FACILITIES AND OTHER RESOURCES

Johns Hopkins Institute for Clinical and Translational Research



Clinical Care Delivery Sites: Johns Hopkins and University of Maryland Medical System

Clinical Care Sites for ICTR Hub Partners

Both Johns Hopkins Health System (JHHS) and University of Maryland Medical System (UMMS) have increased the geographic reach of their clinical care facilities in the last decade beyond the large Baltimore-Washington region. Johns Hopkins Health System has a clinical site in Hagerstown, MD (80 miles to the west of Baltimore). UMMS has a clinical site in La Plata, MD (70 miles to south of Baltimore) and in Chestertown MD (80 miles to east of Baltimore). Tidal Health, a Johns Hopkins Clinical Research Network partner is in Salisbury, MD (120 miles to east of Baltimore).

The Johns Hopkins Institute of Clinical and Translation Research (ICTR) serves the entire Johns Hopkins University medical research community. The services are provided at multiple sites on several Johns Hopkins campuses. The campuses include the East Baltimore campus (where Johns Hopkins Hospital, Bloomberg School of Public Health, and the School of Nursing are located), the Bayview Medical Campus (where the Bayview Medical Center, National Institute on Drug Abuse, and National Institute on Aging are located), the Carey Business School in downtown Baltimore, and on the Homewood campus, the Johns Hopkins University (where the Whiting School of Engineering and School of Arts and Science are located). Although separated on geographically distinct campuses, these services have been integrated under the ICTR to facilitate discovery by investigators in the School of Medicine, Bloomberg School of Public Health, and School of Nursing as well as the Whiting School of Engineering, Zanvyl Krieger School of Arts and Sciences, and the Carey Business School.

JOHNS HOPKINS UNIVERSITY

JHU is one of the world's leading academic institutions. Eminent professors mentor top students in the arts and music, the humanities, the social and natural sciences, engineering, international studies, education, business and the health professions. Those same faculty members, and their research



colleagues at the university's Applied Physics Laboratory, have each year since 1979 won Johns Hopkins more federal research and development funding than any other university. The university has nine academic divisions and campuses throughout the Baltimore-Washington area. The Krieger School of Arts and Sciences, the Whiting School of Engineering, the School of Education are based at the Homewood campus in northern Baltimore. The Schools of Medicine, Public Health, and Nursing share a campus in east Baltimore with The Johns Hopkins Hospital. The Carey Business School is in downtown Baltimore. The Peabody Institute, a leading professional school of music, is located on Mount Vernon Place in downtown Baltimore. The Paul H. Nitze School of Advanced International Studies is located in Washington's DuPont Circle area. The Applied Physics Laboratory is a division of the university co-equal to the nine schools, but with a non-academic, research-based mission. APL, located between Baltimore and Washington, supports national security and also pursues space science, exploration of the solar system and other civilian research and development. Johns Hopkins also has a campus near Rockville in Montgomery County, Md., and has academic facilities in Nanjing, China, and in Bologna, Italy. It maintains a network of continuing education facilities throughout the Baltimore-Washington region, including centers in downtown Baltimore, in downtown Washington and in Columbia, Maryland. When considered in partnership with its sister institution, the Johns Hopkins Hospital and Health System, the university is Maryland's largest employer and contributes more than \$9.1 billion a year to the state's economy.

JHU has earned a reputation for research excellence. Twenty-nine winners of Nobel Prizes have had an association with The Johns Hopkins University, either as graduates of Johns Hopkins or as faculty of the university before, at the time of or subsequent to their receipt of the prize, including 16 recipients of the Nobel Prize in Medicine or Physiology. Current faculty members include 78 Institute of Medicine Members, 8 Lasker Medical Research Award Recipients, and 34 National Academy of Science Members.

Health-related research is a particular strength across the institution with annual research funding of \$1.4B from the National Institutes of Health, private foundations, and industry collaborations. Multiple Schools of the University are active in clinical and translational (C&T) health-related research which provides a dynamic environment that fosters ground-breaking discoveries and unparalleled training for the next generation of C&T investigators. This section first describes each of the six JHU Schools that are most engaged in C&T research, followed by a description of a sampling of the key multidisciplinary Centers and Institutes which play a critical role in the C&T research, drawing on faculty and resources from multiple schools across the university to create a synergistic environment for discovery.

JOHNS HOPKINS SCHOOL OF MEDICINE

When the Johns Hopkins University School of Medicine was founded in 1893, the unusual mandate was that the field of medicine was to be treated as a form of graduate study

and include scientific research, and physicians and scientists were thought of as one and the same. Despite tremendous growth, advances in technology and changing pressures in healthcare, the link between medicine and scholarship remains unbroken. The School of Medicine includes 2,407 full-time and 1,776 part-time faculty members. It annually ranks as the top one or two schools in terms of research grants from the National Institutes and consistently is ranked among the top three medical schools in the nation by U.S. News & World Report. The School of Medicine has approximately





1,000,000 sq. feet of research space across the multiple locations. In an effort to promote clinical research and

provide more convenient access to research participants, we have expanded the number of research sites. Several of our large outpatient clinical centers like Greenspring Station, also have research space.

Henrietta Lacks Memorial Building: This new 34,000-square-foot building will be constructed on Ashland and Rutland avenues. The Henrietta Lacks Memorial Building will support multidisciplinary and complementary programs of the Berman Institute for Bioethics, the Johns Hopkins University School of Medicine, and other university divisions. Flexible program and classroom space will be available to support education and research. It will also have meeting space for community use. The building will adjoin Deering Hall, a historic structure that is home to the Berman Institute of Bioethics.

BLOOMBERG SCHOOL OF PUBLIC HEALTH



The Johns Hopkins Bloomberg School of Public Health (also referred to as The Bloomberg School or BSPH) is the oldest and largest public health training facility in the world, and a leading international authority on the improvement of health and prevention of disease and disability. The school's mission is improvement of health through discovery, dissemination, and translation of knowledge and the education of a diverse global community of research scientists and public health professionals. Overall, the school has ranked first in public health according to U.S. News and World Report since 1994. The Bloomberg School has 919 primary faculty and 808 affiliated faculty, and 3,607 students from more than 60 countries. It is home to over sixty Research Centers and Institutes with research ongoing in the U.S. and more than 130 countries worldwide. The School ranks #1 in federal research support from the National Institutes of Health (NIH), receiving nearly 25 percent of all funds distributed among the 40 U.S. schools of public health.

In the 1990s, the School recognized the need for additional space to accommodate the increase in faculty size and student enrollment, allow growth to continue, and encourage interdisciplinary

collaboration by consolidating into one building faculty who were housed in different locations. Construction, from 1996 to 2004, doubled the size of the Wolfe Street Building, from approximately 357,000 to 759,000 square feet.

Among the 10 Departments of the BSPH, the Department of Biostatistics and the Department of Epidemiology have a particularly prominent role in the ICTR.

THE JOHNS HOPKINS SCHOOL OF NURSING

The Johns Hopkins Hospital and the nursing training program both opened in 1889. In the ensuing decades, founders M. Adelaide Nutting, Isabel Hampton Robb, and Lavinia Dock established what would become the national model for nursing education. In 1983, after turning out generations of exceptional nurses, the School of Nursing was established as the eighth division of the Johns Hopkins University— and opened its doors to students in 1984. In 1998, the School moved to a new state-of-the-art education and research building on the East Baltimore campus, the Anne M. Pinkard Building.





In March 2017, the France-Merrick Foundation of Baltimore, Md. has donated \$2 million to the Johns Hopkins University School of Nursing to fund the expansion of the Pinkard building. Today, under the leadership of Dean Sarah Szanton, PhD, RN, FAAN, the School of Nursing continues to redefine nursing education through a unique combination of academic rigor, extraordinary nursing scholarship, and unparalleled opportunities for nursing graduates.

The Johns Hopkins University School of Nursing has 106 Full-time and 130 Part-time faculty with nine endowed chairs and 18% of faculty have joint appointments. The faculty obtained \$26.6 million in total sponsored research project

funding in 2021 and the school ranked 1st in research funding from NIH nationally. In addition, the JHSON is ranked among the top nursing PhD programs in the U.S. by the National Research Council with a Center of Excellence in Nursing Education designated in 2010 by the National League for Nursing.

The Pinkard Building at the Johns Hopkins School of Nursing (JHSON) opened in 1998 at six levels and 92,813 square feet. Completed in 2021, a construction and renovation project added an open, community-facing front entrance and 41,000 square feet to present students, faculty, and visiting scholars with a flexible space for learning, research, and innovation. Pinkard now features 220-seat and 105-seat auditoriums as well as a wealth of smaller classroom and meeting spaces; three 12-bed nursing practice laboratories; a Carpenter Conference Center for local and global collaboration; a spacious and open first-floor Hub for networking, studying, and teamwork; landscaped courtyard and green spaces for reflection and celebratory events; and the Martha Hill Research Commons for faculty and Ph.D. work within specialty centers for aging, administration, cardiovascular care, community health, global initiatives, and mental health.

The Johns Hopkins University School of Nursing Information Technology Services department, located on the third floor of the School of Nursing, offers general technology support, application development, research data management, and instructional technology support to faculty, staff, and students of the school. They maintain a local area network consisting of over 30 physical and virtual servers and approximately 500 PC workstations, Apple Mac systems, and a variety of mobile devices. Network peripherals and systems include monochrome and color printers, copier / scanning systems, storage area networks and network attached, and storage devices. All servers, workstations, and other systems are protected against malware attacks. ITS staff have expertise in security management and maintain policies and controls to prevent network intrusion and ensure security of sensitive data, including encryption solutions, data access auditing, content scanning as well as full utilization the Johns Hopkins Enterprise firewalls and other perimeter devices. The client applications currently in use include, but are not limited to Microsoft Office 365 Suite, SPSS, Stata, f4analyze, RefWorks Reference Manager, and the Sunrise Clinical Manager Electronic Health Records system. The department maintains the technology used in all classrooms and conference rooms, as well as advanced clinical simulation devices and software used in the practice labs. A wireless network managed by the Johns Hopkins enterprise is installed that provides secure wireless connectivity throughout all of the school's facilities. All School of Nursing faculty and staff also have access to many Johns Hopkins Enterprise research resources such as SAFE (Secure Analytic Framework Environment) Desktops. These are virtual desktops that provide investigators (whether engaged in research or



other data-intensive activities) with a robust and secure environment to analyze and share sensitive data (e.g. PHI, PII) with colleagues.

Johns Hopkins University Research Administration (JHURA)

JHURA, located at 1101 E. 33rd Street, Baltimore, Maryland, facilitates the submission of all sponsored project proposals, both system to system and others, on behalf of the School, negotiates and executes agreements, and provides advice and guidance regarding applicable rules and regulations. JHURA also handles the drafting and negotiating of Subawards.

Nursing Office for Research Administration – Science, Excellence, and Innovation (NORA) provides support to faculty, students, and staff on proposal development, budget creation, and compliance with regulatory requirements of research sponsors, JHU, and SON. NORA works directly with Johns Hopkins University Research Administration for proposal submissions and post-award management. It also handles all post-award activities under awarded grants such as account reconciliations. NORA also provides services to faculty, students, and staff, including consultation on research design and conduct including data management and analysis; information on funding sources; dissemination of research resources for grant submission within the School of Nursing and encourages leadership for nursing research with the School, University, and community. This group consists of the Vice Dean for Research, and a research start-up program administrator.

WHITING SCHOOL OF ENGINEERING (WSE)

The WSE has prided itself on being a leader in innovation and research. Its national acclaim is demonstrated by its highly-ranked departments of Biomedical and Mechanical Engineering by US News and World Report. WSE faculty members are leaders in their fields, oversee world- renowned laboratories, publish extensively in peer-reviewed journals, and receive wide recognition for their work through competitive funding, honors, and awards. In the 2022, WSE published 1170 publications.232 full-time faculty. In 2022-2023, WSE faculty received eight NSF CAREER Awards, three DARPA Young Faculty Awards, two IEEE awards, one TIME Most Influential People award, among other awards and honors.



The Whiting School received \$193 million in research funding. The school's 22 major research centers and institutes include the Center for Cancer Nanotechnology Excellence, the Johns Hopkins Engineering in Oncology Center, and the Environment, Energy, Sustainability, and Health Institute interdisciplinary initiatives Also included is the Whiting School of Engineering's Malone Center for Engineering in Healthcare (2016), under the leadership of Greg Hager, the Mandell Bellmore Professor in the Department of Computer Science. Housed in the 56,000 square-foot Malone Hall research facility, the Malone Center is a multidisciplinary research initiative that will foster partnerships among engineers, clinicians, and scientists across Johns Hopkins University to catalyze, develop, and deploy innovations aimed at improving the efficiency and effectiveness of healthcare. The Systems Institute will take a multi-disciplinary approach to reengineering entire systems of national importance including medicine health care delivery, network-enabled systems, information security, national infrastructure, and education. The Individualized Health Initiative, a university-wide effort, will bring together engineers, life scientists, and medical researchers to focus on bringing information science into the practice of medicine with an initial emphasis on cancer. The school encompasses over 275,000 square-feet of office and lab space in nine buildings on the Homewood campus, which includes state-of- the-art facilities and equipment.

The School of Engineering's fourteen academic departments include the top-ranked Department of Biomedical Engineering. There are a large group of faculty in the Biomedical Engineering Department working in the area of cardiovascular electrophysiology, cardiovascular imaging, and systems biology.

The Johns Hopkins Department of Biomedical Engineering was founded in 1962. The ongoing vision for the department is to produce new knowledge from outstanding laboratories and facilitate the transfer of that knowledge into patient care at the fastest pace possible. The Johns Hopkins Department of Biomedical Engineering is a collaboration between the Johns Hopkins School of Medicine and Johns Hopkins Whiting School of Engineering. They also have several BME-Affiliated Research Centers and Institutes across Johns Hopkins University: Applied Physics Laboratory, Center for Bioengineering Innovation and Design, Center for Cardiovascular Bioinformatics and Modeling, Center for Hearing and Balance, Center for Imaging Science, Center for Magnetic Resonance Micro-imaging, Institute for Computational Medicine, Mind Brain Institute, and

Translational Tissue Engineering Center.

The Johns Hopkins Department of Biomedical Engineering recently opened a new Biomedical Design Studio providing a premiere work space and resource for students to brainstorm, design, and develop prototypes for solutions to real-world clinical and global health challenges.

The WSE also has an Office of Research and Translation which assists with commercialization of WSE faculty innovations, increasing corporate engagement, providing expanded resources for proposal development, and establishing new industry partnerships to increasing our students' experiential education and internship opportunities.

ZANYVL KREIGER SCHOOL OF ARTS AND SCIENCES

The Zanvyl Krieger School of Arts and Sciences is the core institution of the Johns Hopkins University's Homewood campus. Whose mission is discovery, and the creation of new knowledge through research and scholarship, and the education of our students, undergraduate and graduate alike. Comprising 22 departments and 33 centers, programs, and institutes, the Krieger School is home to students interested in the arts, humanities, natural sciences, and social sciences. The school's academic programs in the humanities, natural sciences, and notable for the wide range of interdisciplinary opportunities they provide. The School offers more than 60 undergraduate majors and minors, 40 full-time graduate programs, and 20 part-time graduate programs and includes 437 full-time tenured and tenure-track faculty members.



CAREY BUSINESS SCHOOL



On December 4, 2006, Johns Hopkins University trustees, in response to a \$50 million gift from William Polk Carey, voted to establish a new business school dedicated to producing innovative leaders with broad, interdisciplinary knowledge. The new Carey Business School opened January 1, 2007, continuing the Johns Hopkins tradition of bringing innovative business management programs to the ever-changing workplace. The Johns Hopkins University Carey Business School develops bold business leaders and transforms organizations, communities, and society through diverse perspectives, multi-disciplined education, and globally conscious entrepreneurship. Currently, the Carey Business School has 88 full-time faculty

members and offers the full-time Global MBA (GMBA), and five full-time, part time or online dual degree programs, the part-time Flexible MBA program; six full-time and part-time Master of Science programs; executive seminars, most of them in conjunction with other Johns Hopkins divisions; and four certificate programs. The school's main campus is in the Harbor East section of Baltimore, at the Inner Harbor. Classes are also offered at campuses in Washington, D.C., Columbia, and Rockville, Maryland. The Johns Hopkins Carey Business School is accredited by the Association to Advance Collegiate Schools of Business (AACSB), the world's leading authority on the quality assurance of business school programs.

WELCH MEDICAL LIBRARY

The mission of the Welch Medical Library is to advance biomedical discovery, education, and health care by providing leadership in the research, management, and sharing of knowledge.

The library collects current scholarly information that supports the research, clinical, administrative, and educational needs of the Johns Hopkins Medicine, Nursing and Public Health. Because the library's emphasis is on providing materials at point of need, the collection is primarily in digital format. The collection covers health, the practice of medicine and related biomedical and allied health care disciplines, public health and related disciplines, nursing, research literature, methodological literature, reviews or state-of-the-art reports, and indepth, authoritative analyses of areas influencing biomedicine and health care. The Welch online collection includes approximately 20,000 journals and 1,200 databases. Johns Hopkins Medicine, Nursing, and Public

Health scholars also have access to both the print and online collections of the collective Johns Hopkins University libraries including over 150,000 journals and just under a million e-books.

Welch Medical Library serves the information needs of the faculty, staff, and students of Johns Hopkins Medicine, Nursing and Public Health. The Library's Informationist Program maintains a full-time staff of 12 Informationists who offer a variety of professional tailored services, including individual and group consultations; searching-from general reference and evidence-based precision to full-scale systematic review participation; citation management; curriculum, classroom, and online instruction; and collaborations on grants and research projects from beginning to end, as they evolve. Informationists are experts at navigating the publishing landscape to respond to complex requests related to research impact, scholarly output, and research dissemination.

The Welch Service Center provides in-person circulation and document retrieval, reference and searching assistance, and reserves services."

The Johns Hopkins University SOM's Office of Faculty Development (OFD) creates and delivers effective programs that develop and nurture our diverse faculty as leaders in clinical care, medical education, and research excellence. The OFD's focus on enriching a culture of inclusion, respect, and engagement is fundamental in accomplishing the Johns Hopkins mission and in enabling the School of Medicine to attract and retain talented faculty. The Johns Hopkins School of Medicine has a rich history of creative faculty development programming that hinges on building community. For example, Writing Accountability Groups (WAGs) were created by Kimberly Skarupski, PhD, MPH and have subsequently been adopted by dozens of universities around the country. The OFD also hosts the Faculty Factory podcast – an international forum for academic affairs and faculty members. As of April 3, 2023, the podcast has had more than 62,113 total downloads and YouTube views from listeners in 84 countries and the Faculty Factory website has drawn 34,002 web visits from users in 122 countries. The free eBook, Habits and Hacks from Hopkins (H3) (published in June, 2022) has been downloaded 347 times and the first free eBook published in the summer of 2021, Snippets for Success: An eBook Brought to You by the Faculty Factory Community has been downloaded 1,118 times.

Johns Hopkins Leadership Programs

Johns Hopkins hosts several leadership training programs including Junior Faculty Leadership Program (OFD), Patient Safety and Quality Leadership Academy (Armstrong Institute), Mary Elizabeth Garrett Executive Leadership for Women Faculty (Office of Women in Science and Medicine and JHU Talent Management), Leadership Program for Women Faculty (Office of Women in Science and Medicine, Office of Faculty Development and JHU Talent Management), Emerging Women's Leadership program (Office of Women in Science and Medicine and Office of Faculty Development), Leadership Development Program and the Leadership Development Program for Influencers (JHU Talent Management), Supervisor Development Program and the Manager Development Program (JHU Talent Management), Carey Executive Education (Carey Business School), Mary Elizabeth Garrett Executive Leadership for Women Faculty (Office of Women in Science and Medicine and JHU Talent Management).

JHU CENTERS AND INSTUTUTES

There are multiple centers and institutes across the JHU Schools that provide an infrastructure for bringing together faculty interested in a particular area or topic. Although each center has a "home" department or departments for administrative reasons, most involve faculty from several departments and divisions of the University. Some also involve faculty from other universities and research organizations. As a result, centers can often undertake a breadth of research and training that faculty associated with only one department cannot conduct alone. Most of the centers and institutes are research-oriented, but they may include practice and service activities; others focus primarily on practice or service Centers are funded primarily through grants from federal agencies, or from gifts and endowments from foundations and philanthropists. Here we describe several key centers that are critical to the clinical and translational research environment.

The Welch Center for Prevention, Epidemiology and Clinical Research (Director: L. Appel, MD, MPH)

The Welch Center for Prevention, Epidemiology and Clinical Research (aka the Welch Center) is an internationally recognized, academic unit that is co-sponsored by the School of Medicine (SOM) and Bloomberg

School of Public Health (BSPH) at Johns Hopkins. The mission of the Welch Center is twofold:

- Improve population health by conducting rigorous research that integrates clinical medicine with public health expertise, and
- Train the next generation of interdisciplinary researchers and scholars

The Welch Center is located in the 2024 East Monument Street Building, which is also the location of the training component of the Institute for Clinical and Translational Research (ICTR). The Welch Center has ~15,000 so ft. of contiguous space, and is only a 5 min walk from the SOM and BSPH. The Welch Center has ~35 core faculty (~60% with a primary appointment in the SOM and ~40% in BSPH, mostly epidemiology) and ~50 associate faculty. Its faculty conduct multi-disciplinary research that fosters collaboration among basic scientists, clinical researchers, epidemiologists, and health services researchers. The Welch Center abounds with trainees – over 100, including MPH, MHS, PhD, and DrPH students from BSPH; medical students and residents from the SOM; and post-doctoral trainees from the BSPH and SOM. Welch Center faculty employ the full range of research methodology, including observational epidemiologic studies; randomized trials; and translational research. The Welch Center provides offices for faculty, research assistants, administrative staff, and trainees. Faculty members are organized into informal program clusters which allows for intensive interactions and collaboration across research areas, remarkably well-sustained during the COVID19 pandemic. The Welch Center has five conference rooms, updated for video conferencing, and a large number of carrels with computers and network access for trainees.

Offices

All on-campus faculty members have an office with state-of-the-art computing with a broad array of office and data analysis software. Faculty and staff offices are equipped with desks, computers, telephones, personal and shared printers, and shared fax machines.

Computing

The Johns Hopkins University maintains an extensive computing network that provides secure access from offsite locations to email and internet files. All computers in the Welch Center have networking capabilities supported by the Client Central Services (CTS) of the University. There are approximately 170 computer workstations (desktop and laptop) at the Welch Center and ProHealth. These computers are networked to facilitate the integration of like tasks across studies and to increase efficiency. Servers are physically located at a secure, off-campus Hopkins location (Mt. Washington) by the Data Services Center of Johns Hopkins. Except for standard MS office suite and anti-virus software, they also have secure connection installed, which allow them to access resources on the application server. The major statistical packages, including Splus, Stata, and SAS, are available for all PCs for data bases and analyses. The Welch Center has networked Polycom video conferencing units to facilitate high-quality audio/video communication with off-site collaborators at ProHealth and other institutions across the world.

The Johns Hopkins ALACRITY Center for Health and Longevity in Mental Illness

The ALACRITY Center is funded through the National Institute of Mental Health Advanced Laboratories for Accelerating the Reach and Impact of Treatments for Youth and Adults with Mental Illness (ALACRITY) Research Centers (P50). The ALACRITY Center's mission is to eliminate premature mortality among people with serious mental illness with its focus on research, training, and community partnerships. The Center is conducting three core pilot studies and developing innovative research methods focused on developing and evaluating implementation strategies to scale up evidence-based interventions shown to be effective in clinical trials at addressing cardiovascular risk factors in people with SMI. The Methods Core is designed to leverage the collective expertise of a diverse group of researchers and will support all ALACRITY Center research activities and contribute to four areas of methods innovation that will yield practical and/or scientific products to inform future scale-up of physical health interventions in community mental health settings. These four areas include: Development of a Human Factors Engineering Toolkit, Evaluating Avatar-Assisted Training and Assessment of Motivational Interviewing, Contributing to Advanced Quantitative Methods (ACHIEVE and SMART Trials), and Building a Systems Model.

The Stakeholder Advisory Board is comprised of approximately 30 members representing payers and policymakers, community mental health program leaders, federally qualified health center leaders, community mental health providers, consumers with SMI, family members of consumers with SMI, and family/consumer SMI

advocacy groups. The Center currently has trainees from various departments across the school. ALACRITY has 26 core faculty members from departments of General Internal Medicine, Psychiatry and Behavioral Sciences, Mental Health, Biostatistics, Health, Policy and Management, Epidemiology, and Health, Behavior and Society. Dr. Daumit is the ALACRITY Center Director. Dr. Ford is an internal Steering Committee member.

BIOS Clinical Trials Coordinating Center and Trial Innovation Center

Led by Daniel F. Hanley, MD, the Johns Hopkins BIOS Clinical Trials Coordinating Center (BIOS CTCC) is an academic research organization (clinical trial data management center, imaging reading center, and enrollment center) within the Johns Hopkins School of Medicine. Its focus is to provide multicenter management to clinical trials evaluating therapeutic, preventive, and diagnostic interventions. BIOS CTCC is disease-agnostic with unique expertise in the coordination and management of trials investigating rare diseases and disorders, acute neurologic ICU conditions, rehabilitation, pain management, and functional outcomes. Dr. Hanley and his team of investigators have an outstanding record of clinical trials coordination, data management, clinical and safety event adjudication, and statistical analysis. Since the 1990s, BIOS CTCC has coordinated international, federally funded, and industry-sponsored trials across a range of conditions for investigators at Hopkins and other academic centers across the United States. Dr. Hanley has been continuously funded by NIH since 1984.

BIOS CTCC and the ICTR, with investigators from Tufts, lead the National Center for Advancing Translational Sciences (NCATS)-funded Johns Hopkins University–Tufts University Trial Innovation Center (JHU-Tufts TIC). Part of the NCATS Trial Innovation Network, the centers work with the Clinical and Translational Science Awards (CTSA) Program to promote innovations in the efficiency and quality of NIH-funded trials. The JHU-Tufts TIC provides investigators high-quality design and operational support and has helped form a long-standing infrastructure for multicenter clinical trials.

Brain Injury Outcomes NeuroImaging Center. The Brain Injury Outcomes NeuroImaging Center (BIONIC) hosts a repository of over 10,000 clinical CT scans, in addition to other types of diagnostic studies from clinical trials. Utilizing existing trial neuroimaging data, the research conducted includes volume, area, mass effect, and distance analyses on a wide range of pathological, physiological, and neuroanatomical biomarkers of interest. Current collaborations are geared toward machine learning and functional cloud-based imaging pipeline development and validation of de-identification of PHI.

Institute of Genetic Medicine (Ambroise Wonkam, MD, Ph.D. Professor and Director): The McKusick-Nathans Institute of Genetic Medicine is working to consolidate all relevant teaching, patient care and research in human and medical genetics at Johns Hopkins and to provide national and international leadership in genetic medicine. Created in 1999, it unifies nine Hopkins Centers and scores of physicians and scientists. It also serves as a focal point for interactions between diverse investigators to promote the application of genetic discoveries to human disease and genetics education to the public. It builds upon past strengths and further develops expertise in the areas of genomics, developmental genetics, and complex disease genetics. In addition, it catalyzes the spread of human genetic perspectives to other related disciplines by collaboration with other departments within Hopkins.

Center for Clinical Trials and Evidence Synthesis (Ann-Margret Ervin, PhD, MPH, Director): The Johns Hopkins Center for Clinical Trials at Johns Hopkins is a multi-departmental multi-disciplinary center housed in the Department of Epidemiology. Founded in 1990, the Center is a collaboration between faculty in departments and centers in the Johns Hopkins schools of Public Health and Medicine. The Center is devoted to the promotion of clinical trials to evaluate preventive, therapeutic, and diagnostic health interventions. The Center mission is to guide and inspire research, scholarship, and intellectual engagement, in the Johns Hopkins community and globally, in the areas of clinical trials and evidence-based healthcare. The core purpose of this Center is to provide local, national and global leadership in clinical trials and serve as an internationally recognized academic curriculum related to clinical trials, systematic reviews, and evidence-based healthcare and to participate in and lead transdisciplinary interactions and involvement in the Center for Clinical Trials and Evidence Synthesis across schools from which the Center faculty is drawn.

Johns Hopkins Urban Health Institute

The UHI serves as an interface between Johns Hopkins and the Baltimore community in which it resides.

The mission of the UHI is to serve as a catalyst that brings



together the resources of Johns Hopkins Institutions with the City of Baltimore, and especially East Baltimore to improve the community's health and well-being, and in so doing serve as a model of community-university collaboration regionally and nationally.

The UHI:

- Serves as a bridge between JHI and Baltimore, facilitating understanding and information sharing so as to improve health outcomes;
- Facilitates collaborations between JHI and the Baltimore community around research, community projects, program planning/implementation and evaluation.
- Improves the understandings of JHI as they relate to the health needs and aspirations of the community; and concurrently, to improve the understandings of the community as to the work that JHI does that has the promise of improving the health and wellbeing of the community.
- Strengthens the capacity of the Baltimore community by bringing the knowledge and skills available through JHI to community identified needs and issues;
- Strengthens the academic offerings and opportunities within JHI as they relate to urban health and development; Initiates sustainable, collaborative interventions that will improve the health and wellbeing of Baltimore and the East Baltimore community.

Center for Population Health Information Technology (CPHIT): The Center for Population Health IT (CPHIT) is a first-of-its-kind interdisciplinary center at The Johns Hopkins University, the vision of which is to make Johns Hopkins a global leader in population-centric Health IT (HIT) research and development. The Center focuses on improving the health and well-being of populations by advancing state-of-the-art Health IT and related internet and mobile-based e-health tools within public and private health care organizations and systems.

The Center integrates internationally regarded Johns Hopkins faculty from the population, information, engineering, social, and clinical sciences. The Center is based in the Johns Hopkins Bloomberg School of Public Health, but works closely with the many academic and research units at The Johns Hopkins University including: the School of Medicine's Division of Health Sciences Informatics, the Armstrong Institute for Patient Safety & Quality, the School of Nursing, the Carey School of Business and the Applied Physics Laboratory. CPHIT.

Johns Hopkins Center on Aging and Health (David L. Roth, PhD, Director): The Center on Aging and Health was established in 1998 to be the Center of Excellence for Aging Research for the Johns Hopkins Medical Institutions. It is sponsored by the Johns Hopkins Schools of Medicine and Public Health. Core Departmental sponsors include the Departments of Medicine, Epidemiology, Biostatistics, Health Policy, Mental Health, and Population and Family Health Sciences. The Center is the home for multidisciplinary research faculty from each of these departments and the School of Nursing, the Older Americans Independence Center, the Program in the Epidemiology of Aging, and the Training Program in the Epidemiology and Biostatistics of Aging. The Center was mandated to provide the focal point for the Johns Hopkins Medical Institutions, to include a critical mass of interdisciplinary research training. With this mandate, COAH aims to establish a critical mass of cutting-edge multidisciplinary science designed to optimizing health in aging and to provide the necessary expertise and infrastructure for the sustainable conduct of such research and its translation into improving the health of older adults. The Center also serves as a training ground for the next generation of researchers on aging.

The goal of the Center is to promote the intellectual interactions that are essential to creative approaches to solving the important health and health care problems for an aging population. The core research in COAH involves population-based and clinical research on the causes and consequences of diseases, frailty and disability in older adults, characterizing groups at risk of adverse health outcomes, understanding social and other resources that promote health over the lifespan, and identifying causes and developing methods for screening and prevention. COAH includes the full breadth of aging research, from the biology of aging to health policy, thus facilitating the translation of research discoveries into applications that will directly improve the health of older adults. The Center provides key infrastructure, such as biostatistics and research design core, that supports clinical and population-based research in gerontology and geriatric medicine.

BIOSTATISTICS AND STUDY DESIGN SUPPORT

The BERD core is administratively housed in the <u>Department of Biostatistics</u>, Bloomberg School of Public Health. By its nature its members are spread throughout the institution. Major other locations for the Core include the <u>Center for Computational Biology</u> (CCB), School of Medicine, <u>Welch Center for Prevention</u>, <u>Epidemiology &</u> <u>Clinical Research</u>, and the <u>Biostatistics</u>, <u>Epidemiology & Data</u> <u>Management (BEAD) Core</u> sponsored by the Department of Pediatrics. Most of our locations are on the East Baltimore (primary) Campus of the Johns Hopkins Medical Institutions, distributed within a maximal distance of approximately eight blocks. The CCB spans the Schools of Medicine, Public Health and the Whiting School of Engineering (WSE) and reports administratively to the WSE on the Johns Hopkins Homewood Campus, a 3.5-mile drive from the East Baltimore Campus. The BEAD unit of the Biostatistics Program spans the East Baltimore Campus and the JHMI Bayview Campus, 3 miles from the East Baltimore Campus. Bayview houses both clinical practices and faculty from many Johns Hopkins Medicine departments and divisions, as well as the Baltimore campus of the National Institutes on Aging, Drug Abuse and Human Genome Research.

The Johns Hopkins University maintains an extensive computing network that provides secure access from offsite locations to email and internet files. All faculty and staff of the Core have computers with networking capabilities supported by the Department or School of residence.

In the **Department of Biostatistics** the computing resources in the consists of a joint high performance computing (HPC) cluster, dedicated department web server and file sharing server, faculty research servers, and personal desktop/laptop for each faculty and staff.

As of May 2023 the HPC cluster has 60 nodes with a total of 3884 64-bit cores and about 25.9 TB DDR-SDRAM in production, plus 5 GPU nodes with 23 Nvida V100 and A100 GPUs. The storage environment on the cluster contains a total of 14PB of storage with a 6PB Lustre storage cluster, 6PB of ZFS NAS storage, and a 2PB ZFS

NAS storage array for offsite disk-to-disk backup, all built on the "dirt cheap storage" philosophy. In addition, a 25 TB NVME SSD based "fast scratch" storage array to support short-term storage of high-IO processing. This shared resource provides the needs for compute-intensive and data intensive research and teaching.

A dedicated department web server provides a platform for users to provide teaching resources and present their research work on the internet. The filesharing server allows



effective collaboration. Some faculty have their own research servers to run special projects.

Each faculty, staff, and student has either a desktop or a laptop with external monitor(s) in the office. They access the server(s) via secure shell (SSH) protocol. Except for standard operating systems, MS Office, and adobe acrobat, major statistical and mathematical computing packages are available, including R, SAS, Stata, Matlab, and Mathematica.

<u>-Advanced Research Computing at Hopkins (ARCH).</u> All JHU faculty and personnel have accounts and access to the extensive parallel and distributed computing capacities provided by the JHU ARCH Center, housed on the Johns Hopkins University Bayview Campus. ARCH follows a "condominium model", with three main units. The first unit is based on an NSF Major Research Infrastructure grant, a second unit contains mainly medium-size condos (for example DURIP/DoD, Deans' contributions condos), and the last unit is a collection of individual research groups condos. All three units are shared, with no physical separation, by all users.

The main cluster, Rockfish, has 34,128 cores (712 nodes) as of Nov. 2022, a combined theoretical performance of 3.3 PFLOPs and Rmax of 2.1 PFLOPs. Rockfish has three parallel file systems (GPFS) with a total of ~13PB of usable space. The Rockfish cluster has Mellanox Infinidad HDR100 connectivity (1:1.5 topology). The system includes:

1) 672 (32,256 cores) standard compute nodes, Intel Xeon Gold Cascade Lake 6248R CPU with 192GB TruDDR4 RAM and 2933MHz, and 1TB NVMe SSD storage.

2) 22 (1056 cores) large memory nodes, Intel Xeon Gold Cascade Lake 6248R CPU with 1.5TB TruDDR4 RAM and 2933MHz, and 1TB NVMe SSD storage.

3) 18 (864 cores) GPU nodes, Intel Xeon Gold Cascade Lake 6248R CPU and 4X Nvidia A100 GPU, 192GB TruDDR4 RAM and 2933MHz, and 1TB NVMe SSD storage.

A second compute cluster run by IDIES, the Homewood High Performance Cluster version 2 (HHPCv2), is an older cluster composed of 350 compute nodes, which provides 4200 cores and 16TB of RAM. The HHPCv2 is only available for usage to those stakeholders that purchase an allocation of compute cores on the cluster. There is a provision in the HHPCv2 management plan that does allow up to 10% of the compute time to be used by non-stakeholders, however this requires authorization from the Deans. The HHPCv2 is only available to faculty and researchers on the Homewood campus.

The IDIES organization also operates the SciServer, which is a cloud-based environment that provides researchers with the ability to spin up a variety of prebuilt compute images. These images have been tailored with tools for astronomy, oceanography, material science, and genomics. A wide variety of curated data sources are also available to researchers using SciServer.

Many of the JHU and JHMI services are run out of the Mt. Washington Datacenter. The Mt. Washington Datacenter is a 11,822 square feet secured facility, with 24/7 staffing for security and on-site management. One service provided out of the Mt. Washington Datacenter is an internal private vSphere-powered cloud, which is run on 364 Cisco UCS servers in production, plus 71 servers at a DR facility, which in total provide 29,804 cores, 495 TB of RAM, and support nearly 6000 VMs.

Department of Biostatistics (Karen Bandeen-Roche, PhD, Chair): The Department of Biostatistics in the Bloomberg School of Public Health is led by BERD leader Dr. Karen Bandeen-Roche. Established in 1917, this is the oldest autonomous department of its kind in the world, and is among the most productive Departments of Biostatistics in research and in training of masters and doctoral students. It currently is first among Biostatistics programs, and departments (tied), in the United States in the US News and World Report ranking. The Department aims to promote effective statistical reasoning and applications in health research. It currently includes 42 full-time faculty, 52 part-time faculty, 44 doctoral candidates, 35 master degree students, 13 postdoctoral fellows and 20 staff. Approximately 50% of the department's Ph.D. graduates over the last 5 years have gone on to academic positions. including at Johns Hopkins, Brown University, Wake Forest University, Stanford University, the University of Washington and Duke University. Faculty members spend roughly half their research time each on developing statistical methods and on applications of substantive importance.



Methodological research is conducted on a broad array of topics, including inference, clinical trials and translation, data science, biomarker development and measurement, longitudinal data analysis, latent variable modeling, spatial statistics, signal intensive data, statistical genetics and genomics, and neuroimaging statistics. The department has major applications in many areas, including aging, basic science, environmental health, epidemiology, health services research, infectious disease, ophthalmology, psychiatry, neurology, pediatrics, and oncology. The Department of Biostatistics offers educational programs leading to the Ph.D., Sc.M, and M.H.S. degrees and more than 65 graduate courses in various learning formats. Approximately half of the courses are designed for students outside of biostatistics; the other half are for students in biostatistics or related fields. In addition to course work, the department supports weekly seminars and "working groups" in which students and faculty interested in a particular topic meet biweekly for an informal seminar or discussion. Currently, working groups are active in aging, causal inference, environmental epidemiology and spatial statistics, genetics, genomics, medical imaging and spectra, and longitudinal/multivariate data analysis. Students learn the application of statistics by collaborating with faculty in research on health or in brief consultation through The Johns Hopkins Biostatistics Center, the Department's unit devoted to consultation. The result is an active, engaging intellectual environment.

Johns Hopkins Biostatistics Center (Gayane Yenokyan, Ph.D., Executive Director): The Johns Hopkins Biostatistics Center (JHBC) was created in 1997 as the practice and consulting arm of the Department. The Center mission is to advance public health and medicine using best practices and comprehensive expertise in biostatistics and data science, through consulting and education. The Center is primarily composed of PhD and MS-level non-tenure track faculty with appointments in the Department of Biostatistics as well as computer programmers and administrative staff. The Data Informatics Services Core (DISC) was initiated within the Center in 2009.

Since its inception, the JHBC has collaborated with hundreds of clinical and public health investigators conducting research at the Schools of Medicine, Nursing, and Public Health, and Johns Hopkins Hospital within the Johns Hopkins Medical Institutions (JHMI) as well as other academic research centers, health research organizations, pharmaceutical companies, and governmental agencies. JHBC faculty research has appeared in top medical and public health journals including Lancet, JAMA, BMJ, Circulation, Pediatrics, Neurology, and *American Journal of Epidemiology*. Several publications received best-paper recognitions in their respective fields and have been cited by numerous researchers. The JHBC has been an integral component of the Quantitative Methods (QM) Core of the Johns Hopkins Institute for Clinical and Translational Research (ICTR) since 2007.

JHBC is an active partner with researchers on questions related to the effective collection, statistical analysis, and interpretation of health research information. These collaborations, across a breadth of subject-matter areas, are supported by fee-for-service contracts and grants, for short- and long-term projects. JHBC is a well-coordinated team providing comprehensive expertise and integrated biostatistics and data management support to meet a project's research goals from study design and data base development to analysis and scientific writing. The data informatics team provides data capture and management expertise that facilitates better organization and use of data capture tools, better accuracy of data capture with defined coding of variables, and a better interface to analysis requirements. The biostatisticians help researchers review the design and implementation to ensure that the research questions can be answered as intended, understand limitations, and study constraints, and better stand up to critical review.

JHBC has supported clinical trials (including as a data coordinating center and for DSMB reporting) and observational studies. It has extensive expertise in standard biostatistics methods, such as power analysis and sampling methods, multivariable generalized linear, longitudinal, multi-level and hierarchical modeling, time-to-event methods (such as Cox regression with time-varying covariates, discrete survival analysis methods, parametric models), confounding adjustment (stratification, regression, propensity scores), and instrument development, validation and reliability. Other, more advanced levels in JHBC portfolio include: causal inference



methods, analysis of large electronic medical record databases, complex surveys, Bayesian methods, predictive modeling, latent variable modeling (including factor analysis, structural equation modeling) and multiple Imputation with chained equations and inverse probability weighting for analysis of missing data. JHBC's team is proficient in the use of STATA, R (and associated applications such as shiny), SAS, SQL, Python, SPSS, and Bugs.

DISC's team is composed of programmers and analysts who work closely with the researchers and the biostatistics team to provide data management expertise including: 1) reviewing database designs and data collection instruments, 2) developing custom data collection systems, 3) preparing data for analysis and reporting, and 4) providing hosting and support for web-based data management systems including REDCap (Research Electronic Data Capture).

Members of the JHBC also work closely with the faculty within the Department of Biostatistics when expertise in a specialized area of research is required. JHBC is also supported by its administrative team who handle the financial and reporting activities.

Department of Epidemiology (David Celentano, PhD, Chair): The Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health is the oldest department of epidemiology in the world. It currently is first among Epidemiology programs in the United States in the US News and World Report ranking. The mission

of the department is to improve the public's health by training epidemiologists and by advancing knowledge concerning causes and prevention of disease and promotion of health. The specific goals of the department are; to provide the highest quality education in epidemiology and thus to prepare the next generation of epidemiologists; advance the science of epidemiology by developing new methods and applications; use the methods of epidemiology to investigate the etiology of disease in human populations; use epidemiologic methods in evaluating the efficacy of preventive and therapeutic modalities and of new patterns of health care delivery; develop methodologies for translating epidemiologic research findings into clinical medicine; and develop approaches for applying the findings of epidemiologic research in the formulation of public policy and to participate in this formulation and the evaluation of the effects of such policy.

The faculty in the department is large and scientifically diverse with over 120 full time and numerous part- time faculty members. Department of Epidemiology faculty conduct research on a broad array of topics including: the prevention and treatment of cardiovascular and renal diseases, cancer, diabetes, and other chronic conditions; identification of genetic factors which contribute to major chronic and infectious diseases; the epidemiology of acute and chronic infectious diseases; social epidemiology; and comorbidity, frailty and physical disability in older persons.

The Department of Epidemiology has a longstanding commitment to high quality post-graduate education and has traditionally awarded more doctorates in epidemiology than any other department in the world. The Department confers 2 Master degrees—of Health Science (M.H.S.) and Science (Sc.M)—as well as the Ph.D. and Doctorates of Science and Public Health. The areas of concentrations and courses offered by the department are wide-ranging, including topics such as cancer, cardiovascular disease, clinical epidemiology, clinical trials, the epidemiology of aging, genetics, infectious disease, AIDS, occupation and environmental epidemiology, renal diseases and diabetes, social epidemiology, tuberculosis and vision. The faculty and researchers associated with the school conduct research both domestically and internationally enjoying collaborations with a wide range of partner organizations in Baltimore City and worldwide. Students are encouraged to specialize in the areas listed above however they are exposed to a wide range of epidemiological topics in their coursework and familiarity with ongoing research within the school by faculty members and their peers.

FACILITIES – Computational Biology Consulting Core (CBCC)

RESOURCES – Office and Computing (Dr. Florea)

<u>Office & Computer</u>: Dr. Florea and group personnel have office space on the 4th floor of the Miller Research Building on the JHU Medical Institutes campus in Baltimore. Dr. Florea's work computer is a Dell Optiplex 9020 dual CPU server (16 GB RAM, 2.1 GHz, 1.0 TB local space), and students have similar dedicated desktop computers.

<u>Center for Computational Biology (CCB) resources.</u> As a member of the Center for Computational Biology and Director of Computational Biology Consulting Core (CBCC), Dr. Florea and CBCC personnel have continued access to the shared CCB computing and storage facilities. Resources include over 900 TB of high-speed storage in Bloomberg 156 and the ability to expand considerably beyond this. For high-performance computing, the group has 6 large-memory servers with RAM ranging from 256GB up to 1 TB of RAM, 32-48 compute cores each, and fast access to the large data storage devices.

Computers and data for the CCB are housed primarily in the data center in Bloomberg Hall, room 156, which was renovated in 2011 to create a flexible, stable environment for a high density of computing equipment that supports research and training on both the Homewood Campus and the East Baltimore (medical) campus. The 3100 sq. foot room is covered with a raised floor fed with cold air from seven Liebert air conditioners, and a dedicated chilled water line is available for water-cooled racks. Bloomberg 156 supports a steady load of at least 450kVA, with potential expansion to 750kVA. To ensure a stable environment for data repositories, 150kVA of power has both battery and generator backup. An NSF grant to Alex Szalay (Prof. of Astronomy and Physics) also upgraded the network infrastructure supporting the space from 1GigE to 10GigE to insure that users throughout campus can access the data center effectively.

Johns Hopkins Claude D. Pepper Older Americans Independence Center (OAIC; Jeremy Walston, MD, Director and Karen Bandeen-Roche, PhD, Director): Frailty is recognized as an age-related condition in which

older adults lose the capacity to cope with stressors and become vulnerable to functional decline, loss of independence, and mortality. Frailty research provides a highly productive framework for clinical, populationbased and biological discovery and for the development of junior investigators for academic careers in frailty and aging research. The mission of the Johns Hopkins OAIC is to provide a hypothesis-driven, frailty-focused, highly interdisciplinary center where supported investigators receive the expertise, resources, and training necessary to make fundamental discoveries related to the origins and causes of frailty and then move these discoveries towards frailty-focused interventions. Since its original funding in 2003, the novel approaches of the Johns Hopkins OAIC have helped to demonstrate that frailty is a syndrome driven by multiple biological mechanisms that are expressed through characteristics of decreased resiliency and reserve in older adults. The OAIC has seven cores that work synergistically to accomplish the goals of the center. Six are longstanding--the Research Career Development Core; the Pilot / Exploratory Studies Core; the Biostatistics Core; the Biological Mechanisms Core; the Clinical Translation and Recruitment Core; and the Leadership and Administrative Core. A seventh, addressing Technological Solutions for research on aging, has been added in 2023. Though these cores, the center supports research training for junior faculty, cutting edge pilot studies, data analytic expertise, biological expertise, clinical translational research support, and scientific leadership. The JHU OAIC collaboration initiative, known as the Pepper Scholars Program, consists primarily of monthly research-in-progress sessions that allow for OAIC- supported investigator interaction and discourse, along with progress updates and access to mentors and methodological experts.

Quantitative Development / Training Opportunities in C/T Research at Johns Hopkins University

Courses in Biostatistics and Other Quantitative Methodologies

BERD faculty members teach prolifically in the JHMI, both in Biostatistics degree programs and in courses targeted to CT and other health researchers in primary areas other than Biostatistics. ICTR-sponsored courses taught by Center faculty include **Methods in Clinical and Translational Research** and **Introduction to Clinical Research**. The former provides a one-day overview. The latter provides an intensive two-week experience emphasizing quantitative methods and is team-taught by the ICTR leadership. Clinical and translational researchers at the institution also have access, with tuition remission, to the full, rich array of courses in Biostatistics and Epidemiology and the Bloomberg School of Public Health.

Graduate Summer Institute of Epidemiology and Biostatistics

The Johns Hopkins Graduate Summer Program in Epidemiology was created in 1983 during the tenures of Dr. Leon Gordis as chair of the Department of Epidemiology, and Dr. D. A. Henderson as Dean of the School of Hygiene and Public Health. The creation of a program at Johns Hopkins resulted from the recognition of an increasing demand on the part of both national and foreign students for intensive training in epidemiologic methods, and statistical methods applied to epidemiologic research. In 1999, recognizing the vital contribution of biostatistics to epidemiologic research, the program became a joint endeavor of the Departments of Epidemiology and Biostatistics, as reflected in its present title.

Epidemiology and Biostatistics of Aging (EBA) Training Program (Karen Bandeen-Roche, PhD, Director): This NIH-Funded T32 training program provides predoctoral and postdoctoral opportunities in aging-related research at Johns Hopkins. It offers education in the methodology and conduct of significant clinical- and population-based research in older adults. The program sponsors bi-weekly research-in- progress meetings that involve trainees, faculty members and others in the Johns Hopkins Medical Institutions interested in aging and health. Each trainee supported by the T32 grant presents an annual formal seminar during his or her training period. These meetings provide a successful forum for students and faculty to report their research, learn methods for presentation of research, and discuss quantitative methods and prominent publications informally. The training program at the University of Maryland and the annual Research on Aging Poster Showcase and Competition, which attracts students, fellows and junior faculty from Johns Hopkins, the University of Maryland, and the Baltimore campus of the National Institute on Aging. The EBA program is in its 32nd year, and the Poster Showcase, its 15th.

Seminars

The local environment features a rich array of seminar opportunities on quantitative topics for clinical and translational researchers. The Department of Biostatistics hosts weekly seminars featuring scholars in both

methodological and applied statistics spanning the nation and world. Most topics are highly relevant to the ICTR: example topics from the current year include machine learning, mediation analysis, biomarker development, statistical genomics, and network interventions. The Department of Epidemiology and its Center for Clinical Trials also host highly relevant, frequent seminar series. Numerous Centers and Working Groups spanning the Schools of Public Health, Medicine and Nursing also host frequent seminars and research-in-progress sessions which feature biostatistics, epidemiology and research design, including the nine BSPH departments which include a statistical or epidemiological focus.

Older Americans Independence Center (OAIC)/ COAH Symposia in Biostatistics

Dating back to the 1990s, the COAH Biostatistics Core, and then the OAIC Biostatistics Core upon its inception, has presented Grand Rounds seminars and symposia that showcase applications of state-of- the-art statistical tools to key research areas of aging science. Since the establishment of this OAIC, symposia have been semiannual. Topics covered have ranged from the development and validation of a physiological index of malnutrition, to modeling multivariate trajectories of physical function and evaluation of hierarchical onset of cognitive impairments, to the use of a crossover design involving only cases to assess the effect of medications on incident fall risk based on within-person drug compliance patterns. Over the past six years we have partnered with the University of Maryland OAIC Biostatistics Core to present pan-Baltimore symposia. Topics have included clinical investigation, causal inference, and longitudinal data analysis. Since its inception, this Grand Rounds series has attracted audiences from public health, medicine and nursing and been viewed by many as an effective model for promoting multidisciplinary research.

Johns Hopkins Armstrong Institute for Patient Safety and Quality

The Johns Hopkins University Armstrong Institute for Patient Safety and Quality is a leading institution at the forefront of advancing research to improve patient safety and quality in healthcare. With a rich history of excellence in healthcare innovation and a multidisciplinary approach to research, the Armstrong Institute has established itself as a world-class entity for driving positive change in healthcare practices. The Institute's commitment to research and innovation is unparalleled, with a team of renowned experts from diverse fields such as medicine, nursing, engineering, social sciences, and human factors contributing to cutting-edge research. The Institute also collaborates with national and international partners to conduct research on patient safety and quality, leveraging its expertise to develop evidence-based solutions to improve patient care outcomes. With a strong focus on translational research, the Armstrong Institute has a track record of successfully implementing its findings in clinical practice, making a tangible impact on patient safety and quality. Map of John Hopkins Medicine service area: Maryland and the Greater Washington D.C. region.

The Institute's dedication to improving healthcare through research, innovation, and collaboration makes it an excellent entity for conducting research aimed at enhancing patient safety and quality in healthcare settings. The Armstrong Institute for Patient Safety and Quality (AI) receives funding from various organizations (federal agencies, private foundations, and international organizations) and is comprised of an interdisciplinary research team of physicians, nurses, psychologists, sociologists, statisticians, epidemiologists and health services researchers with faculty from the Johns Hopkins University School of Medicine, the Johns Hopkins Bloomberg School of Public Health and the Johns Hopkins University School of Nursing. AI has established an extensive collaborative network including the World Health Organization (WHO) World Alliance for Patient Safety (WAPS), and we are currently working with approximately 30 state hospital associations to improve care. In addition, this organization has developed tools and training programs (CUSP, Lean Six Sigma) that engage healthcare workers in the United States and around the world to develop/expand their quality and safety programs

Baltimore CONNECT

Baltimore CONNECT serves low-income individuals in East Baltimore via its network of 30 community-based organizations. It is a collaborative network of community, faith-based and neighborhood organizations which advocate for the needs of people in Baltimore, and connect them to comprehensive and coordinated health and human services. Albert Wu, MD, MPH, Director for the Center of Health Services and Outcomes Research at the BSPH is president of this network.

JOHNS HOPKINS MEDICINE AND JOHNS HOPKINS HEALTH SYSTEM

Johns Hopkins Medicine (JHM), which combines The Johns Hopkins University School of Medicine and The Johns Hopkins Health System, has become a laboratory for innovative strategies in community-based research.

The health system includes four community hospitals and several provider groups, each with a distinct culture and patient mix, expanded the referral base and potential sites for JHM trials.

The resulting geographic and demographic diversity among hospitals and providers makes The Johns Hopkins Health System a unique resource for an academic research partner. The six health system hospitals and the Johns Hopkins Community Physician group serve patients in three states; provider sites include both urban (Baltimore, Washington, D.C., and St. Petersburg, FL), and suburban settings. Several community hospitals in the system are very research-intensive, with two holding long-standing major contracts with NIH institutes to host and support NIH clinical research.

As the integrated academic home for Hopkins research, JHU is extending to its broader health system community the compliance oversight and best practices that are the hallmark of JHU research. Unified electronic systems for medical records (EPIC), IRB submissions, clinical research management, contracting, and conflict-of-interest disclosure (each discussed elsewhere in this proposal) are key elements of this strategy, together with an administrative structure that combines central compliance with an indispensable element of local review and accountability. Through the ICTR, and in cooperation with The Johns Hopkins Health system, JHU will shape the future of community research partnerships, in areas that range from contracting, IRB review, and insurance, to auditing, investigational drug control, and data security.

The Johns Hopkins Clinical Research Network: An Alliance of Academic and Community Health Systems (JHCRN)

The JHCRN is a regional translational research organization linking Johns Hopkins Medicine with a diverse network of community-based health care delivery systems that offers researchers the opportunity to collaborate with other purpose-driven researchers, and access to over 5 million potential research participants. Johns Hopkins has developed strong relationships with regional medical institutions to create a powerful network to facilitate discovery. The JHCRN includes Luminis Health, Tidal Health, Reading Hospital (an affiliate of Tower Health), George Mason University and WellSpan.

The JHCRN includes both academic medical centers and community-based practices, as well as practices in urban, suburban, and rural settings. Notably, the JHCRN allows a seamless platform for efficient study conduct by using one protocol and handling all regulatory issues by the regulatory offices of Johns Hopkins Medical Institutions.

The JHCRN is designed with a formal organizational structure and governance that spans the leadership of each of the affiliate member institutions, as well as a Working Group and a Physician Investigators Committee comprised of representative leadership of each of the affiliate member institutions. Policies and procedures have also been implemented and a governing structure is in place. Each participating affiliated institution has agreed to a detailed contract outlining the responsibilities and the relationship among the institutions, including the agreement for Network protocols to use Johns Hopkins IRB, to have a single budget for Network protocols, indemnification, and a financial contribution that includes an annual fee plus half the salary of a Network Coordinator, with Johns Hopkins providing the other half of the salary. The Network Coordinators are an essential part of the process. They are experienced research nurses or clinical research associates whose employment badges represent both Johns Hopkins and the affiliate institution with whom they are working. They physically spend half time in the research office of the affiliate institution and the other half at Johns Hopkins. In addition, there is an Administrative Coordinator and Faculty representing the disciplines of Oncology, Surgery, and Internal Medicine at Johns Hopkins.

Thus, the JHCRN creates a bridge for research between Hopkins and community-based medical centers by linking physician-scientists and staff from Johns Hopkins Medicine with community-based medical centers in the region. JHCRN directly addresses the many complexities of conducting multi-site and multi-institutional trials by providing investigators with a larger patient pool and a seamless platform that uses common research protocols. Rapid start-up and timely completion of research studies are hallmarks of the JHCRN. Each of the JHCRN institutions who will participate in this study are described below.

JHCRN COMMUNITY SITES

Johns Hopkins works in collaboration with Luminis Health in Annapolis, MD, Tidal Health Peninsula Regional in Salisbury, MD, Tower Health - Reading Hospital in Reading, PA, George Mason University in Fairfax, VA and

WellSpan in South Central PA. Johns Hopkins Medical Institutions (JHMI) also includes Suburban Hospital in Bethesda, MD; Sibley Memorial Hospital in Washington, DC; and Howard County General Hospital in Columbia, MD. These hospitals are geographically in urban, suburban, and rural areas, serving a diverse population of ethnicities and economics.

TidalHealth is a rural integrated health system located on the Delmarva Peninsula, serving residents living in Maryland, Delaware, and Virginia. With a proud 123-year history, the health system continues to grow and evolve and is now comprised of 2 community hospitals, TidalHealth Peninsula Regional and TidalHealth Nanticoke, a free-standing medical facility TidalHealth McCready Pavilion, Alice B. Tawes Nursing and Rehabilitation Center, and TidalHealth Medical Partners, a multi-specialty practice with more than 300 physicians and advanced practitioners. As one of the largest employers in the region, TidalHealth's nearly 5,000 employees meet the needs of a diverse community, which grows substantially each summer as vacationers flock to the area's beaches. Together the hospitals are licensed for 410 beds. Some of the health system statistics for 2021 include nearly 20,000 adult admissions; 2,844 deliveries; just over 100,000 Emergency Department visits; 572, 846 outpatient registrations; 22,903 surgical procedures; and 662,245 physician office visits. TidalHealth's research is centralized via the TidalHealth Richard A. Henson Research Institute.

Luminis Health, comprised of Anne Arundel Medical Center, Doctor's Community Medical Center, and the J. Kent McNew Family Medical Center, is an integrated health system with 611 licensed beds across three hospitals serving seven counties in central Maryland. Luminis health sees over 35,000 inpatient admissions, 156,000 emergency visits, and provides care at over 80 care sites. The health system has 1,770 medical staff members and over 6,500 employees. Luminis Health includes the Luminis Health Research Institute which is actively involved in multidisciplinary, industry sponsored and investigator-initiated research.

Reading Hospital in West Reading, PA, is the flagship hospital for TowerHealth. This hospital is a 700+ bed academic medical center and recognized as a Healthgrades "America's 50 Best Hospitals" in 2022 and 2023. It is a nonprofit organization, has over 31,000 total discharges, and is associated with TowerHealth Medical Group, a network of over 800 primary care physicians, specialty care physicians, and advanced practice providers. Reading Hospital serves a disproportionately low-income community and functions in the top quintile of U.S. health systems in the ration of uncompensated care to total operating expenses. The Clinical Trials Office at Reading Hospital is a centralized unit which provides support and clinical research for patients, caregivers, and medical professionals. Tower Health works to streamline the regulatory, contractual, and financial aspects of conducting research, as well as provide operational support to researchers to conduct innovative trials.

<u>WellSpan Health</u> is a community-based, teaching health system serving South Central Pennsylvania and northern Maryland with a diverse population of more than 1.5 million people. The integrated system is comprised of eight award-winning hospitals, six regional cancer centers, more than 200 patient care locations, a level one Trauma Center, a Heart and Vascular Center and several comprehensive stroke centers certified by The Joint Commission. In addition, WellSpan Health provides a robust environment for medical students, residents, and fellows, with some of the top teaching hospitals in the country. Our teaching hospitals include WellSpan Chambersburg Hospital, WellSpan Good Samaritan Hospital, WellSpan York Hospital and WellSpan Waynesboro Hospital – which has been named a Top Teaching Hospital in the country by The Leapfrog Group for the last two years.

George Mason University (GMU) is Virginia's largest public research university located near Washington D.C. George Mason University has grown significantly since its inception in 1957 with a single building and 17 students, now boasting a diverse student body of more than 39,000 students from 130 countries and all 50 states. Leaders, educators, and researchers within the College of Health and Human Services (CHHS) at George Mason University joined the Johns Hopkins Clinical Research Network in 2021. GMU's Mason and Partners (MAP) interprofessional clinics serve the uninsured, immigrant, and refugee community within Prince William and Fairfax counties in Northern Virginia. These bridge-care model, free clinics, located in Manassas, Manassas Park, Woodbridge, Springfield, and Culmore, provide integrated medical, behavioral, and social service care for vulnerable populations located in low income and medically underserved areas. Additionally, the Population Health Center, located on the GMU campus offers integrated primary and behavioral care to the community, while providing experiential learning and workforce training opportunities for students within a multidisciplinary setting, and shared space with local community partners. The Population Health Center offers

several physical exam rooms, research rooms, DXA, fMRI, gait function, metabolic cart, and electronic medical record capabilities and staffed by licensed nurse practitioners. Collectively, the MAP clinics, and the Population Health Center, represent both the diversity of the populations served across the JHCRN, and the vast array of opportunities for health-related research collaborations.

INSTITUTE FOR CLINICAL AND TRANSLATIONAL RESEARCH Administration

Johns Hopkins University has health related faculty spread out over the three different campuses. Each of these campuses has clinical facilities and laboratories where our investigators do their research. We have therefore deliberately chosen to be where our faculty are, and make our services as geographically available and accessible as possible. We are a diverse institute, covering the translational pathway from the earliest pre-clinical work to knowledge translation, and it seems only appropriate to us to be physically ubiquitous as well.

The **ICTR Administrative Offices** are located on the 16th floor of an office building located at 750 E. Pratt Street in Baltimore City. The ICTR occupies 8,065 square feet. This space is comprised of twelve offices and thirty-three cubicles, one and a half conference rooms, a mechanical space, and a reception area. All core administrative services are housed at this location.



The ICTR also maintains ancillary administrative offices in the Carnegie building of the Johns Hopkins Hospital, on the East Baltimore Medical Campus. This 940-square-foot suite of six offices is situated close to the Clinical Research Unit resources on the East Baltimore campus, making it an ideal location for Clinical Research Unit administration. Additional administrative offices are located in the 301 Mason Lord Drive building on the Bayview Medical Campus, also adjacent to the Clinical Research Unit space of the Bayview Outpatient and Domiciliary Unit. There is office space for the Research Participant Advocate at each campus within this administrative space. Also housed at the Carnegie building location is administrative staff for the Johns Hopkins Clinical Research Network, and some of the ICTR's IT staff. This suite also contains a small computing work area for investigators or study teams to use when scanning data collection forms, or designing and building data collection tools under the instruction of one of our Biomedical Informatics Program IT staff and a similar computing work area for investigators.

ICTR Operations are spread widely throughout the buildings and two campuses that make up the Johns Hopkins Medical Institutions. Our Clinical Research Unit Program resources occupy both regulated and non-regulated space within the Johns Hopkins Hospital (East Baltimore campus), and the 301 Mason Lord Drive building (Bayview Medical Campus). Our Translational Science Core Programs occupy wet lab space in the oncology research buildings of the Sidney Kimmel Comprehensive Cancer Center and the Broadway Research Building, (East Baltimore campus), and the Mason F. Lord Building (Bayview Campus). Our education programs occupy space near the East Baltimore campus and the Bloomberg School of Public Health. Finally, many of our consultative services – including Informatics, Biostatistics and Clinical Research Design, Ethics and Regulatory Support, and Community Engagement operate largely out of faculty offices, located within the departments of the health-related schools of the University.

ICTR Training Programs

The **Clinical Research Training Program (formerly TL1, now T32)** brings the (JHU) Schools of Medicine, Bloomberg School of Public Health, (JHU and UMB) Schools of Nursing, University of Maryland Baltimore School of Pharmacy, and the Morgan State University School of Community Health and Policy together to stimulate and maintain interest in a clinical and translational research career during their medical school or other doctoral training programs. The program provides exposure to and training in clinical research for 10 pre-doctoral trainees during their early professional development, specially tailored to their degree of interest and commitment. Trainees receive intensive and hands-on learning experiences that prepare them to be exemplary clinical researchers (in any discipline, specialty, or subspecialty) and teachers of clinical research. Finally, the program increases the diversity of trainees and of the academic faculty participating in clinical research. Due to similar missions, shared space, and cross program oversight, JHU K12 and T32 program directors, Drs. Gebo and Atkinson and UMB K12 and T32 program director Drs. Chang and Colloca, will network and share activities and share resources. K12 scholars and T32 trainees will have myriad opportunities to network and foster collaboration and both groups will attend the Annual Translational Science National Meeting. Due to their faculty status, K12 Scholars can serve as mentors for Trainees.

The Clinical Research Scholars Program (formerly KL2, now K12) brings the Johns Hopkins University and the University of Maryland Baltimore (UMB), Schools of Medicine, Public Health, Nursing, Engineering, Business, Pharmacy, Law, Dentistry, and Social Work together to develop and support junior faculty to become independent, ethical, innovative, and transformative clinical and translational research leaders. Scholars gain broad knowledge of the translational research pathway, develop the skills to adapt and enhance translational research models and collaborate within multidisciplinary team environments to advance and generate new knowledge to improve human health. Scholars receive practical training in conducting research, exposure to innovative research approaches and technology, "hands-on" mentored research experience, and comprehensive career development activities designed to create an environment that encourages an interdisciplinary approach and maximizes the probability of successful careers in clinical and pre-clinical translational research.

Building Interdisciplinary Scholars in Women's Health K12 Program (BIRWCH) exists to develop highly qualified, independently funded, networked, and ethical researchers leading interdisciplinary research teams to improve women's health. BIRCWH highlights core strength areas of mentored interdisciplinary research with highly experienced, nationally and internationally recognized, senior faculty active in research related to: 1) diseases specific to women (e.g. women's cancer and reproductive biology), 2) sex/gender differences in disease expression (e.g. immunology, neuroscience, cardiovascular disease, and genetics), and 3) social determinants of women's health and disparities (e.g. violence against women, trauma, addictions, and poverty). BIRCWH scholars participate in most KL2, now K12, scholar activities.

Graduate Training Programs in Clinical Investigation (GTPCI) are the first of their kind. A joint venture between the Johns Hopkins Bloomberg School of Public Health (BSPH) and the Johns Hopkins School of Medicine (SOM), GTPCI trains clinicians to be more effective clinical scientists. Students gain the skills necessary to design and conduct clinical investigations of emerging medical treatments and technologies, and to apply new diagnostic techniques and approaches to the study of human pathophysiology. We train mostly faculty, postdoctoral fellows, and other allied health professionals working with human subjects in clinical investigation. At any point in time, there are approximately 25 trainees in the Masters program. Our graduates pursue careers in academia, and as independent clinical investigators at pharmaceutical firms and federal regulatory agencies.

Research Coordinator Support Service (RCSS)

An experienced clinical investigator will tell you that a study coordinator can make or break their research. A good study coordinator is an invaluable jack-of-all-trades, able to take on very divergent and significant amounts of work – from recruiting and enrolling subjects, phlebotomy and data collection to preparation and maintenance of paperwork, development of study budgets, and the reviewing of bills, charts and reports. Yet for all the importance this role has within a study team, finding well-trained, experienced, affordable personnel is a significant challenge. Finding a part-time study coordinator is even more challenging; however, it is just this sort of person who could be of the most benefit to junior faculty with smaller projects, or even seasoned investigators with pilot studies.

The Research Coordinator Support Service (RCSS) addresses this challenge by providing a resource for faculty and research fellows at Hopkins. RCSS provides a pool of study coordinators for low-cost and able to be hired in hourly increments as needed by the study teams that hire through RCSS. The RCSS is a pool of research coordinators that Investigators can contract for on a part time basis. This pool consists of both trained and experienced coordinators (currently 8), as well at trainees from the Coordinator Apprenticeship Program (CAP) that have reached their first year of training (currently 7). The coordinators home offices are located at 301 Mason Lord Drive, Bayview office, but they perform work duties wherever is requested by the study team that hires them.

Community & Collaboration Core and Recruitment Innovation Unit (CCC/RIU)

The CCC and RIU group, headed by Dr Cheryl Dennison Himmelfarb, is located in the ICTR's 750 East Pratt St. building. These building sites provide access to numerous conference and classrooms where meetings and classes related to the community engagement core can occur. Dr. Himmelfarb, core faculty Dr. Hae-Ra Han and the CEAL DMV administration team have their offices in the Anne M. Pinkard Building which is located on East Baltimore Medical Campus, allowing for frequent in-person meetings among the core faculty. The Day at the Market program's administrative team is located in ICTR's 2024 building, with a permanent community stall at the Northeast Market operated by the Baltimore City Public Market Corporation. The market hosts events 2 to 3 times a month and accommodates up to 20 research, health education and outreach teams to engage market customers. Centro Sol headquarters is located in the Bayview Campus within the Mason F. Lord building which has conference rooms for trainings. There are several institutes and centers at Johns Hopkins who work closely with CCC and RIU related to its goal of fostering community engagement throughout the research process and promoting communities' understanding of clinical research conducted at Johns Hopkins. These institutes and centers are housed across Johns Hopkins University. Faculty, staff, and community partners from these institutes and centers have collaborated with Community Engagement in developing trainings and workshops for researchers during the last five years. These institutes and centers have also cosponsored events and have assisted the Community Engagement core in conducting consultations for researchers needing guidance on various aspects of their community-engaged research. In the coming grant period, faculty, staff, and community partners from these institutes and centers will continue to play a central role in providing consultations and will also play a vital role in developing new initiatives related to developing community stakeholders' capacity to effectively partner with researchers, including the Johns Hopkins Government and Community Affairs, the Center to Eliminate Cardiovascular Health Disparities, Baltimore Diabetes Research and Training Center, Centro Sol, Baltimore CONNECT, Memory and Alzheimer's Treatment Center, Center of Excellence for Cardiovascular Health Nursing, Center for Adolescent Health Public Health, Center for the Prevention of Youth Violence Public Health, Center for Injury Research and Policy Public Health, Center to Reduce Cancer Disparities, Center on Aging and Health, Urban Health Institute, Homewood Community Partners Initiative.

Center to Eliminate Cardiovascular Health	Medicine			
Baltimore Dishetes Descende and Training	Madiaina			
Baitimore Diabetes Research and Training	Medicine			
Center				
Centro Sol	Medicine			
Baltimore Connect	503b collaboration of 30 community			
	based organizations			
Memory and Alzheimer's Treatment Center	Medicine			
Center of Excellence for Cardiovascular Health	Nursing			
Center for Adolescent Health	Public Health			
Center for the Prevention of Youth Violence	Public Health			
Center for Injury Research and Policy	Public Health			
Center to Reduce Cancer Disparities	Public Health			
Center on Aging and Health	Public Health			
Urban Health Institute	Public Health			
Homewood Community Partners Initiative	Homewood			

ICTR DRUG DISCOVERY AND DEVLOPMENT CORE

(Dr. Barbara Slusher, Director)

Medicinal Chemistry Unit (Dr. Takashi Tsukamoto, Unit Director)

• **Tsukamoto laboratory:** The laboratory is consistent of 2 individual 800 sq. feet chemistry labs each with 4 10-foot hoods. Each hood is equipped with water, dry air, dry nitrogen (generated by in-house nitrogen generator), high vacuum, a double bank vacuum manifold, and a rotary evaporator. The lab has full access to a JOEL 500 MHz NMR (JNM-ECZL500R) with a sample changer and multi-probe capacity (¹H/¹³C/³¹P/¹⁹F) operated by the Department of Pharmacology. The lab is also equipped with analytical and preparative LC/MS instrument, a Biotage Isolera automated chromatography system, a lyophilizer, flammable material storage cabinet, and Parr hydrogenation apparatus. In-house chemical reagents are managed by ChemCart Reagent Inventory to maximize productivity without inflating reagent expenses and storage space. As a part of Johns Hopkins Drug Discovery program, the laboratory members use electronic lab notebook system operated by ChemCart in order to effectively capture, manage, share, search and securely protect accumulated experimental data. All members have online access to Hopkins library resources including SciFinder, MDL Crossfire Beilstein database. The lab also has 10 tokens for access to the Schrödinger's Small Molecule Drug Discovery Suite.

Computer-Aided Drug Design (CADD) Unit (Dr. Alex MacKerell, Unit Director)

MacKerell laboratory: The CADD Center has the following equipment/computer resources: five clusters with a total of 8948 cores, 213 GPUs, and a Gluster based storage system that has capacity of 258 TB scalable to 1.2 PB plus a second archival storage system that mirrors the primary solution that is located at a different site in case of disaster. In addition, it includes a quantum mechanics server, 22 Linux workstations, 7 MAC laptops, and ACCESS Supercomputing annual resource. CADD resources are located in two server rooms that are linked via fiber optic and GB Ethernet to laboratories and to the Internet2 network. Both rooms have individual cooling units and are connected to emergency power. Resources are monitored 24/7 by facilities.

Assay Development and Screening Unit (Drs. Jun Liu and Ajit Thomas, Co-Directors)

- Liu laboratory: Laboratory has the following equipment: a DuPont RC5 ultraspeed centrifuge, a Beckman super-speed centrifuge, a Beckman analytical HPLC, a PCR thermocycler, a Hewlett-Packard UV spectrophotometer, two -80°C freezers, six -20°C freezers, six refrigerators, two CO₂ incubators, two regular incubators for bacterial and yeast cultures, two shakers for bacterial and yeast cultures, a BioRad 2D gel apparatus, a Kodak imaging system with CCD camera for protein and DNA agarose gel documentation, a Microbeta instrument for counting radioactivity and luminescence, an Agilent LC-Mass spectrometer, a Biotag and a ISCO Flash Liquid Chromatography system for purification of small molecules, and a Tecan workstation for liquid handling and high-throughput screening. The Johns Hopkins School of Medicine also provides a 400-MHz and a 500-MHz NMR and a Mass Spec facility for walk-in service for synthetic organic chemists.
- Thomas laboratory: Laboratory includes a 200 sq. ft tissue culture facility with BSL2 certification which allows the culturing and maintenance of cell lines and is licensed to perform radioactive assays. The biochemistry laboratory has an array of centrifuges including a Beckman tabletop ultracentrifuge and a Beckman high capacity, high speed, floor centrifuge. The laboratory is also equipped with UV-Visible light spectrophotometers (384-well), high content fluorimeters (upto 1536-well), luminometer (384-well), a Fluorescence Imaging Plate Reader (FLIPR), TopCount radiometric detector, scintillation counter, large shaking incubators, with and without refrigeration, electrophoresis equipment and imaging system, ZetaView nanoparticle tracker, a gel drying system, speed vac concentrating system, balances, pH meters, micro-centrifuges, vortexers, and sonicators.

In Vitro ADME and *In Vivo* Pharmacokinetics and Bioanalysis Units (Dr. Rana Rais, Unit Director; Dr. Michelle Rudek, Unit Co-Director)

Rais laboratory: The laboratory has four state of the art mass spectrometric systems, (a) Two triple quadrupole mass spectrometers (b) A Hybrid quadrupole-orbitrap mass spectrometer and (c) and a QTOF mass spectrometer. The Thermo TSQ Vantage and TSQ Altis Plus triple quadrupole mass spectrometers are equipped with an atmospheric pressure ionization source (electrospray ionization) coupled with an HPLC chromatographic system; Thermo Xcalibur software (version 2.0) utilized for

data acquisition and analysis. The Thermo Q Extractive Focus hybrid quadrupole-orbitrap mass spectrometer consists of Ion Max API source (electrospray ionization) with a front end of Thermo Dionex Ultimate 3000 UHPLC system and Thermo Xcalibur software (version 4.0) as data acquisition and analysis system. The Agilent 6520B Quadrupole TOF mass spectrometer is equipped with a Dual electrospray ionization and APCI source, and coupled to an Agilent 1290 UHPLC. It consists of MassHunter workstation software (version B.06.01) as data acquisition software and MassHunter workstation software (version B.07.00) as data analysis software. Tissue preparation operations in the lab utilize equipment including two refrigerated table top ultracentrifuges, vortex mixers, a sonic tissue dismembrator, mechanical shaker, incubator (VWR Forced Air General), pH meters, shaking water bath, water bath sonicators, nitrogen evaporator (Zymark turbovap), vacuum concentrator (Eppendorf Vacufuge), and multiple storage freezers (-20 and -80°C). These instruments are regularly used for the unambiguous identification and sensitive quantitation of small molecules in biological matrices.

Rudek laboratory: Includes centrifuges (refrigerated and non-refrigerated), high speed microcentrifuge, two Meyer NEvap analytical evaporators, homogenizers (Ultra Turrax T-25), mechanical shaker, pH meter, shaking water bath, sonicator, vacuum manifolds (for cartridges or 96well plates) and Milli-Q Gradient ultrapure water system. Currently, the laboratory has four mass spectrometric systems. The three Triple Stage Quadrupole Mass Spectrometer Systems include: one SCIEX 4500 Benchtop Triple Stage Quadrupole Mass Spectrometer System with a Turbo ionspray source (Atmospheric Pressure Chemical Ionization and Electrospray Ionization) with a Shimadzu Nexera X2 UHPLC chromatographic system and a UV detector (Shared Instrument Grant: S10OD020091); one AB Sciex 5500 Benchtop Triple Stage Quadrupole Mass Spectrometer System with a Turbo ionspray source (Atmospheric Pressure Chemical Ionization and Electrospray Ionization) and an upfront Waters Acquity UPLC system (Shared Instrument Grant: S10RR026824); and one SCIEX Triple Quad[™] 6500+ with SelexION with IonDrive High Energy Detector+ with a Shimadzu Nexera X2 UHPLC chromatographic system. The data acquisition and analysis software is Analyst version 1.6 or greater. The one linear ion trap mass spectrometer system consists of an AB Sciex 5500 Benchtop Q-trap[™] Mass Spectrometer System with Turbo ionspray source (Atmospheric Pressure Chemical Ionization and Electrospray Ionization) and an upfront Waters Acquity UPLC system.

Biomarker Development: Imaging Unit (Dr. Maureen Kane, Unit Co-Director)

 Kane laboratory: UMB Imaging Center has a Thermo HM550 Cryostat. Samples are prepared for analysis using an HTX TM-Sprayer automated matrix deposition system. An EVOS XL digital inverted microscope with camera is available with access to an Aperio image analysis system. Both matrixassisted laser desorption/ionization (MALDI) and desorption electrospray ionization (DESI) ionization are available. MALDI-MSI data will be acquired on either a Bruker SolariX 12T FT-ICR mass spectrometer equipped with a MALDI source, or a Bruker UltrafleXtreme MALDI-TOF/TOF mass spectrometer. DESI-MSI data will be acquired on a Waters Select Series cyclic-IMS Q-TOF. Images will be analyzed using the following bioinformatic software: flexImaging (Bruker) and SCiLS Lab for MALDI imaging mass spectrometry (SCiLS) and HDI software (Waters) for DESI imaging mass spectrometry.

Biomarker Development: Proteomics Unit (Dr. Robert Cole, Unit Director; Dr. Paul Shapiro, Unit Co-Director)

Cole laboratory: consists of approximately 1800 square feet of renovated lab space with independent temperature and humidity control on the 5th floor of the Wood Basic Science and Hunterian Bldgs. The Director's office (266 sq.ft.) with a conference area and offices for four full time PhD and MS level Proteomic Specialists (250 sq. ft) are also located on the 5th floor of the Wood Basic Science and Hunterian Bldgs. The facility has five mass spectrometers, including four Thermo Orbitraps (2 Explorises, Lumos-ETD, and Q-Exactive Plus) and a Sciex Voyager DE-STR MALDI-TOF (matrix assisted laser desorption ionization with a time-of-flight). Thermo Orbitraps are interfaced with two dimensional nanoflow liquid chromatographic systems (Thermo Vanquish Neo, Thermo EASY-nLC 1000/1200, Waters NanoAcquity,) or a capillary electrophoresis system (ZipChip, 908 Devices). Two Aglient 1100/1200 capillary chromatography separations. A laminar flow clean hood is used for gel band extraction and enzymatic digestions. A Barocycler (Pressure Biosciences, Inc) provides efficient and rapid protein digestion. The Core also has one and two-dimensional gel electrophoresis and gel

imaging equipment. The Facility has a suite of bioinformatics software, including Byoinic, Mascot, MSFragger, PEAKS, Proteome Discoverer, Scaffold, Panorama and Skyline. All staff have PC computers with dual screens. All proteomic data is stored on a mirrored 30TB NAS server in the Core's office suite from which the director and staff consult and review data with Hopkins investigators. Basic Sciences Network Office houses and maintains the Core's 10 core Xeon Mascot server for searching protein databases, the 4TB NAS server for password protected transferring of large datasets and results files to investigators, and the backup mirrored 30TB NAS server with investigators proteomic data. Archive data is duplicated and store for at least 10 years in two separate locations, one in the core and the backup copy in the Basic Science Network Office. Additional PC computers have instrument vendor or bioinformatics specific software. Services are requested, managed and administered via The iLab Solutions Core Management Program. The MALDI-TOF, as well as the gel electrophoresis equipment, are available to investigators for self-service work after successfully completing a training workshop. Investigators can reserve Core self-service equipment via the Facility's iLabs website.

 Shapiro laboratory: Equipment includes several protein purification systems (e.g., BioRad and , Äkta Pure HPLC systems, Waters 2535 semi-preparative and analytical HPLC purification system), centrifuges (e.g., Avanti/Sorvall RC-2 and Beckman L8-80M ultracentrifuges), enzymatic and molecular interaction equipment (e.g., Applied Biosystems StepOne Real-Time PCR System, Biacore T200 Surface Plasmon Resonance Instrument, MicroCal Ultrasensitive PEAQ-ITC Microcalorimeter Cell, JASCO J-810 CD spectrophotometer with fluorescence, Molecular Devices SpectraMax M5 microplate reader), analytics, imaging and documentation systems (e.g., ProteinSimple WES, LI-COR, Odyssey M and Azure Biosystems C300)., Nikon E800 and Ti microscopes with NIS Elements imaging software for high-content screening, and shared access to the department's Mass Spectrometry Center (described below) and NMR facility (e.g., Varian 400 and 500 MHz) for saturation transfer difference (STD)-NMR.

Pharmaceutical Manufacturing and Enabled Clinical Trial Formulations Unit (Dr. James Polli, Unit Director; Stephen Hoag, Unit Co-Director)

The GMP Facility includes three 500 sq. ft fully equipped industrial pharmaceutics laboratories and six GMP pharmaceutical manufacturing suits, as well as rooms for the receipt and storage of GMP materials. The laboratory is equipped to perform preformulation research, excipient screening, physical characterization of polymorphs, formulation and process development for immediate and controlled release dosage forms, GMP manufacturing, packaging, labeling and shipping of clinical supplies. The Quality Control (QC) laboratory allows for testing using official USP methods (e.g. assay, content uniformity, impurities, dissolution, stability). Manufacturing equipment ranges from small-scale to pilot-scale, i.e., from gram quantities to about 50 kg. Validated stability cabinets allow for stability studies per ICH. Equipment can manufacture tablets, capsules, oral and topical liquids, semisolids, transdermal patches, suppositories and nasal sprays, including placebo liquids, capsules and tablets. The facility has DEA licenses.

- Hoag laboratory: Equipment includes: additional solid state analytical capabilities (e.g. particle size/shape characterization via optical microscopy, scanning electron microscopy, static and dynamic light scattering and sieve analysis); particle size reduction mills (e.g. fluid energy mill, hammer mills such as Fitzmill and Quardo Comill); granulators (e.g. high shear granulator and fluid bed granulators); equipment for thermal and rheological analysis of polymers; additional tablet presses and capsule filling machines; a compaction simulator to develop formulations with a small amount of material; and equipment to assess pediatric formulations for texture and taste masking (e.g. tribology and electronic tongue).
- Polli laboratory: Equipment includes: Various specialized in vitro drug dissolution systems (e.g. small volume systems, fed simulation, fiber optic systems for supersaturation/precipitation kinetics). Two Waters Acquity UPLC systems with photodiode array and fluorescence detection. Four 6-foot chemical fume hoods, rotary evaporators, and shared access to department NMR facility (Varian 400 and 500 MHz), for prodrug synthesis. 100 sq. ft tissue culture facility with radioactive permissions for performing drug permeability measures. Two -80°C freezers, two 20°C freezers, two refrigerators, and cold room.

Advanced Protein Characterization for Therapeutic Protein Development Unit (Dr. Maureen

Kane, Unit Director)

Kane laboratory: The Mass Spectrometry Center is equipped with 20 mass spectrometers for investigator use. The available instrumentation is as follows: AB Sciex 6500 QTRAP hybrid tandem quadrupole - linear ion trap mass spectrometer with a Shimadzu UHPLC, Advion expression-L compact mass spectrometer, Agilent 7700 ICP-MS inductively coupled plasma mass spectrometer, Agilent 8900 ICP-MS/MS inductively coupled plasma mass spectrometer, Bruker AmaZon X ion trap mass spectrometer, Bruker UltrafleXtreme MALDI TOF/TOF mass spectrometer, Bruker SolariX 12T FT-ICR mass spectrometer, Thermo Q-Exactive HF quadrupole-obitrap mass spectrometer with Waters nanoACQUITY UPLC, two Thermo TSQ Altis tandem guadrupole mass spectrometer with Dionex UltiMate 3000 rapid separation UHPLC, two Thermo Orbitrap Fusion Lumos hybrid mass spectrometer with Waters nanoACQUITY UPLC, two Waters TQ-XS tandem quadrupole mass spectrometer with AQUITY UPLC. Waters TQ-S tandem guadrupole mass spectrometer with AQUITY UPLC, Waters SYNAPT G2Si HDMS Q-TOF mass spectrometer with ion mobility separation coupled with nanoACQUITY UPLC System with HDX Technology, Waters SYNAPT G2S HDMS Q-TOF mass spectrometer with ion mobility separation, and Waters Select Series cyclic ion mobility Q-TOF mass spectrometer coupled with DESI mass spectrometry imaging source. For protein mapping, equipment includes Precellys PegLab 24 Tissue Homogenizer, a positive-pressure solid-phase extraction system, 2 x benchtop centrifuges, two N-Evap nitrogen evaporators, an analytical balance, and a Thermo SpeedVac are available for sample preparation. One or more mass spectrometry platforms from the Maryland Mass Spectrometry Center would be utilized: Waters SYNAPT G2S HDMS Q-TOF Mass Spectrometer with Ion Mobility Separation coupled with Nano ACQUITY UPLC System, Waters SYNAPT G2Si HDMS Q-TOF Mass Spectrometer with Ion Mobility Separation and HDX, Thermo Orbitrap Fusion Tribrid Mass Spectrometer with Waters NanoAcquity UPLC, Thermo Q-Exactive HF hybrid guadrupole-orbitrap mass spectrometer with Waters nanoACQUITY UPLC. Data analysis will be carried out using a combination of the following bioinformatics tools: Mascot (Matrix Science), Proteome discoverer (Thermo), Prosight (Thermo), Pinpoint(Thermo), Progenesis QI for Proteomics(Nonlinear Dynamics), ProteinLynx Global Server (Waters) and Ingenuity Pathway Analysis (Qiagen).

Pharmacometrics Unit (Dr. Joga Gobburu, Unit Director)

• **Gobburu laboratory:** Equipment includes: 2 dedicated computing clusters. The first cluster is powered by a Xeon E5 2698 v3 2.3GHz 32 core CPU's with Hyperthreading (64 threads), 16 GB RAM or higher, Linux operating system, 500 GB storage capacity as the main application server plus head node. This is designed to spawn jobs to 8 computer nodes via a job scheduling engine (sun grid engine). Each compute node has Xeon E5 2698 v3 2.3GHz 16 core CPU's with Hyperthreading (32 threads) 16 GB RAM or higher, Linux operating system, and shared storage. The second cluster has the same configurations for the head node and compute nodes, but 6 computer nodes rather than 8. A total of 256 cores power the Pharmacometric Unit. Each cluster has the following software: Pumas on JuliaHub, Pumas-CP on JuliaHub, R, Rstudio Server, Rstudio Connect, and Sun Grid Engine.

ICTR Clinical Research Units

The **Clinical Research Unit** resources occupy space on both the East Baltimore Medical Campus and the Bayview Medical Campus. These units, their current locations, and the amount of space are described below. *Inpatient/Overnight Services for Adult Research Participants*

<u>JHH</u>: Nelson 5 is an acute intermediate care inpatient medical unit. The unit is staffed by JHH staff nurses trained in research procedures as well as clinical practice. Resources include capacity for continuous cardiac monitoring and biological isolation of subjects.

JHBMC: The JHBMC Domiciliary Unit is a 13,842 sq. ft. space on the 4th floor of the 301 Building on the JH Bayview Campus, this unit has 10 overnight dedicated research rooms including 8 overnight study rooms that have video and audio monitoring for overnight studies. Bariatric beds are available. Specialized and routine sleep studies including chronobiology resources are available. This unit provides 24/7 service for investigators and is staffed with 8 nurses (6 RNs, 2 LPNs) and 2 technicians (who support overnight and outpatient visits). This facility also houses space for Cardiovascular Imaging, the Exercise and Body Composition Program. The space is shared with the JHBMC Outpatient Research Unit.

<u>Outpatient Services for Adult Research ParticipantsJHBMC Outpatient Research Unit</u> provides space for phlebotomy, interview rooms, procedure rooms, gyn exam room, dental exam room, sample processing lab, -70 freezer, echocardiography and endothelial function testing, metabolic stress testing resources, DXA, Biodex for muscle strength testing. Nurses administer protocol-guided medications, including supporting insulin clamps, IVGTT, and pharmacokinetic studies.

JHH Outpatient Research Unit: In 2020, the JHH Outpatient Research Unit moved into newly renovated space in the Blalock Building, located only several hundred feet from its previous location in the Carnegie Building. The 5385 square foot unit includes 11 full-service exam rooms, 2 interview rooms, a phlebotomy room, sample processing lab, -70 freezer, infusion center, and a DXA scanner. Full-time staff includes 3 research nurses, a licensed practical nurse, a phlebotomist and a technician who assist investigators with protocol specific evaluations (e.g., vital signs, collection/processing of specimens, administration of questionnaires, EKG's.) Experienced RN/LPN's provide nursing evaluation and observation, administer medications and provide emergent support for research projects in this specialized research setting. CRU staff also provide skills training for research teams.

Inpatient and Outpatient Services for Pediatric Research Participants JHH: The Pediatric CTSA team helped design a new inpatient and outpatient facility located in the Charlotte R. Bloomberg Children's Building. The inpatient unit is 20 beds, of which 7 at any one time can be reserved for ICTR-approved research. The outpatient unit, which includes 7 clinical exam rooms, an infusion facility, 2 procedures rooms, pediatric phlebotomy room, a formula and research kitchen is open to investigators with CTSA-approved protocols Monday - Friday 7 AM to 6 PM. The services are supported by 1.0 RNs, and 1 CNA/pediatric phlebotomist

NBU Neurobehavioral Unit

(Located at Kennedy Krieger adjacent and connected to JHH) this unit supports programs related to development disorders or other conditions affecting the CNS. The resources of the Behavioral Psychology Department at Kennedy Krieger include: (1) a 15-bed Neurobehavioral inpatient treatment unit with dedicated individual therapy/observation rooms, classrooms, day programming areas, and simulated home environments; (2) a similar inpatient behavioral feeding disorders unit; (3) an outpatient suite of ten interview/treatment rooms with one-way mirrors and audio-video equipment for observation purposes. These capabilities can be made available to ICTR investigators when other CRU resources are unable to deal with the special needs of children with severe impairments or challenging behaviors.

ProHealth (Director: L. Appel, MD, MPH)

The ProHealth Clinical Research Unit is a dedicated research facility that has been the site for numerous, influential NIH-sponsored studies. This 15,000 ft² clinical research unit is located off-campus in the Woodlawn suburb of Baltimore, approximately 10 miles from the East Baltimore campus of the SOM and SPH.

This community-based research facility is convenient to participants from Baltimore City, Baltimore County, Arundel County, and Howard County. Space for recruitment and data collection on the first floor of ProHealth is separate from the metabolic kitchen and intervention suite on the second floor, thereby allowing for blinded ascertainment of outcome variables by data collection staff. The facility has 9 examination rooms, 2 phlebotomy stations, 2 procedure rooms, and 4 large meeting rooms that can be used for study meetings, staff meetings, and participant recruitment and appreciation events. It also has a large metabolic kitchen and dining room for ~20 participants.

The leadership of ProHealth has been remarkably stable. Since the inception of ProHealth in 1989, Drs. Appel and Miller, and Ms. Charleston have provided steady administrative and scientific support for the > 50 studies conducted at ProHealth. The Hopkins JHUSOM/DOM and the Division of General Internal Medicine staff oversee administration of ProHealth. Jeanne Charleston, Director of Research Operations, oversees space and allocation of staff across studies.

The core investigative team at ProHealth has an outstanding track record in the design, conduct and analysis of community-based studies, including cohort studies, feeding studies, behavioral intervention trials, and supplement trials. Major studies conducted at ProHealth include:

- Observational epidemiologic studies
 - Cohort Phase of AASK
 - Phases 1 4 of Chronic Renal Insufficiency Cohort Study (CRIC)
 - Randomized feeding studies (General Population)
 - <u>Dietary Approaches to Stop Hypertension (DASH)</u>
 - Dietary Approaches to Stop Hypertension Sodium (DASH-Sodium)
 - o Optimal Macronutrient Intake to Prevent Heart Disease (OmniHeart)
 - Optimal Carbohydrate Intake to Prevent Heart Disease (OmniCarb)
 - 5+ Nuts and Beans
 - Dietary Approaches to Stop Hypertension for Diabetes (DASH4D)
 - Randomized feeding studies (Chronic Kidney Disease)
 - o GoFish
 - o CKD-K
 - o SodaPop
 - 5+ Nuts and Beans for Kidney
 - Behavioral intervention trials
 - o <u>Trials of Non-Pharmacologic Interventions in the Elderly (TONE)</u>
 - Trials of Hypertension Prevention, Phases 1 and 2 (TOHP1 and TOHP2)
 - PREMIER
 - o LookAHEAD
 - Diabetes Prevention Program (DPP)
 - o Diabetes Prevention Program Outcomes Study (DPP-OS)
 - Trials of health information technologies to promote weight loss
 - Weight Loss Maintenance Trial (WLM)
 - Practice-Based Opportunities for Weight Reduction (POWER)
 - Survivorship Promotion In Reducing IGF-1 Trial (SPIRIT)
 - Behavioral Weight Loss Program for Cancer Survivors in Maryland (ASPIRE)
 - Vitamin supplement trials
 - Folic Acid Supplementation Trial (FAST)
 - Vitamins, Teachers, and Longevity Pilot Study (VITAL Pilot)
 - o <u>Study To Understand fall Reduction and vitamin D</u> in You (STURDY)
 - Trials to Improve Physical Health in Persons with Serious Mental Illness
 - o Achieving Healthy Lifestyles in Psychiatric Rehabilitation (ACHIEVE)
 - Comprehensive Cardiovascular Risk Reduction Intervention in Persons With Serious Mental Illness (IDEAL)
 - Trial of Integrated Smoking Cessation, Exercise and Weight Management in Serious Mental Illness (TRIUMPH)
 - Randomized Trial of a Healthy Weight Intervention for Youth With Serious Emotional Disturbance (CHAMPION)
 - Pharmacologic blood pressure studies
 - <u>A</u>frican-<u>A</u>merican <u>S</u>tudy of Hypertension and <u>K</u>idney Disease (AASK)

Hallmarks of their studies include the following:

- Successfully completing studies on time and on budget.
- Exceeding recruitment goals while enrolling a highly diverse population. In most studies, 30-50% of
 participants are Black and >50% are women. See Table below, which highlights our success in recruiting
 and retaining participants. ProHealth investigators have met their recruitment goals in every study
 conducted at ProHealth over the past two decades.
- Achieving high rates of follow-up data collection, typically at least 95% for the primary outcome variable
- Promoting the careers of junior faculty and trainees through creative ancillary studies
- Disseminating study results and influencing policy.

	Recruitment							Retention			
	Goal	Enro	lled	N (%) Women		Ν	(%)	Duration of	% with FU		
	(0)			Minority				FU	data		
reeding Studies (General Population)											
DASH	114	124	(109%)	59	(48%)	86	(69%)	3 m	99%		
DASH-Na	100	104	(104%)	58	(56%)	78	(75%)	3.5 m	99%		
OmniHeart*	80	84	(105%)	42	(50%)	57	(68%)	6 m	92% ^A		
OmniCarb*	80	90	(113%)	61	(68%)	54	(60%)	6 m	90% ^A		
Feeding Studies (Chronic Kidney Disease)											
GoFish	30	31	(103%)	14	(45%)	20	(65%)	4m	97%		
CKD-K	26	29	(115%)	17	(59%)	21	(72%)	2m	97%		
SodaPop	30	31	(103%)	10	(32%)	30	(90%)	2m	100%		
5+ Nuts and Beans Kidney	150	150	(100%)	96	(64%)	150	(100%)	4m	93%		
Behavioral Intervention Trials											
PREMIER*	200	211	(106%)	142	(67%)	117	(55%)	18 m	95%		
WLM**	200	233	(117%)	156	(67%)	93	(40%)	2.5 yr	94%		
POWER*	390	415	(106%)	264	(64%)	183	(44%)	2 yr	95%		
Supplement Trials											
STURDY**	**	373	**	165	(44%)	146	(39%)	2 yr	97%		
CKD Cohort Studies											
AASK Trial	65	64	(98%)	22	(34%)	100	(100%)	3.5-5 yr	97%		
CRIC Phase 1	235	276	(117%)	130	(47%)	116	(42%)				
CRIC Phase 3	108	112	(104%)	55	(49%)	73	(65%)	ongoing	ongoing		
*Cross-over trial – % with any outcome data in at least 2 periods.											

JOHNS HOPKINS ALL CHILDRENS HOSPITAL

JOHNS HOPKINS ALL CHILDREN'S CAMPUS (Florida)

The Johns Hopkins All Children's main campus encompasses seven contiguous city blocks adjacent to downtown St. Petersburg, FL, and includes Johns Hopkins All Children's Hospital, the Johns Hopkins All Children's Outpatient Care Center, the Johns Hopkins All Children's Child Development and Rehabilitation Center, the Johns Hopkins All Children's Research & Education Building, and three Ronald McDonald House sites. Founded in 1926 as the American Legion Hospital for Crippled Children, and subsequently renamed All Children's Hospital, the hospital grew over the past near-century from a small community hospital into a major pediatric academic health system in the Southeast region of the United States. In 2011, the health system became a member of Johns Hopkins Health System and was re-branded as Johns Hopkins All Children's Hospital, becoming the Southern pediatric campus of Johns Hopkins Medicine.

Clinical Environment

Johns Hopkins All Children's Health System is a non-profit entity that provides tertiary level medical care in nearly all of the pediatric medical and surgical subspecialty areas for a catchment area of seventeen counties across the state of Florida, home to over 1.3 million children. Nearly 70% of patients served are insured through Medicaid/Medicare.

JHACH is a ten-floor, 738,000 square foot, state-of-the-art facility on the main campus with a 259-bed inpatient capacity comprised of: a 97-bed Neonatal Intensive Care Unit; a 28-bed Pediatric Intensive Care Unit; a 22-bed Cardiovascular Intensive Care Unit; a 28-bed Neuroscience and Surgery Unit; and a 28-bed Cancer and Blood Disorders and Hematopoietic Stem Cell Transplantation Unit. In addition, there are 12 state-of-the-art operating suites, an Emergency Center and a Diagnostic Imaging department. The 3rd floor of the Hospital houses BabyPlace, a 45-bed Mother-Baby unit, 14-bed Antepartum Unit, a Labor and Delivery suite, an OR suite, and a Well-baby Nursery. On average, 4,000 babies per year are born at BabyPlace. In fiscal year 2019 (i.e., prior to the onset of the COVID-19 pandemic), there were over 6,000 hospital admissions and 46,000 Emergency Center visits.

The Hospital is adjacent to and connected via an enclosed walking bridge to a five-floor main campus Outpatient Care Center (OCC), which houses individual subspecialty and general pediatrics clinics, multidisciplinary clinics, diagnostic services, the Department of Pathology and Laboratory Medicine, and physician and administrative offices. Through a network of strategically located OCCs in the region that are connected with the main campus OCC, Johns Hopkins All Children's Health System brings diagnostic, rehabilitation and subspecialty care services to communities throughout the region, including federally-designated underserved areas and populations. The Health System's network of OCCs extends over 150 miles, from Citrus County in the North to Ft. Myers in the South. In fiscal year 2019 (i.e., prior to the COVID-19 pandemic), approximately 400,000 outpatient visits were conducted throughout the OCC network.

Scientific Environment

Johns Hopkins All Children's is an integrated member of Johns Hopkins University School of Medicine, and the primary campus home to over 40 full-time JHU SOM-employed faculty and over 125 health-system employed physicians who have JHU SOM faculty appointments. Academic and clinical affiliates include the University of South Florida Department of Pediatrics and the National Cancer Institute-designated H. Lee Moffitt Cancer Center, both based in nearby Tampa, FL. Since its integration into Johns Hopkins Medicine in 2011, Johns Hopkins All Children's has undergone progressive expansion of its research faculty, its research infrastructure and staff, and the number and complexity of the research studies it conducts.

Research & Education Building

In October 2018, the new, stand-alone, state-of-the-art 230,000-square-foot research and education facility opened on the Johns Hopkins All Children's main campus. Connected via an enclosed walking bridge the Outpatient Care Center and located across the street from the Hospital, the Research & Education Building is a 7-floor facility dedicated to innovation in pediatric education and research. Encouraging a team-based, collaborative, multidisciplinary approach to medical education and scientific discovery, the facility includes research and education faculty and staff administrative offices, "wet" and "dry" laboratories for basic science and clinical and translational research (including data and analytic sciences, such as machine learning), interdisciplinary collaboration zones, and both "wet" and "dry" research cores and shared resources Additionally, the collaborative learning space includes a 250-seat auditorium, conferencing facilities with advanced videoconferencing equipment, and a large state-of-the art Pediatric Simulation Center.

Institutes

The REB is home to six Johns Hopkins All Children's Institutes: the Institute for Brain Protection Sciences; the Cancer and Blood Disorders Institute; the Heart Institute; the Maternal Fetal and Neonatal Institute; the Institute for Fundamental Biomedical Research; and the Institute for Clinical and Translational Research.

The <u>Institute for Clinical and Translational Research</u> is comprised of seven Centers/Programs of strategic emphasis: the Center for Pediatric Early-Phase Trials; the Center for Pediatric Health Equity Research; the Clinical Coordinating Center for Pediatric Multicenter Studies; the Data Coordinating Center for Pediatric Multicenter Studies; the Center for Clinical/Translational Research Training, Education, Engagement and Mentorship (TEEM); the Center for Machine Learning and Analytic Methodology; and the Program in Pediatric Biospecimen Science. The <u>Institute for Fundamental Biomedical Research</u> is comprised of the Center for Metabolic Origins of Disease, the Center for RNA Biology, and the Program in Tumor Microenvironment and Immuno-oncology.

Research Cores, Shared Resources, Offices, and Departments

The Research & Education Building houses five shared resource cores/units that support basic science research:

Research Animal Resources; Shared Instrumentation; Tissue-Based Diagnostics and Research; RNA Biology; and Molecular Determinants (multi-omics). Additional genomics capabilities and other cores and shared resources for clinical/translational and basic science research are readily accessible via the JHM Institute for Clinical and Translational Research and the Genomics Research Core Facility and Center for Computational Biology in the JHM Institute for Genetic Medicine on the JHU SOM main campus in Baltimore.

The Research & Education Building also houses ten clinical/translational research cores/shared resources: the Research Operations Shared Resource; the Clinical Research Unit; the Investigational Drug Services Unit; the Investigational New Drug/Investigational Device Exemption Support Unit, the Regulatory Affairs / Quality Assurance (Internal Monitoring) Unit; the Epidemiology and Biostatistics Unit, the Database Design and Data Management Unit, the Clinical Data Acquisition Unit, the Machine Learning and Predictive Analytics Unit, and the Johns Hopkins All Children's Pediatric Biorepository. The Biorepository facilities comprise over 5,000 square feet of specialized processing and storage space capable of holding nearly 3 million samples. The Biorepository has been continuously accredited by the College of American Pathologists since 2015 and utilizes 2D-barcoded long-term freezer storage aliquot tubes in lieu of patient/participant identifying information. The main Biorepository facility (3000 sq. ft.) is located in the Research & Education Building, and includes a BIOS automated -80C freezer with a capacity of 2.3 million samples, an MVE Chart Vario 1879P with a capacity for 80,000 samples, and a liquid nitrogen freezer for vapor-phase storage of up to 60,000 specimens. Laboratory areas have environmental monitoring for temperature and humidity, and all storage equipment is continuously temperature monitored using NIST certified sensors connected to a remote alarm system for 24/7 alerts (TempTrack). Additional Biorepository facilities are located in the Johns Hopkins All Children's main campus OCC (connected by enclosed walking bridge to the Research & Education Building), and include a Biorepository Shipping/Receiving Room, Processing Area, and Short-Term Storage Room. The latter (760 sq. ft.) houses sample storage equipment including; three Hamilton SAM robotic freezers for automated ultra-low temperature storage of up to 70,000 specimens, two 20 cu ft. -80°C chest freezers for storage of up to 120,000 specimens, one liquid nitrogen freezer for vapor-phase storage of up to 60,000 specimens, and a cryocart for ultra-low temperature specimen transport between buildings. Lastly, an Operating Suite Biorepository Satellite (20 sq. ft.) facility is located within Johns Hopkins All Children's Hospital adjacent to the Pathology Frozen Section room and Operating Suites.

Institutional Review Board (IRB) Resources

The Research & Education Building houses the JHACH Office of Human Subjects Research (OHSR, informally referred to as the "IRB Office"). The JHM JHACH IRB is one of 7 IRB panels in the JHM IRB system, and functions as the HIPAA Privacy Board at JHACH. The JHACH OHSR is a full-service local office of the JHM OHSR (the latter being based on the main JHU SOM campus in Baltimore), which supports all functions of the JHM JHACH IRB, follows all JHM OHSR policies and processes, and functions under delegated authorities by the JHM OHSR.

Grants Administration

The JHACH Department of Research & Grants Administration is located in JHAC Research & Education Building. The JHACH Department of Research & Grants Administration is a full-service local office of the JHM Office of Research Administration (ORA, the latter based on the JHU SOM main campus in Baltimore), which follows all JHM ORA policies and processes, and functions under delegated authorities by the JHM ORA. Research administrative work (e.g., pre-award and post-award activities and support) for federal grant proposals and awards for research activities on the JHACH campus is performed collaboratively among staff in JHM ORA on the JHU SOM main campus and staff in the JHACH Department of Research Administration. All sub-award activity performed by non-JHU-employees on the Johns Hopkins All Children's campus are managed through the local non-profit research entity, All Children's Research Institute.

Library Resources

JHACH library resources include the Johns Hopkins All Children's Hospital Medical Library in St. Petersburg, FL and the Welch Medical Library on the JHU SOM main campus in Baltimore. Together, these libraries provide a variety of resources that support the teaching, research, and patient care goals of the institution. Faculty, staff, and students can search a range of databases, access >3000 biomedical and scientific journals through institutional subscription, search the holdings of all seven Johns Hopkins University libraries, and take advantage of the library's information services and classes, including resources and training in data storage and management. Medical journals, books, and all other electronic content are available both on and off campus

through a remote access system.