaedic Surgery at Howard County General Hospital, has seamlessly integrated his research studying the outcomes of his patients with shoulder disorders. He recently reported excellent outcomes of patients with proximal humeral fractures treated with expandable intramedullary cages, providing evidence to support this approach for the management of such patients for whom other alternative may be less desirable.

NEW DEVELOPMENTS FOR THE UPCOMING YEAR

Expand research opportunities in the community. CAPRES is focused on expanding and strengthening participation in the Johns Hopkins Medicine discovery mission across the health care system. As the clinical footprint of Johns Hopkins Medicine grows outside of the Baltimore academic hospitals, CAPRES is poised to support clinical research in the community so that patients will have more opportunities to participate in clinical research in the settings in which they receive care and closer to home.

Facilitate collaboration. CAPRES will continue to enable cooperation between academic research faculty and physicians at the community hospitals by connecting individuals and programs in working disease-specific areas. Our goal is for clinical trials and research programs to be available to patients at multiple locations within the health system to increase patient access and advance research objectives.

As new studies are designed or implemented in Baltimore, Investigators should ask the questions: Will patients in the community benefit from opening the study at one or more of the CAPRES locations? Will my research benefit by the inclusion of patients who receive their care in the community? If the answer to one or both of these questions is yes, the CAPRES team can help to facilitate the implementation of research studies at multiple JHM locations.

Promote the culture of discovery. CAPRES is engaged in education about the research process for health system personnel who do not work in research to understand how they can

participate in the discovery mission. An interactive pilot educational session introducing the clinical research process was held at Howard County General Hospital with glowing evaluations. CAPRES will bring this educational session to other JHM locations, including the health system Nursing Evidenced Based & Research Council. CAPRES will continue to train researchers through semi-annual (September and March), live educational programs at the community locations.

BEST WAY TO WORK WITH PROGRAM

The Associate Dean for CAPRES, Mark Sulkowski and the CAPRES Director, Jackie Lobien are eager to talk and meet with interested clinicians and researchers to discuss how CAPRES can help support and grow research programs to meet the needs of patients in the community and scientific objectives.

Dr. Sulkowski works in Baltimore at Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center and Greenspring Station; he can be contacted at msulkowski@jhmi.edu.

Ms. Lobien works primarily at Suburban Hospital and can be found most weeks at each of the CAPRES locations. Jackie acts as the liaison between principal investigators, co-investigators, research nurses, study coordinators and research offices at Johns Hopkins Medicine and the three CAPRES sites. She can be contacted at jlobien1@jhmi.edu