

FACILITIES AND OTHER RESOURCES

For Johns Hopkins Institute for Clinical and Translational Research

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 <http://www.jhu.edu/>

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. Thirty-six 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 17 recipients of the Nobel Prize in Medicine or Physiology. Current faculty members include 60 Institute of Medicine Members, 8 Lasker Medical Research Award Recipients, and 35 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

www.hopkinsmedicine.org/som

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 2695 full-time and 66 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 two 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, now have research space.



BLOOMBERG SCHOOL OF PUBLIC HEALTH

<http://www.jhsph.edu>



The Johns Hopkins Bloomberg School of Public Health (also referred to as The Bloomberg School or JHSPH) 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 670 full-time and 709 part-time faculty, and 2,243 students from 81 nations. 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 JHBSPH, the Department of Biostatistics and the Department of Epidemiology have a particularly prominent role in the ICTR.

THE JOHNS HOPKINS SCHOOL OF NURSING

<http://nursing.jhu.edu>

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. The expansion will add more than 41,000 sq. ft of new space and five additional stories to be used for collaborative spaces, small group study rooms and expanded PhD and Post-doctorate work and research space. Today, under the leadership of Dean Patricia M. Davidson, PhD, MEd, 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 80 Full-time and 130 Part-time faculty with six endowed chairs and 146 joint appointments. The faculty obtained \$35.9 million in total sponsored research project funding in Federal fiscal year 2016 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 School of Nursing structure is currently six levels and 93,290 square feet. It consolidates the School's teaching, research and administrative activities. Space is provided for faculty, clerical, research staff and data management personnel. The School contains a 90-seat flexible space classroom, two adjoining 63-seat classrooms; two 110-seat lecture halls (one with capability for distance learning); three 12-bed practice laboratories (one with capability for distance learning); research space with state-of-the-art laboratories; one 40-seat computer classroom; one 45-seat classroom (with capability for distance learning); two 18-seat seminar rooms; two 15-seat group study rooms; three 16-seat computer/interactive video labs; and a 230-seat auditorium. The entire building is equipped with MediaSite webcast technology.

The Johns Hopkins University School of Nursing maintains a local area network consisting of 29 physical and 15 virtual Microsoft (MS) Windows servers and approximately 500 MS Windows XP workstations, five MS Windows Vista systems and four Apple Macintosh systems. Network peripherals and systems include a tape library device, monochrome and color printers, copier / scanning systems, storage area networks and network attached storage devices. In addition to the network systems and peripherals previously described, the school maintains six computer labs. These labs consist of a 40-seat teaching lab, two 13-seat application labs, a 16 seat Doctoral Lab, another 10-seat application lab on the buildings

lower level and final 9-seat application lab in the NIRC. The first floor café area, second floor lab area, third and fifth floor provide wireless network access for notebook and other computing devices.



The JH SON Office for Science and Innovation (OSI), formerly known as the Center for Nursing Research, has encouraged leadership for nursing research within the School, University, community and profession, and facilitates excellence in nursing research. Research is coordinated between the Office for Science and Innovation, Office of Finance Administration, and Johns Hopkins University Research Administration as well as Johns Hopkins Medical Institutes. The OSI provides both pre- and post-award services to faculty, students, and staff, e.g., information on funding sources and grant

application processes; including consultation on research design and conduct including data management and analysis; advice on faculty development and continuing education in research; dissemination of research and funding information; and resources such as texts and conference rooms. In these ways, the OSI facilitates faculty and student research by offering programs and resources to support the development, submission, conduct and publication of research; and by providing the needed information technology to foster research. The OSI works in collaboration with the School of Nursing department chairs and Center faculty to provide a supportive environment for faculty, students, and staff involved in research. The OSI and ICTR meet at least once a year to coordinate services.

WHITING SCHOOL OF ENGINEERING (WSE)

<https://engineering.jhu.edu/>

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 2015-2016 academic year alone, WSE faculty published more than 700 referred publications and gave over 300 invited talks. Currently, WSE has 163 academic and 29 research faculty, 29 teaching faculty, and 44 associated research scientists and engineers. In 2014 – 2016, WSE faculty received six NSF CAREER Awards, two Presidential Early Career Awards (PECASE), and four Office of Naval Research Young Investigator Awards.



In FY 2015, the Whiting School received \$113.2 million in research funding. The school's more than 20 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 newly formed 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 nine 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. This includes Drs. Natalia Trayanova (whole-heart electromechanics), Rajat Mittal (cardiac fluid dynamics), Dr. Andre Levchenko (systems biology, micro-fluidics and nano-devices for investigating protein networks and signaling pathways).

The Department of Biomedical Engineering runs the top-ranked Biomedical Engineering Undergraduate and PhD Program in the U.S. PhD students are given enormous flexibility in how they structure their education. Students are allowed to work with any mentor in the Johns Hopkins University. The PhD Program has more consecutive years of funding than any other T32 program supported by the NIGMS. A pre-doctoral program in human genetics was founded at JHU in 1957, and is now operated by the Institute for Genetic Medicine. Activities include courses in human genetics and medical genetics, a postdoctoral training program in human genetics, research conferences and journal clubs, as well as clinical conferences and an intensive summer course in mammalian genetics at The Jackson Laboratory in Bar Harbor, Maine.

ZANYVL KREIGER SCHOOL OF ARTS AND SCIENCES

<http://krieger.jhu.edu/>



The Zanyvl 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 social sciences are renowned for their excellence and intensity, 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

<http://carey.jhu.edu/>

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

<http://welch.jhmi.edu/welchone/>

One of the leading medical libraries in the world, the library is evolving into a user-focused, service-oriented entity rather than a traditional brick and mortar repository for physical materials. The library is less a place that users actually visit, and more a large group of services. These services are provided both electronically and by library staff, are applicable to a primarily electronic collection, and are accessible by many devices, from anywhere in the world. The electronic collection includes more than 7,200 electronic journals, more than 400 databases, more than 13,000 e-books and more than 2,500 videos. The WelDoc Service provides access to materials not in the Hopkins collections.



In all, Welch users have access to more than a million e-resources because when any Hopkins library licenses an e-resource it subscribes for all JHU libraries whenever possible. The Welch Medical Library has moved aggressively to meet the demand for electronic resources and the need for more specialized library services provided by an information expert at the points of work and care for faculty, staff and students. This new information services delivery model is called embedded informationist services. The Welch Medical Library's Embedded-Informationist Program maintains a full time staff of 11 clinical, public

health and basic science librarians who provide expert services to their assigned departments as embedded informationists within those departments. By actively extending expert informationist services out of the library building in order to collaborate with JHMI community members in their own work environments, Welch expects to strengthen the research, teaching and clinical efforts and increase the productivity of JHMI departments, centers and institutes.

JHU CENTERS AND INSTITUTES

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.

- **Welch Center for Prevention, Epidemiology, and Clinical Research** (Lawrence J. Appel, MD, MPH, Director): The Welch Center is a multidisciplinary academic unit that is co-sponsored by the School of Medicine and Bloomberg School of Public Health. As part of its mission, the Welch Center conducts patient-oriented clinical, epidemiologic, and translational research that promotes adoption of best practices in clinical settings and populations. Through patient-oriented research, the Welch Center evaluates the application of laboratory discoveries as well as the adoption of best practices in clinical settings and populations. Because biologic, environmental, and clinical factors interact in causing illness and disability, the Center's work is fundamentally interdisciplinary, relying on active collaboration among faculty members from the Schools of Medicine, Public Health, and Nursing. Welch Center faculty members employ the full range of research methodology, including longitudinal observational studies, randomized trials, and effectiveness and outcomes studies. The Welch Center has ~ 15,000 ft² of contiguous space and is located in the same building on the East Baltimore campus. The Welch Center provides a highly effective and stimulating environment as well as primary office and meeting room space for its 30 faculty members, and 40 associate faculty members. In terms of faculty appointments, 15 core faculty have primary appointments in the Division of General Internal Medicine, 8 in the SPH Department of Epidemiology, and 5 in other academic units. Virtually all faculty have joint or adjunct appointments in the Schools of Medicine and Public Health. The Welch Center abounds with trainees, over 100, who likewise have diverse backgrounds (medical students from SOM; masters and PhD students in Epidemiology and other SPH departments; and post-doctoral fellows from several disciplines, including Cardiology, Epidemiology, and General Internal Medicine). Research is facilitated through close, collegial affiliations with existing academic units at Hopkins. These include the Division of Cardiology, Division of General Internal Medicine, Division of Nephrology, Division of Geriatrics, Department of Epidemiology, Department of Biostatistics, the Chronic Disease Informatics Program, the ProHealth Clinical Research Unit, the Diabetes Research and Training Center, the Institute for Clinical Translational Research (ICTR), the Center for Clinical Trials, and the DEcIDE Network at Hopkins. The Welch Center offers weekly research-in-progress seminars. <http://www.jhsph.edu/welchcenter>

The Welch Center also has a critical role in the ICTR education programs. KL2 scholars (masters and PhD tracks) have dedicated space that includes individual carrels and flexible conference space, and immediate access to Dr. Pete Miller and the KL2 administrator.

- **Institute of Genetic Medicine** (David Valle, MD, Henry J. Knott 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. <http://www.hopkinsmedicine.org/geneticmedicine/>
- **Center for Clinical Trials and Evidence Synthesis** (Kay Dickersin, PhD, 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 <http://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-center-for-clinical-trials/>.

- **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 well-being 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. <http://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-center-for-population-health-information-technology/>

- **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 Roybal Center for Translational Research, 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 activities on aging and the home and "go-to" place for collegial interaction for research on aging and 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. <http://coah.jhu.edu/>.

iLab SOLUTIONS

<https://johnshopkins.corefacilities.org/landing/42#/cores>

iLab is a centralized online system with a portal designed to assist researchers in navigating the multiple resources available (as outlined below) at Johns Hopkins Medicine. This system includes core facilities from the Bloomberg School of Public Health, Krieger School of Arts and Sciences, School of Medicine, and Whiting School of Engineering. Core facilities provide equipment and services to investigators through the iLab portal.



Johns Hopkins Centers and Institutes:

Autoimmune Disease Research Center (ADRC) autoimmune.pathology.jhmi.edu/aboutcenter.cfm	The Johns Hopkins Autoimmune Disease Research Center offers leadership in the study and development of improved diagnosis, treatment and prevention of autoimmune diseases. Researchers located in basic science departments throughout the Johns Hopkins Medical Institutions are engaged in fundamental research on the immune response study the causes of its dysregulation and the reasons why they lead to disease. Center clinicians are working to develop new methods to improve the diagnosis and treatment of one or more of the autoimmune diseases. Epidemiologists and geneticists in the ADRC are seeking out the environmental factors or the genetic traits that increase the risk of developing an autoimmune disease. The Center creates the opportunity for all of these Johns Hopkins investigators to come together in advancing the battle against autoimmune diseases through research, education and better communication, resulting, eventually, in improved clinical care.
Berman Institute of Bioethics www.bioethicsinstitute.org/	The mission of the Johns Hopkins Berman Institute of Bioethics is to conduct advanced scholarship on the ethics of clinical practice, biomedical science, and public health, both locally and globally, and to engage students, trainees, the public, and policy-makers in serious discourse about these issues. The Berman Institute is now one of the largest centers of its kind in the world and consists of more than 41 core and affiliated faculty from the Johns Hopkins School of Medicine, School of Nursing, Bloomberg School of Public Health, and the Krieger School of Arts and Sciences.
Biomolecular NMR Center bionmr.jhu.edu	The Johns Hopkins Biomolecular NMR Center is an inter-campus research facility, encompassing the Johns Hopkins University (JHU) and the Johns Hopkins School of Medicine (SOM). The mission of the Biomolecular NMR Center is to provide a facility that allows researchers in the Hopkins community to use NMR Spectroscopy to address structural, mechanistic, and functional questions in biological systems. Research areas include, but are not restricted to, three-dimensional structure determination of proteins and nucleic acids, biomolecular interaction and dynamics, and the development of NMR methodology to advance the scope of applications. The core facility is home to four main spectrometers. The highest field spectrometer on site is a Varian Inova

	800 MHz spectrometer equipped with a triple resonance room temperature probe. The facility is also home to 600 MHz Bruker Spectrometers, Avance and Avance II models. They both have triple resonance cryoprobes. The final magnet located on the Homewood Campus is a Varian Inova 500 MHz magnet located in Remsen Hall.
<u>MRB Molecular Imaging Service Center and Cancer Functional Imaging Core</u>	Noninvasive imaging has become a powerful tool in the investigation of various disease processes. Spectacular advances in MR, PET, SPECT, ultrasound, optical imaging as well as other modalities now provide unparalleled opportunities for combined anatomic, functional and molecular imaging. The MRB Molecular Imaging Service Center and Cancer Functional Imaging Core provides state-of-the art small animal imaging equipment, including MRI, multiphoton microscope, PET, SPECT, Ultrasound, Optical imaging, X-ray and CT, to support the wide range of scientific projects within the diverse research community of the Johns Hopkins University and beyond. Trained technologists will assist investigators in the use of the facilities.
<u>The Cardiovascular Physiology and Surgery Core</u>	The Cardiovascular Physiology and Surgery Core is available to provide the Johns Hopkins community and beyond three types of cardiovascular procedures on small animals, including, but not limited to, mouse and rat: echocardiography, survival surgery, and hemodynamics. Other procedures may be possible after discussion with the core surgeons.
Center for AIDS Research (CFAR) <u>/hopkinscfar.org</u>	Johns Hopkins University Center for AIDS Research is working to develop a new generation of HIV/AIDS researchers and recruit under-represented minorities into the HIV/AIDS field by providing training, support, and mentoring of junior investigators and those not in the HIV field. CFAR also endeavors to recruit new investigators from relevant disciplines into HIV/AIDS research to address the growing need for knowledge in emerging areas that affect the AIDS epidemic. By promoting transdisciplinary innovation, integration and collaboration CFAR enhances productivity and mobilizes the capabilities and capacity of Johns Hopkins University to combat the HIV epidemic in Baltimore through training, outreach and community-based intervention studies. Examples of resources available via CFAR include specimen repository, access to HIV related data and sample sets, grant development and implementation toolkits, lightning round specific aims reviews, K club and K2R clubs for junior investigators to name a few.
Center for Bioengineering Innovation and Design <u>cbid.bme.jhu.edu</u>	The Department of Biomedical Engineering at Johns Hopkins University is internationally recognized as a leader in biomedical research and education. With a footing in both the Whiting School of Engineering and the Johns Hopkins School of Medicine, BME students have access to a wealth of clinical and scientific depth across both Johns Hopkins campuses. Students work with researchers, clinicians, engineers, and experienced industry advisors to design, build, and test devices to solve clinical problems in both advanced health systems and the world's low-resource health delivery settings. Over the past five years, Design Teams Students have completed 58 medical technology projects with sponsors, received 18 provisional patents (with nine patent applications pending),

	<p>entered four licensing agreements, and have formed six start-up companies. Teams will have access to a state-of-the-art Design Studio and resources to build and test early-stage ideas.</p>
<p>Center for Brain Imaging Science www.brainscienceinstitute.org/cores/center-for-brain-imaging-science/</p>	<p>Established as a research center by Brain Science Institute, the Center for Brain Imaging Science (CBIS) is dedicated to provide state-of-the-art image analysis technologies to researchers in Hopkins community. Currently, several MRI and PET imaging centers at the university provide access to an array of modern imaging capabilities. CBIS works with these imaging centers, offering researchers support in acquiring, processing and analyzing data.</p> <p>Collaborating imaging centers include the F. M. Kirby Research Center equipped with three modern human MRI scanners including 3T and 7T Philips scanners; the NMR Service Center/Center of Magnetic Resonance Microimaging with 4.7, 9.4 and 11.7T animal scanners located in Traylor and MRI building; the ICMIC Center with 9.4T animal MR scanner as well as microPET and microCT for small animal studies; and the Radiology MRI Service Center with four human MR scanners including 1.5T (Siemens, GE) and 3.0T (Siemens, Philips).</p> <p>CBIC also has close ties with Center for Imaging Science (CIS) on the Homewood campus aimed at furthering its existing cutting-edge image analysis technologies and putting them to best use. CBIS also has close ties with Center for Imaging Science (CIS) on the Homewood campus aimed at furthering its existing cutting-edge image analysis technologies and putting them to best use.</p>
<p>Center for Clinical Trials and Evidence Synthesis jhsp.hopkins.edu/research/centers-and-institutes/johns-hopkins-center-for-clinical-trials-and-evidence-synthesis/</p>	<p>The Johns Hopkins Center for Clinical Trials and Evidence Synthesis was founded in 1990 as a collaborative effort of faculty from both the Bloomberg School of Public Health and the School of Medicine and is part of the Johns Hopkins Institute for Clinical and Translational Research (ICTR). The Center for Clinical Trials and Evidence Synthesis conducts three main types of research including clinical trials and other types of cohort studies to investigate the safety and effectiveness of interventions and to investigate variables that affect health; systematic reviews and meta-analyses to synthesize the findings of multiple studies and to inform clinical practice recommendations; and methodological research related to the conduct and reporting of clinical trials and evidence syntheses CCTES works closely with colleagues around the world and within the School, including the departments of Biostatistics, Epidemiology, Health Behavior and Society, Health Policy and Management, Environmental Health and Engineering, International Health and Mental Health; Johns Hopkins School of Medicine; Center for Excellence in Regulatory Science and Innovation (CERSI).</p>

<p>Center for Global Health hopkinsglobalhealth.org/</p>	<p>The Johns Hopkins Center for Global Health was founded in May of 2006 as a unique collaboration between all of the Johns Hopkins University schools that harnesses the expertise of its dedicated health and medical professionals to address a myriad of global health challenges: HIV/AIDS, malaria, tuberculosis, malnutrition, hepatitis and other threats to health, especially in developing countries. The Center mission is to facilitate and focus the extensive expertise and resources of the Johns Hopkins institutions together with global collaborators to effectively address and ameliorate the world's most pressing health issues.</p>
<p>Center for Imaging Science www.cis.jhu.edu</p>	<p>The overall goal of the Center for Imaging Science (CIS) is to participate in the worldwide establishment of the analytical models for image and pattern understanding analogous to the models generated in the Shannon era for communications and information transmission. Our guiding principle is that, while the 20th Century was focused on sensors for generating images, videos and multi-dimensional datasets, the fundamental challenge of the 21st Century is the information extraction for the generation of the metadata of understandings. We will achieve this goal by organizing an intradepartmental faculty focused on the fundamental challenge of the 21st Century: going from pixels and patterns to understandings. Researchers at the Center for Imaging Science (CIS) are developing systems that can interpret images of natural scenes, CT scans and other data obtained with bio-medical imaging devices, and aerial and satellite images acquired by remote sensing.</p>
<p>Center for Inherited Disease Research (CIDR) cidr.jhmi.edu</p>	<p>The Center for Inherited Disease Research's mission is to support the genetics community by providing high quality, cutting-edge genomic services and technologies in order to expand our understanding of disease and catalyze discoveries that translate to patient care. CIDR provides high quality next generation sequencing and genotyping services to investigators working to discover genes that contribute to common disease. CIDR provides high quality next generation sequencing and genotyping services to investigators working to discover genes that contribute to disease. On-site statistical geneticists provide valuable insight into analysis issues as they relate to study design, data production and quality control. In addition, CIDR has a consulting agreement with the University of Washington Genetics Coordinating Center (GCC) to provide statistical and analytical support, most predominantly in the areas of GWAS data cleaning and methods development. CIDR rapidly implements new technologies, offers new services and increases throughput while maintaining strict quality standards.</p>
<p>Center for Integrated Health Care www.jhsph.edu/research/centers-and-institutes/roger-c-lipitz-center-for-integrated-health-care</p>	<p>The Lipitz Center, located at the Johns Hopkins Bloomberg School of Public Health, is committed to improving the health and quality of life for people with complex health care needs by conducting research and disseminating new knowledge. The Center is also committed to preparing the next generation of leaders in this discipline. The Center strives to discover and disseminate practical, cost-effective approaches to providing comprehensive, coordinated, compassionate health care to chronically ill people and their families. The Center's multidisciplinary</p>

	activities span Johns Hopkins University's Schools of Medicine, Nursing, and Public Health.
Center for Mental Health Initiatives www.jhsph.edu/research/centers-and-institutes/center-for-mental-health-initiatives/	<p>The mission of the Center for Mental Health Initiatives is to improve the lives of persons with mental illness by fostering the collaboration of researchers and clinicians and by providing leadership in the implementation of public mental health initiatives. Center affiliates include researchers and clinicians from the Departments of Mental Health and International Health at the Johns Hopkins Bloomberg School of Public Health, Department of Psychiatry at the Johns Hopkins University School of Medicine and the Community Psychiatry Programs at the Johns Hopkins Hospital and the Johns Hopkins Bayview Medical Center. Center research focuses access to Wellness, monitoring recovery and pharmacogenetics, wellness and recovery. A fourth series of projects involving mental health in developing countries is underway. The plight of seriously mentally ill persons in urban settings is the foremost priority. Likewise the plight of those with mental disorders in low resource countries, especially countries with recent collective traumas such as wars or natural disasters, is a priority.</p>
Center for Metabolism and Obesity Research www.hopkinsmedicine.org/institute_basic_biomedical_sciences/research_centers/metabolism_obesity_research/	<p>CMOR is an interdepartmental and interdisciplinary center established to support the advancement of our understanding of the basic biological mechanisms that regulate metabolism, and how they are dysregulated in disorders such as obesity, diabetes, stroke, and cancer. CMOR also works to facilitate the translation of discoveries to applied knowledge for therapeutics in these fields. Centralized Services for Metabolism Research (CSMR) provides access to: (1) shared equipment for rodent metabolic testing; (2) controlled settings (temperature, humidity, light, air flow, low general human activity) required for accurate assessments of whole-body metabolism and animal behavior; (3) expertise of JHMI faculty who each have 15-30 years' experience in rodent behavioral and metabolic testing and data analysis. metabolic testing and data analysis.</p>
Center for Mind-Body Research www.jhsph.edu/research/centers-and-institutes/johns-hopkins-center-for-mind-body-research/	<p>The goal of the CMBR is to develop and nurture the intellectual community of mind-body researchers at Johns Hopkins University. The CMBR brings together 45 faculty members representing 15 disciplines and having primary faculty appointments in the Schools of Medicine, Nursing, and Public Health.</p>
Center of Cancer Nanotechnology Excellence ccne.inbt.jhu.edu/	<p>The Johns Hopkins Center of Cancer Nanotechnology Excellence brings together a multi-disciplinary team of scientists, engineers, and doctors to develop nano- technology-based diagnostic platforms and therapeutic strategies for comprehensive cancer care. Faculty members associated with The Johns Hopkins Institute for NanoBioTechnology (INBT) have received a \$13.6 million grant from the National Cancer Institute (NCI), to establish a Center of Cancer Nanotechnology Excellence (CCNE). The Johns Hopkins CCNE is one of several NCI-funded centers launched through a program that started in 2005.</p>

<p>Center on Aging and Health coah.jhu.edu/</p>	<p>The Johns Hopkins Center on Aging and Health (COAH) is dedicated to research that will prevent disease, disability and frailty, and improve the health and well-being of older adults. COAH aims to lead on an international level in advancements to optimize the health and quality of life of older populations, and to see our discoveries pay off as added years of healthy life for older adults. COAH is home to an interdisciplinary group of research faculty from all three schools, as well as the Claude D. Pepper Older Americans Independence Center (Pepper Center), Edward R. Roybal Center for Translational Research, and other key research programs. COAH also houses training programs in the Epidemiology and Biostatistics of Aging, and in Clinical and Population-based Research on Aging, as well as the Bloomberg School of Public Health's Certificate in Gerontology program. The Center is a focal point for interdisciplinary aging research and training at the Johns Hopkins Medical Institutions.</p>
<p>Center for Infection and Inflammation Imaging Research (Ci3R) hopkinsmedicine.org/ci3r</p>	<p>Non-invasive imaging has powerfully augmented the investigation of various disease processes in fields such as Oncology, Infectious Diseases and Inflammation. In conjunction with the Molecular Imaging Center, the Center for Infection and Inflammation Imaging Research core provides state-of-the art small animal imaging equipment, including PET, SPECT and CT, to support the wide range of scientific projects within the diverse research community of the Johns Hopkins University and beyond. The Center is located within the Cancer Research Building-II Animal Facilities and run by faculty members from the Departments of Pediatrics, Medicine and Radiology. The Center also collaborates with the Center for Imaging Science for the development of advanced imaging tools. Additional nuclear imaging instruments are also available at the Edward D. Miller Research Building.</p>
<p>Center for Proteomics Discovery http://www.centerforproteomicsdiscovery.jhmi.edu/</p>	<p>The Center for Proteomics Discovery at Johns Hopkins University School of Medicine is equipped with some of the most advanced mass spectrometers for proteomics analysis. The goal of this Center is to provide advanced mass spectrometry analysis to users, which includes identification, quantification and characterization of proteins and their post-translational modifications. In addition, the Center will be involved in educating and training researchers in proteomics techniques and analysis through workshops and seminars. The Center is equipped with the most advanced mass-spectrometry platforms to provide a wide range of analyses to researchers: •Mass Spectrometry and •Liquid Chromatography. The Center also provides proteomics services to JHU researchers, external investigators and industries including Profiling, Quantitation, and Post translational Modifications.</p>
<p>Centralized Services for Metabolism Research (CSMR)</p>	<p>Centralized Services for Metabolism Research (CSMR) provides access to: (1) shared equipment for rodent metabolic testing; (2) controlled settings (temperature, humidity, light, air flow, low general human activity) required for accurate assessments of whole-body metabolism and animal behavior; (3) expertise of JHMI faculty who each have 15-30 years' experience in rodent behavioral and metabolic testing and data analysis.</p>

Center for Translational Molecular Imaging (CTMI) <u>CTMI</u>	<p>Center for Translational Molecular Imaging (CTMI) at Johns Hopkins Bayview is the first Academic Research Organization (ARO) created to develop, and bring to patients, the best new imaging and therapeutic agents that make possible the vision of individualized medicine. Representing the collaboration of several departments, CTMI addresses unmet medical needs in areas including cancer, cardiovascular disease, as well as brain diseases in psychiatry and neurology (e.g. Alzheimer's, schizophrenia, autism). Nimble and focused on clinical uses, CTMI will rapidly usher many discoveries made by Johns Hopkins scientists, and their collaborators in industry and elsewhere, from lab to clinic</p>
<u>Computational Biology Consulting Core</u>	<p>The Computational Biology Consulting Core (CBCC), within the JH Institute for Genetic Medicine, offers state-of-the-art computational biology services to biomedical researchers at the Johns Hopkins University. We offer comprehensive analyses of sequencing data for a variety of genomics and sequencing-based experiments. We can handle most types of data, including Illumina, PacBio, 454, and Sanger reads, and we have experience with a variety of sequencing protocols (RNA-seq, ChIP-seq, whole-genome and whole-exome sequencing, etc). Available analyses include transcriptomics (RNA-seq), metagenomics, ChIP-seq analysis, genome assembly, sequence alignment, and SNP and structural variant detection.</p>
Wilmer Imaging and Microscopy <u>hopkinsmedicine.org/wilmer/micf</u>	<p>The Microscopy and Imaging Core Facility (MICF) is located on the mezzanine level of the Robert H. and Clarice Smith Building at the Wilmer Institute, and in 1,100 square feet of dedicated laboratory space. The facility provides state of the art light and electron microscopic instruments and consultation to researchers at the Wilmer Eye Institute. The MICF staff members are committed to provide equipment support and consultation for experimental designs involved in cell imaging, instrument selection, instrument training, sample preparation, and image analysis to its users.</p>
Deep Sequencing & Microarray Core <u>microarray.jhmi.edu</u>	<p>The DSMC provides cost-effective and time-efficient access to cutting-edge genomic technologies and expert assistance with experimental design and data analysis, as well as statistical and bioinformatic data analysis on primary data and downstream functional analyses. Current available services include NextGen Sequencing, Third Gen Sequencing, microarray, Nanostring nCounter, and DNA/Chromatin and RNA shearing,</p>
Engineering in Oncology Center <u>psoc.inbt.jhu.edu/</u>	<p>The Johns Hopkins Physical Sciences Oncology Center (PS-OC) takes a trans-disciplinary, integrated approach, bringing together experts in physics, biomedical engineering, cancer biology, ecology, and clinical medicine, to transform our understanding of metastatic cancer, created new standards of care and improve patient outcomes. The results of the experiments described here will help solve the puzzle behind the molecular and physical mechanisms underlying the initial steps of the spread of cancer, that is metastasis, invasion and migration, and help</p>

	<p>develop predictive models for these mechanism, all leading to new therapeutic targets.</p> <p>Our work follows the journey of cancer cells, traveling both alone and collectively as a group, from the confined, low-oxygen (hypoxic) spaces inside a tumor to the invasion of distant organs. We are discovering the mechanisms of these early critical steps in cancer cell invasion and migration and identifying key targets in what is known as the “metastatic cascade”. Additionally, computational biophysicists are using mathematics to systematically develop a quantitative understanding of the physical cues involved in the metastatic cascade. Finally, we are tackling this problem with a multidisciplinary team. The Johns Hopkins PS-OC projects share innovative biophysical methods and experts, both from Johns Hopkins University and from our Collaborating Institutions..</p>
ES Cell Targeting hopkinsmedicine.org/core/ES_Targeting	<p>The ES Core Facility (ECF) was founded by the NINDS Core Center Grant. The mission of ECF is to effectively produce Embryonic Stem cell lines with a high probability of germline transmission.</p>
Environment, Energy, Sustainability and Health Institute e2shi.jhu.edu/	<p>The Institute's goals are to establish Johns Hopkins University as a world leader in, and provide a single point of contact for, integrative approaches to global environmental change, sustainability, and their related health challenges, to promote the development of interdisciplinary research collaborations and proposals, to stimulate enhancement and coordination of environmental curricula at the undergraduate and graduate levels, facilitate translation of research into sound policy, and to develop collaborative partnerships with the business sector, federal, state, and local agencies, environmental groups, and Baltimore community organizations. Support available includes seed grants, fellowships, and research in the areas of climate modeling, climate and health, climate policy and decision-making, development of technology and energy materials, health impacts of energy, and behavioral intervention and decision making tools.</p>
Eukaryotic Tissue Culture Facility http://biophysics.med.jhmi.edu/eukaryotic-tissue-culture-facility	<p>Within the JH Department of Biophysics and Biophysical Chemistry, the Eukaryotic Tissue Culture facility supports JHMI researchers with the culturing of insect and mammalian cells. The facility operates with two service models: (1) a ‘assisted’ model, where facility staff carry out cell culture and expression for users, and (2) an ‘independent’ model, in which JHMI researchers use facility instrumentation. The facility is designed to provide JHMI researchers with space and equipment for eukaryotic expression and for training laboratory personnel, thereby avoiding a need for individual labs to set up their facilities for eukaryotic cell growth and protein expression. The facility provides eukaryotic protein expression in BSL-2 tissue culture laboratory, and laboratory equipment for insect cell and mammalian cell culture, including tissue culture hoods, refrigerators, chilled centrifuges, incubators, liquid nitrogen storage, microscope, cell counter, Centrimate tangential flow system.</p>
Evidence Based Practice Center	<p>The Johns Hopkins Evidence-based Practice Center (JHU EPC) was established in 1997 as a charter member of the 14 EPCs currently</p>

www.jhsph.edu/research/centers-and-institutes/johns-hopkins-evidence-based-practice-center/	<p>supported by the Effective Healthcare Program (EHC) of the Agency for Healthcare Research and Quality (AHRQ) of the U.S. Department of Health and Human Services (HHS). The EPC draws on a wide variety of clinical and methodologic experts from the more than 100 departments, institutes, and centers of the School of Medicine and the more than 60 in the School of Public Health. Given the comprehensive expertise of the Johns Hopkins Medical Institutions in research, clinical practice, and education, the EPC is able to bring together collaborative interdisciplinary teams with in-depth clinical and methodologic expertise to tackle challenging issues in all areas of clinical medicine, public health, and healthcare policy. The EPC produces comprehensive systematic reviews of important medical topics using interdisciplinary teams that integrate clinical expertise with expertise in evidence-based methods, including meta-analysis, decision analysis, benefit-harms analysis, and cost-effectiveness analysis. The EPC also collaborates with other EPCs and AHRQ programs to advance the methodology of systematic reviews, their transparency, and their use in dissemination and translation of findings.</p>
<p>Flow Cytometry at Johns Hopkins hopkinsmedicine.org/flowcytometry/downtown</p>	<p>The Ross Flow Cytometry Core Facility is managed by Division of Hematology, Department of Medicine. The core offers state-of-the-art flow cytometry cell analysis and high-speed sorting to the research community at Hopkins and is currently equipped with Becton Dickinson FACSAria IIu Cell Sorter with three lasers (488 nm, 633 nm and 405 nm) (9 Colors) capable of 4 way sorting. The core is also equipped with analytical instruments: LSR II with four lasers (488 nm blue laser, 633 nm red laser, 405 nm violet laser, and 355 nm ultraviolet laser); FACSCalibur with two lasers (488 nm, 633 nm and 405 nm).</p>
<p>Flow Cytometry at Bayview hopkinsmedicine.org/flowcytometry/bayview</p>	<p>The flow cytometry service center within the Bayview Immunomics Core (BIC) brings the highest standard of flow cytometry experience to the modern biomedical sciences. The core is uniquely embedded among research groups interested in problems related to immune based human diseases and relevant animal models and promotes an interactive and collaborative approach. This core has an extensive research base and considerable expertise in flow based approaches to address neuroscience related research. The flow cytometry instrumentation has the capability of performing simple and complex multiparametric (up to 14 fluorochromes) analysis of cell subpopulations and high speed sorting. The core maintains a special order FACSAria cell sorter (BD Biosciences) with 14-fluorescence parameter capability, a six color FACSCanto (BD Biosciences), and several analysis workstations for off-line data analysis. The FACSAria and FACSCanto are maintained using the highest standards of quality control and are available for analysis to certified and trained users. Cell sorting is performed by flow core staff only with free consultation services for investigators.</p>
<p>Fogarty AIDS International Training and Research Program</p>	<p>The Johns Hopkins University Fogarty AIDS International Training and Research Program (Hopkins AITRP) is a campus-wide program involving faculty and trainees in departments in both the Bloomberg School of Public Health and the School of Medicine. Primary BSPH departments</p>

www.jhsph.edu/research/centers-and-institutes/johns-hopkins-fogarty-AIDS-international-training-and-research-program/	<p>participating in the program are: Biostatistics, Epidemiology, International Health and Populations & Family Health Sciences. Primary SOM departments are Clinical Investigation, Medicine, Pathology, Pediatrics and OB/GYN in the School of Medicine. Campus and School-wide centers such as the Center for Global Health, Center for Immunization Research, Center for Clinical Trials, Center for TB Research, Center for Communications Programs and the Bioethics Institute serve as resources for faculty and training programs.</p>
<p>Genetic Resources Core Facility (GRCF) grcf.med.jhu.edu/</p>	<p>The Genetic Resources Core Facility (GRCF) is a Johns Hopkins University service center with six divisions. Collectively, these divisions produce a number of products and services to aid researchers performing studies in molecular biology and genetics. These include: bioprocessing, biorepository, bioshipping, cell line testing, DNA handling, digital PCR, genotyping, methylation, RNA services, sequencing, and single cell genomics.</p>
<p>George W. Comstock Center for Public Health Research and Prevention www.jhsph.edu/research/centers-and-institutes/george-w-comstock-center-for-public-health-research-and-prevention/</p>	<p>Established in 1962 in Hagerstown, Maryland, George W. Comstock Center for Public Health Research and Prevention conducts research on the prevention of disease, particularly heart disease, cancer and stroke; provides a base of operations for faculty and students who are interested in community-based research; serves as a resource for the Washington County (Maryland) Health Department in the areas of public health surveillance and assessment. The Comstock Center is expanding its activities and is engaging a wider community of scientists, students and prevention experts across multiple departments inside and outside the Johns Hopkins Bloomberg School of Public Health.</p>
<p>GRCF Biorepository and Cell Center cellcenter.grcf.jhmi.edu</p>	<p>The mission of the Cell Center is to facilitate basic scientific research by providing expertise and service in all aspects of mammalian cell culture. We evaluate new products, technology, and services to enhance existing products and services. Continued success has enabled the lab to open its doors to the Hopkins community at large and to expand its services to include cryogenic storage in an on-site biorepository, bioprocessing such as mammalian cell culture and blood processing and domestic / international bioshipping.</p>
<p>GRCF DNA Services grcf.med.jhu.edu/</p>	<p>The GRCF seeks to provide access to all levels of DNA Sequencing. With over 20 years of experience, the facility can help investigators design projects utilizing the appropriate technology including high throughput sequencing on three Illumina HiSeq 2500's, medium throughput sequencing on 2 Illumina MiSeqs, "traditional" sequencing using either the Sanger Sequencing chemistry (on AB 3730's) or Pyrosequencing, using a Qiagen Q24 system, whole exome and Custom Capture Sequencing using Agilent SureSelect or Illumina's TruSeq Custom Amplicon, and whole genome sequencing via Illumina Genome Network (or in-house)</p>
<p>GRCF Cell Line Authentication grcf.med.jhu.edu/</p>	<p>The Fragment Analysis Facility (FAF) was established to facilitate scientific research by providing technical assistance with genotyping and nucleic acid purification.</p>

GRCF Genotyping Services SNP Center grcf.med.jhu.edu/	<p>The Genetics Resources Core Facility offers several different methods of genotyping including high throughput genotyping on the Illumina platform, medium throughput genotyping on the Life Technologies Open Array platform with TaqMan® assays, and lower throughput genotyping via individual TaqMan®, Qiagen Pyrosequencing assays or STR/VNTR analysis. Most platforms offer specialized content for humans and mice, but we can work with you to genotype other organisms as well. The GRCF also offers STR profiling for Cell Line Authentication.serving JHU and the scientific community at large.</p>
Center for Health Services and Outcomes Research (CHSOR) www.jhsph.edu/research/centers-and-institutes/health-services-outcomes-research/	<p>The Center for Health Services and Outcomes Research (CHSOR), formerly the Health Services Research and Development Center, was established in 1969 and serves as the nexus at Johns Hopkins for research and training in patient centered outcomes and health services research. Our faculty and students focus on generating, synthesizing, and implementing evidence about health care delivery to inform decisions and direct evidence-based policy. CHSOR maintains an array of patient-reported outcome (PRO) tools and instruments developed by CHSOR members and their collaborators. Databases are also available via CHSOR and its collaborators for health services and outcomes research including the National Health and Aging Trends Study (NHATS), Marketscan Commercial Claims and Encounters Database, Medicare Current Beneficiary Survey (MCBS), Premier Research Services Database, and Annual Hospital Survey databases.</p>
High Throughput Center	<p>The High Throughput Biology Center, or HiT Center, of the Institute for Basic Biomedical Sciences is an interdisciplinary and interdepartmental effort. The three independent research labs that make up the HiT Center push the frontiers of research technologies and apply those techniques to fundamental questions of biology. The faculty members in the HiT Center combine approaches from a variety of disciplines including biology, physics, chemistry, mathematics, computer science and engineering, with the goal of selectively using high-throughput techniques to accelerate hypothesis-driven research and to speed development of new hypotheses. In addition to its active research programs, the HiT Center's core components offer resources to study interactions of chemical compounds, gene products, cells and organisms and the networks formed by these interactions. The Deep Sequencing & Microarray Core offers state-of-the art sequencing and array hybridization and analysis services. ChemCore is a compound screening and robotics service with access to compound libraries, and skill in assay development. The HiT Center also delivers gene-specific reagents to Hopkins researchers through Genomics Resources, which provides automated picking of bacteria-containing plasmids, lentiviral-ready shRNA clones, and yeast deletion (YKO) strains</p>
Histology Core	<p>The Bayview Histology Core provides frozen and paraffin embedding and sectioning for basic research investigators at the Johns Hopkins Bayview Campus, including basic brightfield staining (i.e., H&E).</p>

<p>Institute for Computational Medicine https://icm.jhu.edu/about/</p>	<p>Today, biological research is entering a new and exciting phase, one in which computational methodologies and modeling will play a critical role in revealing the causes and treatment of human disease. At the forefront of this frontier is the Institute of Computational Medicine (ICM). The Institute is an extraordinary initiative that builds on groundbreaking research at both The Johns Hopkins University Whiting School of Engineering and the School of Medicine. ICM's mission is to develop quantitative computer models of human disease, personalize these models using data from individual patients, and apply them to improve disease diagnosis and treatment.</p> <p>ICM research includes cardiovascular disease, cancer, HIV/AIDS and other immune system disorders, neurological disorders, infectious disease, neuro-developmental disorders and neuro-psychiatric disease. The multi-disciplinary nature of research in ICM means that core faculty come from many departments of the Schools of Medicine and Engineering. In the Whiting School of Engineering these are the Departments of Applied Mathematics and Statistics, Biomedical Engineering, Computer Science, and Mechanical Engineering. In the School of Medicine, these are the Departments of Biomedical Engineering, Emergency Medicine, and Neurosurgery.</p> <p>Research areas include computational anatomy, computational molecular medicine, computational physiological medicine and computational healthcare.</p>
<p>IGM Computing Core</p>	<p>The Institute for Genetic Medicine provides primary data storage in quarter-terabyte increments. The core hardware implementation is modular and grows with demand, with approximately 70 terabytes of usable storage currently deployed. Storage can be accessed over the network in various ways from Mac and Windows desktop systems via Windows Filesharing (samba) from the computational grid via NFS (Network Filesystem) from hosted servers via iSCSI or NFS. All primary data storage is backed up nightly to our Tivoli Storage Manager backup service. One backup copy is kept onsite for on-demand restores; a second encrypted backup copy is stored offsite for disaster recovery. The Core enterprise-class backup/archive solution is based on IBM's Tivoli Storage Manager (TSM) software and supports a wide range of client operating systems including MacOS, Windows and Linux.</p>
<p>JHBSPH Malaria Mosquito & Parasite Core</p>	<p>The Malaria Mosquito and Parasite Core (MMPC) is a Johns Hopkins Malaria Research Institute (JHMRI) service center which was created by combining the Insectary and Parasite Cores to streamline services and provide a better experience for researchers. MMPC provides mosquitoes, mosquitoes infected with malaria parasites, blood, various stages of malaria parasites, training, consultation and other services in the field of malaria research</p>
<p>JHBSPH Biological Repository (JHBR)</p>	<p>The Johns Hopkins Biological Repository (JHBR) Service Center is able to provide Johns Hopkins University investigators with a variety of laboratory and repository services for conducting large or small scale epigenetic, natural history, clinical trial, prospective and case-control studies. The JHBR Service Center provides, on a fee-for-service basis, a</p>

	<p>wide range of services including, but not limited to, phlebotomy, blood and other body fluid collection, specimen fractionation and processing, testing, storage, as well as DNA and RNA isolation. Established in 1984, JHBR consists of 2,000 square feet of biosafety level 2 and 3 laboratories on the 6th floor of the Johns Hopkins Bloomberg School of Public Health (JHSPH), as well as 6,000 square feet in an offsite facility (3 miles from JHSPH) to house 60 liquid nitrogen vapor phase cryogenic units. These units recently replaced biological specimen storage in -80 degree C and -150 degree C mechanical freezers as part of JHSPH's "Greening the Lab" initiative. JHBR is certified by the Clinical Laboratory Improvement Amendment (CLIA) to perform HIV-1 viral load RT-PCR, HCV and HBV serological tests, and maintains participation in proficiency programs through College of American Pathology (CAP), American Association of Bioanalysts (AAB), and Virology Quality Assurance Program (VQA) for all expert testing services. Currently, a fully automated platform for DNA and RNA isolation and quantification system is now in place to support the growing number of epigenetic studies</p>
<p><u>Johns Hopkins University ChemCORE</u></p>	<p>The JHU ChemCORE facility is an integrated robotics and chemical repository unit, started from 2004. ChemCORE enables the access to large chemical libraries, genomic resources, expertise of assay development and implementation, and state-of-art robotic capability. Currently, ChemCORE provides comprehensive compound screen services and technology development, with the capacity to routinely carry out 300,000 compounds screening for various targets. Facility can also assist with transfer of assay to other NIH screening facility and coordinate the activity with their expertise.</p>
<p>Johns Hopkins Systems Institute <u>systems.jhu.edu/</u></p>	<p>In April of 2011, a major new research initiative, the Johns Hopkins Systems Institute, was launched at Johns Hopkins University (JHU). This interdisciplinary research facility, based in JHU's Whiting School of Engineering, includes faculty from across the university. In 2016, the Systems Institute was renamed to the Center for Systems Science and Engineering.</p> <p>The Center for Systems Science and Engineering takes a multidisciplinary approach to modeling, understanding, and optimizing systems of national importance, including medicine, health care delivery, national infrastructure, information security, disaster response, and education. In addition to engineering faculty, the institute utilizes the expertise of researchers from the schools of Medicine, Public Health, Nursing, Arts and Sciences, Business, and Education; and from JHU's Applied Physics Laboratory, already one of the nation's leading centers of systems engineering.</p> <p>The primary role of the Institute is to serve as the focal point of inter-campus collaborations on systems research. The Center's Systems Research Group brings together faculty from Engineering, Public Health, and Medicine with a common interest in using systems methods to advance our understanding of complex problems. CSSE is also developing new graduate courses and programs in systems research, and serves as a source of systems faculty and researchers who are</p>

	interested in applying existing systems technology and methods to practical problem solving
<u>Lowe Family Genomic Center</u>	The Lowe Family contributions created the Genomics Center at Johns Hopkins Bayview where researchers are working to identify the genes that contribute to flares and remissions of vasculitis, rheumatoid arthritis, systemic lupus and other chronic inflammatory diseases, including acute and chronic lung diseases and allergic disease.
Microscope Facility <u>https://microscopy.jhmi.edu/Services/services.html</u>	Since 1989, the Johns Hopkins University <u>School of Medicine</u> Microscope Facility has provided light, fluorescence and electron microscopy services to over 200 users throughout <u>Johns Hopkins University</u> and the local area. We are one of the <i>largest and most popular</i> facilities in Baltimore providing microscopy and imaging services. Our imaging resources have facilitated numerous publications and grant proposals for our users throughout the local research community. Our mission is to facilitate clinical and basic science research.
Microscopy/ Confocal Imaging Core <u>hopkinspcc.org/microscopy/</u>	The Microscopy Core at the Johns Hopkins Bayview offers confocal laser scanning microscopy services to the Hopkins community and beyond. Located in the Johns Hopkins Asthma & Allergy Center, the Microscopy Core is available to help researchers develop technical solutions for special research needs.
Mouse Forward Genetics Center <u>brainscienceinstitute.org</u>	The study of genetic mutations has driven many major discoveries in neuroscience, but the capacity to assess the effect of mutations in an unbiased way – across the entire genome – has largely been restricted to studies in worms and other invertebrates. This Center uses innovative techniques to insert tagged gene modifiers, so that large numbers of “tagged” mutations will be present in each mouse pup, greatly facilitating the assessment of the consequences of these mutations in nervous system development and function. The mouse lines developed in this Center will be available to all Johns Hopkins neuroscientists.
<u>MRI Research Service Center</u>	Our mission is to explore and investigate all the various aspects of magnetic resonance research in medicine. We also serve as a research resource for members of the Department of Radiology, the Johns Hopkins Hospital and the community at large. We invite and encourage research innovation, as well as collaboration at the local, national and international level, and work to provide state-of-the-art technology to researchers and clinicians. The Division of MR Research serves as an interdisciplinary resource for NIH-funded investigators, clinicians, and scientists from this institution and many others in Maryland and throughout the country. The Division of MR Research has available brain/heart chemistry with MR, Breast MRI, Cancer MR, Cardiac MRI, Interventional MRI, MRI Service Center, NMR/Histology Service Center, Quantitative functional MRI (fMRI), <u>Small Animal Imaging Resource Program</u> , and Spectroscopy facilities as well as the Radiological Imaging Graduate program.
PhenoCore (Animal Phenotyping)	The Phenotyping Core aims to promote functional genomics and other preclinical translational science at Johns Hopkins, by assisting and

hopkinsmedicine.org/mcp/pheno/core	collaborating in the characterization and use of genetically and phenotypically relevant animal models of disease and gene function.
Johns Hopkins Deep Sequencing & Microarray Core Facility http://www.microarray.jhmi.edu/	Provides cost-effective and time-efficient access to cutting-edge genomic technologies and expert assistance with experimental design and data analysis for the following services: NextGen Sequencing, Third Gen Sequencing, Microarray, Nanostring, DNA, Chromatin, and RNA shearing, Data analysis using software packages which include Partek® , Spotfire® , and Ingenuity® Pathway Analysis .
Proteomics Core, Mass Spectrometry Core hopkinsmedicine.org/msf	The mission of the Hopkins A.B. Mass Spectrometry /Proteomic Facility is to accelerate discovery by giving Hopkins investigators access to cutting edge technologies in mass spectrometry and proteomics.
Research Animal Resources	Research Animal Resources (RAR) is Johns Hopkins' centralized provider of veterinary medical care and research animal support. Visit these pages for information regarding all aspects of animal care and veterinary assistance for your animal research. RAR faculty provide clinical genotyping, surgical support, rodent anesthesia equipment and technical services, phlebotomy and research use drug services, as well as diagnostic testing, quarantine, and rodent health surveillance.
Response Evaluation Criteria In Solid Tumors (RECIST) and Special Imaging Reads/Non-RECIST Response Evaluations	Since 2006, Johns Hopkins Department of Radiology has offered special research radiologic reads, including reads according to various RECIST guidelines, as outlined in research cancer trial protocols. The resource currently has a staff of six radiologists, licensed in CT – Body/Neuro and MRI radiologic reads, who perform these reads. This service, largely, but not exclusively, extends to varying RECIST guidelines, to include - RECIST 1.0, RECIST 1.1, modified immune response, immune response, lymphoma specific reads, as well as Lugano/Rano criteria, as required by oncologic research study protocols.
The Rheumatic Disease Research Core Center (RDRCC)	This core is a novel resource that provides essential infrastructure to collect unique and valuable sets of samples (e.g. serum, DNA, RNA) from well pedigreed patient cohorts. Additionally, this Core offers a range of assays designed to detect autoantibodies and other analytes in patient sera, and to immunostain tissue sections to visualize specific proteins. The RDRCC mission is to facilitate innovative studies on Rheumatic diseases. The Center is committed to ensuring high quality sample collection, processing and immunoassays with a rapid turnaround time.
Sidney Kimmel Comprehensive Cancer Center (SKCCC) Laboratory hopkinsmedicine.org/kimmel_cancer_center/research_clinical_trials/research	Our Cancer Center has led the world in deciphering the mechanisms of cancer and new ways to treat it. The strength of our research and treatment programs was recognized early on by the National Cancer Institute, becoming one of the first to earn comprehensive cancer center status and recognition as a "Center of Excellence." One of only 69 40 cancer centers in the country designated by the National Cancer Institute (NCI) as a Comprehensive Cancer Center, the Johns Hopkins Kimmel Cancer Center has active programs in clinical research, laboratory research, education, community outreach, and prevention and control.

SKCCC Bioinformatics Shared Resource (BISR) cancerbiostats.onc.jhmi.edu	<p>Efficient utilization of the data generated by the experiments is of strategic scientific importance and requires bioinformatics support. The bioinformatics shared resource guarantees the availability of comprehensive bioinformatics expertise to Cancer Center members. This resource comprises faculty and support staff able to support data acquisition (including study design, feasibility of objectives, availability of public-access genomic information, data storage, and data annotation), statistical quality control (including artifact detection, preprocessing, and normalization of data from genomic technologies), data analysis (including visualization, modeling, inference and interpretation), and development of innovative customized bioinformatics tools, and education.</p>
SKCCC Cancer Cytogenetics Core hopkinsmedicine.org/kimmel_cancer_center/research_clinical_trials/research	<p>Cancer cytogenetics expertise is needed to provide critical data for research projects in many Programs of the SKCCC. The Cancer Cytogenetics Shared Resource has been providing such expertise to SKCCC researchers since 1986. Services offered include Metaphase cytogenetics (G-band metaphase analysis/karyotyping, Aneuploidy assessment, Breakage/aberration analysis ,Species confirmation) and Fluorescence in situ hybridization (FISH)</p>
SKCCC Cell Imaging Core Facility cellimaging.onc.jhmi.edu	<p>Its mission has been to provide state-of-the-art cell imaging technologies to SKCCC members. Services include light and fluorescence microscopy, stereo and confocal microscopy, infrared imaging, time lapse, and laser microdissection. Images can be acquired using a variety of video and CCD cameras, and then analyzed and manipulated with cutting edge image analysis software programs</p>
SKCCC Experimental Irradiator Core hopkinsmedicine.org/kimmel_cancer_center/research_clinical_trials/research	<p>The Experimental Irradiator Core, which has been in existence since 1986, maintains and operates sources of ionizing radiation for use by SKCCC members in their experimental studies. The primary resources of the Core are:four Cs-137 irradiators,a parallel opposed dual x-ray source system (CIDX) , an image guided orthovoltage small animal radiation research platform (SARRP). equipped with on-board cone-beam CT, a GammaCell 40 irradiator ,a Mark I irradiator and a GammaCell 1000 irradiator ,</p>
SKCCC Flow Cytometry Core hopkinsmedicine.org/kimmel_cancer_center/research_clinical_trials/research	<p>Overall, this Core provides essential services for SKCCC investigators ranging from basic two color analyses to complex cell sorting experiments, involving up to 13 colors, training, data analysis and consultation services. Immune assays include multiplex cytokine analysis and ELISPOT/ FLUOROSPOT. The Core's instrumentation includes — a BD Influx cell sorter and LSR/Fortessa cell analyzer and an iSPOT Spectrum (AID) ELISPOT/ FLUOROSPOT reader.</p>
SKCCC Microarray Core microarray.onc.jhmi.edu	<p>The Microarray Core has provided services to Cancer Center members and to the Hopkins Medical Campus and operates in conjunction with support from the Department of Medicine. Operates with array platforms from Illumina and Agilent Technologies, and is equipped with Illumina is can and Agilent upgraded scanner for high-density array image acquisition. Array services include genome-wide gene and microRNA expression, DNA methylation, copy number variation (CNV), single nucleotide polymorphism (SNP) and ChIP-on-chip analysis. Different</p>

	sample types are accommodated such as clinical specimen, sorted cells or paraffin-embedded tissue blocks.
SKCCC Next Generation Sequencing Phone nextgenseq.onc.jhmi.edu/	To maintain and build on the Sidney Kimmel Comprehensive Cancer Center's (SKCCC) record of excellence in the fields of cancer genetics and epigenetics, the SKCCC has established a new Next Generation Sequencing Center (NGSC) as a shared resource since January 2009. Services include : Human exome sequencing, ChIP-sequencing, RNA-seq, DNA methylation analysis, Eukaryotic and microbial whole genome sequencing, microRNA sequencing as well as purely computational requests
SKCCC Oncology Tissue Services Tissue Microarray (TMA) Lab Core tmalab.jhmi.edu	Formerly the Tissue Microarray Core at Johns Hopkins, this service was initially funded by the Prostate SPORE but has grown into a user-supported University Service Center/Shared Resource. Since 2005. Services offered include : Tissue Microarray (TMA) design and construction , Whole slide scanning ,TMA scanning , Cytogenetics ,Customized immunohistochemistry and nucleic acid detection services and Free image analysis tools
Welch Center for Prevention, Epidemiology, and Clinical Research	Founded in 1989, the Welch Center for Prevention, Epidemiology, and Clinical Research is an impressive academic unit that is affiliated with Johns Hopkins School of Medicine and the Bloomberg School of Public Health. Through its educational programs and its research, the Welch Center promotes the application of rigorous methods to conduct clinical, epidemiologic, and translational research of the highest quality. Our faculty includes physicians with a keen interest in public health and epidemiologists with a deep appreciation of clinical factors that influence health outcomes.
WSE Hopkins Extreme Materials Institute (HEMI) https://hemi.jhu.edu/	The Hopkins Extreme Materials Institute was formed in 2013 with the mission to provide global intellectual readership to advance the fundamental science associated with materials and structures under extreme conditions and demonstrating extreme performance. With the completion of Malone Hall in 2014, HEMI started building characterization facilities to push materials research. These facilities contain equipment to study and test the micro structures of materials and the behavior of those materials under different conditions. HEMI facilities are open for use to HIME and JHU affiliates and collaborators at set rates. Training is available and required on the equipment for users.
WSE The Materials Characterization and Processing Core (MCP)	The Materials Characterization and Processing (MCP) core provides analytical instrumentation, preparation equipment, and processing capabilities for the development and characterization of new materials. The MCP serves the entire JHU community mainly focusing on inorganic characterization and processing. Included in the facility are: Scanning Electron Microscopy, Nanoindenters, Xray Photospectroscopy, Auger Spectroscopy, X-ray Diffractometry, and various sample preparation equipment. The center is scheduled to be consolidated into a new 2500 sq. ft. center in Maryland Hall rm 30 near the end of 2016.
Zebra Fish Core Center (FINZCenter)	Housed within the Institute for Genetic Medicine, the Institute of Genetic Medicine Center for Functional INvestigation in Zebrafish (FINZCenter)

provides specialized services including, microinjection of zebrafish embryos, and establishment of transgenic lines, morpholino-based gene knockdown strategies, whole mount in situ hybridizations, and in vitro fertilization. Other services comprise adult fish and embryo sales, and transgenic line screenings. Training courses are also available at times to be advertised during the year.

INFORMATICS

The Maryland Research Computing Center (MARCC) is a shared computing facility located on the Bayview Campus of Johns Hopkins University and funded by a State of Maryland grant to Johns Hopkins University through IDIES. MARCC is jointly managed by Johns Hopkins University and the University of Maryland College Park. MARCC offices are located in the Bloomberg Building (Homewood campus) of Johns Hopkins University. The main cluster at MARCC has over 19,000 cores and a combined theoretical performance of over 900 TFLOPs. The compute nodes are a combination of Intel Haswell and Ivy Bridge processors and Nvidia K80 GPUS connected via FDR-14 Infiniband interconnects. It also features two types of storage: 2 PB Lustre (Terascala) and 15 PB ZFS/Linux. The standard compute nodes contain 2 Intel Xeon E5-2680v3 (Haswell) processors, with 12 cores and 128 GB DDR4, 2.5 GHz (Marked TDP frequency) or 2.1GHz AVX base frequency. Each node has a theoretical speed of 960 GFlop/s. The large memory nodes are Dell PowerEdge R920 servers with quad Intel “Ivy Bridge” Xeon E7-8857v2, (3.0GHz, 12 core, 30MB, 130W). Each ndoe has 1024 core, 2. GB RAM. The GPU nodes are Dell PowerEdge R730 servers with dual Intel Haswell Xeon E5-2680v3 (12 5 GHz, 120W), 128 GB of 2133 MHz DDR4 RAM. (AVX frequency: 2.1GHz) and two Nvidia K80s per node. The FDR-14 Infiniband topology is 2:1 with 56 gbps bandwidth. The lustre file system provides an aggregate bandwidth od 25 gbps (read) and 20 gbps (write). <https://www.marcc.jhu.edu/>

Johns Hopkins Epic Data Warehouse

The Johns Hopkins Epic Data Warehouse (EDW) is built on the Epic Caboodle data warehouse infrastructure using Microsoft SQL Server and contains data for 5M patients. The EDW is used to support the research, clinical, and educational needs of Johns Hopkins. In addition to data from the Epic Electronic Medical Record, we have extended the EDW to contain data beyond the medical records,

Note: Proposed Research infrastructure support shown for reference only. Not included as part of the proposed EDW infrastructure request.

JHM Clinical Enterprise Data Warehouse
Draft 1.1
September 5, 2012

including claims data and patient satisfaction data. EDW is the data source for the Epic SlicerDicer product, which provides self-service data access to 26,000 users across the enterprise and which can be used to generate counts for research study feasibility assessments. We are now building an enterprise suite of Tableau dashboards on top of the EDW and are prototyping a research data exploration tool in Tableau to facilitate IRB-approved data finding. The EDW is supported by one warehouse architect and two senior software engineers.

eIRB The eIRB system, launched in 2005, is a paperless, electronic method to submit, track, and review the scientific, regulatory, and compliance information required for the safe conduct of human subjects research at the School of Medicine, School of Nursing, and School of Arts and Sciences. The system provides a platform for the IRBs and other research compliance committees together with the JHM research community to share critical information regarding the submission and review of new applications, amendments, protocol events, and continuing reviews.

Based on web infrastructure from ClickCommerce (now Huron Consulting), eIRB currently serves over 14,000 users and manages over 10,000 active protocols (including exempt and non-human subjects research). Its customizable workflow enables Hopkins leadership to interact with principal investigators to ensure compliance with federal and local regulations as well as to provide assistance in study design and execution.

In 2011 and 2012, the system was upgraded with a new data architecture and an updated infrastructure, enabling faster throughput for users and greater capacity for the institution. eIRB functions as the “source of truth” for studies using CRMS, and there is a bidirectional link between the two systems.

Clinical Research Informatics Services

<http://ictr.johnshopkins.edu/clinical/clinical-resources/clinical-research-informatics-core/>

The Clinical Informatics Resource Core provides data management consulting services to develop data management plans and multiple client-server data systems to accommodate a variety of data collection, storage, and data management needs. MS SQL is used as a primary data storage repository. Additionally, database tools such as REDCap (www.project-redcap.org), MS Access, FileMaker Server, and Teleform (scantron) provide a wide and flexible selection of data collection/storage options for investigators and their protocols.

In addition to the services above, the Core provides a comprehensive array of data integration solutions. By providing integration with ITCR laboratory (e.g., DEXA, Endopat, Endothelix, Biodex, metabolic stress system) and enterprise testing systems (e.g. ProSoft and Xcelera for echocardiography) and other external research data systems such as the Core chemistry laboratory, the CRU is able to migrate data between systems electronically, eliminating the need for study staff to enter data manually. This automation increases data quality by reducing the opportunity for the introduction of errors via manual data entry. We can move large data sets in a rapid and secure manner. Data are made available for secure sharing among investigators by automating the transformation of outside vendor proprietary data formats into common data structures. Data for each investigator's protocol is exported to their study specific databases, which are also stored on our dedicated servers.

Division of Health Sciences Informatics The academic home in the School of Medicine for biomedical informatics researchers, the Division has a small number of primary faculty and about 30 faculty with secondary appointments. Housing an active teaching program, it hosts 3 masters programs---available to fellows for matriculation--- a post-baccalaureate Certificate program, and a PhD focused on clinical re-engineering through informatics. Courses available to ICTR trainees include: ME 600.903 Introduction to Biomedical and Public Health Informatics, ME 600.902 Leading Change Through Health IT, ME 600.900 Health Information Systems: Design to Deployment, ME 600.904 HIT Standards and Systems

Interoperability (material from this course has been placed in opencourseware), ME 600.901 Health Sciences Informatics: Knowledge Engineering and Decision Support, ME 600.905 Clinical Informatics, ME 600.809 Topics in Clinical Informatics, ME 600.711 Health Informatics for Disease Prevention and Management, ME 600.906 Real Time Disease Surveillance, and ME 600.907 Database Querying in Health. The last course, in particular, enables learners to take advantage of electronic health record data for research purposes. The Division also hosts a weekly Grand Rounds series, which is Web cast to an audience of about 400, that brings in experts and policy leaders from around the country, around the region, and from within the institution. Non-ICTR students, through their capstone and research projects, can assist ICTR faculty in their own research.

The Johns Hopkins Medicine Technology Innovation Center (TIC)

http://www.hopkinsmedicine.org/technology_innovation/

The TIC is composed of 30 technical technologists who specialize in the following areas: software development, systems development, design thinking, analytics, and data architecture. The JHM TIC is led by Paul Nagy, PhD, a world-renowned radiology informatics and patient safety and quality leader, and by Dwight Raum, the Chief Technology Officer of Johns Hopkins. The TIC is strategically placed within Johns Hopkins Medicine and Johns Hopkins Enterprise IT, pulling clinical researchers and enterprise IT personnel into projects and product development as required.

BIostatISTICS, EPIDEMIOLOGY and RESEARCH DESIGN (BERD)

The BERD core is administratively housed in the Department of Biostatistics, Bloomberg School of Public Health. By its nature its members are spread throughout the institution. Major other locations for the Core include the Center for Computational Biology (CCB), Center for Computational Genomics (CCG), Institute of Computational Medicine (ICM), Division of Biostatistics & Bioinformatics of the Department of Oncology, School of Medicine, Welch Center for Prevention, Epidemiology & Clinical Research, the Johns Hopkins Center on Aging and Health (COAH), and the Biostatistics, Epidemiology & Data Management (BEAD) Core sponsored by the Department of Pediatrics. All but two 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 ICM (Computational Medicine Program) spans the School of Medicine 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 off-site 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 August 2016 the HPC cluster has 80 nodes with a total of 3024 64-bit cores and about 21.3 TB DDR-SDRAM in production. The total mass storage is about 4PB Lustre storage cluster, 1PB of ZFS NAS storage for home directory and archive, and 1PB of ZFS NAS storage for disk to disk backup. 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 file sharing 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.

The **Computational Biology Consulting Core** (co-led by Dr. Florea) is affiliated with, and has access to the computing resources of the Center for Computational Biology led by Dr. Salzberg. These include over 230 TB of high-speed storage in Bloomberg 156 and the ability to expand considerably beyond this. For high-performance computing, our 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. For grid-based computing, CCB has a share in the HHPC2 cluster, a BeoWulf computing grid shared among multiple Hopkins faculty. The cluster includes over 2500 cores with 4GB per core connected via QDR Infiniband. General purpose file servers with hundreds of Terabytes are on the same Infiniband switches. The two infiniband switches are interconnected to the Data-Scope system, a 6 Petabyte storage and computing grid, through multiple 10Gb/s Ethernet links. The Deans of the JHU Schools provide funds to cover most of the management and operational costs of the HHPC.

Computers and data for the Center for Computational Biology (CCB) in the McKusick-Nathans Institute of Genetic Medicine 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. This network infrastructure includes a Cisco Nexus 7000 chassis that can accommodate 100GigE connections currently being built.

Within the **Institute of Computational Medicine** (ICM) the following equipment is maintained: One 250-node IBM iDataPlex compute cluster. The compute nodes each have 2 Intel Xeon E5472 (Seaborg chipset) 3.00GHz Quad Core processors, for a total of 8 processors per node. 16 nodes have 64 GBs of memory. The remaining compute nodes each have 32 GB memory. Each compute node communicates with the SAN via a 4X DDR InfiniBand switched fabric. GPFS, IBM's high-performance parallel file management solution, provides file system access. This system can be used as a computational server available to *Galaxy*, 1 Petabyte storage area network with fiber channel connection to the cluster, One

IBM 3584 Ultrascable Tape Library with 8 LTO4 drives compressed storage capacity 800 TBs. Tivoli Storage Manager 6.3 is used to manage backup, archive, and restore for all systems, Three Dell PowerEdge R900 servers. Each are configured with 4 Quad Core 2.4GHz processors and 128GB memory. Both run CentOS Linux. Each R900 has a 10 TB storage system. Two machines are used to run virtual machines for the CVRG Project. They will be used to host the PFINDR search user interface, and the web-interface for review of matched terms and corresponding ontology terms. The third will be dedicated for use in this project, and will be used to host an instance of Bioportal, 3 Dell PowerEdge R720 servers as virtualization hosts with 12 Intel Xeon E5-2620 2.00GHz processors each with 64GB RAM running VMware ESXi 5.1 Enterprise as the hypervisor. A 60TB (raw capacity) iSCSI SAN composed of a Dell MD3601 array and a Dell MD1200 disk array, which may be expanded to a total of 192 drives.

Our members in the Welch Center, BEAD, and Center on Aging and Health utilize the Computer Network Services and Security for the Johns Hopkins Department of Medicine. Department of Medicine Network Services (MNET) consists of an operations manager, five network analysts, one microcomputer support specialist and two Help Desk operators. MNET networking group offers full, PC support. Currently, this office supports more than 1,100 faculty and staff and spans three campuses. The office also maintains software licensing for several applications. MNET backs up departmental servers, five days a week. Tapes are stored in a secure location and catalogued twice monthly.

There are approximately 40 computer workstations (desktop and laptop) at the **Center on Aging and Health (COAH)**. COAH is networked to facilitate the integrations of like tasks across studies and to increase efficiency. The server is dedicated solely to Center studies to ensure that data integrity is maintained and that study timelines are not impacted by lack of available computing time. The system is capable of remote transmission and upgrades to writeable / rewritable DVD drives that permit the efficient and reliable archiving of data files. The center currently owns a database server with 5000M storage space and a web server with 140M storage space, both of which sit on the Department of Medicine's server (Pentium 450 server with 128GB DDR-SDRAM memory and 4TB disk storage) located offsite, remotely accessible through LAN with 10GB speed. Windows systems run Windows 7. 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, SAS, are available for all PCs for data bases and analyses. COAH has a networked Polycom video conferencing unit to facilitate high-quality audio/video communication with off-site collaborators.

COAH houses a secure room designed to hold highly restricted linked electronic data. The COAH cold room has a solid door, no exterior windows, a non-networked workstation, no Ethernet access and restricted key access thus offering maximum protection against violations of confidentiality. The 4TB computer can hold Medicare or Medicaid claims files, EHR data or claim files linked to national survey data. Data is backed up to external hard drives that are stored in a fire-proof cabinet within the cold room. The Center staff have considerable expertise in the acquisition, safe storage, management and analyses of these sensitive data.

BEAD unit members of the BERD additionally utilize two computing systems. The data server at the JHU Institute of Clinical and Translational Research Bayview Clinical Research Unit Informatics (ICTR-CRU) maintains an array of both physical and virtual servers and systems. The majority of the ICTR-CRU servers are virtual systems running on an integrated server/SAN systems on an iSCSI backbone. Two Dell servers running VMware vSphere virtualization host approximately 12 virtual development and production servers and desktops (SQL, FileMaker, Web, Teleform). The ICTR-CRU has standalone PCs as well as servers running the statistical software Stata (Version 13). The host servers run on an iSCSI backbone tied to a Dell PowerVault SAN storage array via redundant switches. The systems have multiple layers of redundancy to minimize the risk of down-time for users. In addition to the server/desktop hosting environment, the ICTR-CRU has several Netgear ReadyNAS storage arrays to

accommodate the large amount of data stored by the CRU. This includes both primary and backup storage environments. Backups of data are maintained at multiple locations to help mitigate the risk of data loss should there be an event at the primary location.

The GeneSTAR High Power Processing Cluster for large scale data analysis (512 cores) has 25 desktop computers, all with maximal SD-RAM and hard drive capacity, linked to an internal secure study network as well as the Johns Hopkins Intranet and the ICTR (Institute of Clinical Translational Research) CDMAS computer system. The CDMAS system at Hopkins provides the a 2nd duplicate secure space for data storage, back-up and remote data access, all via a secure system using a Microsoft NT Server. GeneSTAR operates an internal secure network based on a Linux system of our own design that interfaces using standard encryption with database processing centers in the School of Public Health, CDMAS, and other parts of Johns Hopkins, all secure. Available software owned by GeneSTAR includes: R, SAS, STATA, SUDDAN, Cyrillic, SAGE and SAS graphics, along with a wide array of genetic software.

All investigators in the BERD currently have office space in the location of their primary residence. The PhD faculty have stand-alone offices; master-degree personnel and staff have either an individual office, a two-person shared office, or cubicle work stations.

Office space for the Department of Biostatistics and Johns Hopkins Biostatistics Center is situated in the Johns Hopkins Bloomberg School of Public Health on the main campus of the Johns Hopkins Medical Institutions. The Department comprises the majority of the third floor of the East Wing of the School of Public Health and includes the main Department office with the Chair's suite, faculty, staff and student offices, conference rooms, public areas, and a library with meeting area and work stations. The Department houses a multidisciplinary faculty of 42 primarily-appointed faculty, core staff and research infrastructure. All offices are contiguous and provide workspaces with computer (Internet), telephone, fax access, copy machine (including scanning) and library resources.

Offices for other BERD members are located in the Division of General Internal Medicine at 1830 E. Monument Street, the Johns Hopkins Institute for Clinical and Translational Research, Bayview campus, the Welch Center for Prevention, Epidemiology and Clinical Research, and the Center on Aging and Health. The latter two groups are situated in the Department of Medicine building at 2024 E. Monument Street. Each location has access to a conference or common room for conducting biostatistical consultations.

Dr. Bandeen-Roche and data analysts who have supported the BERD have offices in the Johns Hopkins Center on Aging and Health (COAH) on the main campus of the Johns Hopkins Medical Institutions is jointly sponsored by the School of Medicine and the Bloomberg School of Public Health. It houses multidisciplinary faculty, core staff, and research infrastructure. In addition, trainees and fellows have office space within the Center; the Center on Aging and Health trains post-doctoral fellows in the School of Medicine and pre- and post-doctoral students in the Departments of Epidemiology, Biostatistics, and Mental Health. The Center offers formal course work and ongoing seminars and journal clubs, and has computer, copying, scanning, fax and library services. The faculty and office administrator have stand-alone offices; trainees have desks or work-stations configured in shared offices. All offices are contiguous and provide workspaces with computer (Internet), telephone, and fax access. The main suite of COAH, including all offices, cubicles, conference rooms and public areas, is approximately 5400 square feet.

Since 2014, the CCB has been headquartered in the Welch Medical Library, 1900 E. Monument St., Baltimore, MD 21205. Affiliated faculty and post-doctoral researchers have office space (~150 sq. ft on average) on the First Floor of the Welch Building, and students (both full-time and summer interns) have dedicated desks and desktop computers in a ~1100 sq. ft shared room, organized as cubicle space. For

its meetings, the group has dedicated access to the First Floor conference room, Welch 106, and shared access to the Second Floor conference room, Welch 204.

Dr. Winslow's laboratory is in the Institute for Computational Medicine (ICM) at the Johns Hopkins University Homewood Campus. Dr. Winslow is director of the ICM. The ICM was chartered in 2005 and is an Institute in both the Whiting School of Engineering (WSE) and the SOM. The ICM reports administratively to the Whiting School of Engineering. The ICM operates financially as do departments in the Whiting School of Engineering. The ICM received: a) an initial financial allocation of \$12M for start-up packages and operational costs; b) dedicated 11,000 net sq. ft of space in the CSEB building; and c) six new faculty slots. Five of these have been filled. This demonstrates that the JHU Whiting School of Engineering and School of Medicine are strongly committed to supporting the faculty of the ICM in their research activities.

The JHU Whiting School of Engineering has provided the ICM with ~ 12,000 net square feet of space in Hackerman Hall. Dr. Winslow's research and development team and administrative staff are located in this building. The development team has approximately 1,200 sq. feet of dedicated space with room for 6 software engineers. A dedicated conference room has video- and web-conferencing capabilities.

The ICM has two well-configured machine rooms. The first is located on the 2nd floor of Hackerman Hall. This machine room is designed for projects involving HIPAA-controlled, individual-level data access. The room is 1,000 net square feet, with space for 22 standard 42" x 24" racks in 3 aisles. A dedicated 300kVA transformer supplies power. Two 25-ton computer room air-conditioning units provide cooling, with facilities and space available for a third. This equipment is managed and monitored by Johns Hopkins University Plant Operations 24/7 and is configured to generate audible, visual, and cell phone alarms in cases of emergency (e.g., loss of chilled water or air conditioning failures leading to increased room temperature). These alarms are sent to the ICM Director of Networking Systems and Computing (Kyle Reynolds) and JHU Plant Operations. Hackerman Hall has a 10GbE backbone, providing 10GbE connectivity to the JHU Homewood campus core, which is one hop away. The machine room has a dedicated Cisco 4500 series switch, providing 10GbE connectivity to the equipment housed there. All networking equipment is managed and monitored by Johns Hopkins Enterprise Networking, which provides 24/7 management of support to all Johns Hopkins networks. Uninterruptible power supplies are installed in each rack as necessary. The University provides all power and machine room maintenance. This machine room has carefully controlled card key access. Systems Administrator Kyle Reynolds and Dr. Winslow have exclusive access to this facility. A camera is used to maintain a visual and time-stamped record of entry and egress to the room at all times. Entry and egress using key card is recorded by the Johns Hopkins University Office of Security Management.

The ICM has a second machine room is located directly across a quadrangle from Hackerman Hall, a distance of about 100 yards, on the 3rd floor of Clark Hall Room 315. The room is 1,000 net square feet, with space for 17 standard 42" x 24" racks in 3 aisles. A dedicated 100kVA transformer supplies power. A Liebert Series 600 UPS provides power conditioning and uninterruptable power. A 20-ton computer room air-conditioning unit provides cooling, with facilities and space available for a second. This equipment is also managed and monitored by JHU Plant Operations 24/7 and is configured to generate alarms as well as reporting back to JHU Plant Operations. Clark Hall's backbone is also 10GbE, and there is a dedicated Cisco 4500 series switches providing 10GbE connectivity to the JHU Homewood campus core, which is one hop away. Access to this room is also card key controlled, available only to the systems administrator.

Library Resources: The Biostatistics Department houses a library that is an important research resource for faculty and trainees. It is physically located in the Department. The library contains major journals,

some dating back as far as the 1920s. Also available are over 2700+ books covering a wide range of subjects.



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. The Department aims to promote effective statistical reasoning and applications in health research. It currently includes 42 full-time faculty, 51 part-time faculty, 38 doctoral candidates, 18 master degree students, 13 postdoctoral fellows and 16 staff. Sixty percent of the department's Ph.D. graduates over the last 5 years have gone on to tenure-track academic positions, including at the Universities of Minnesota, Pennsylvania, Michigan and Washington, and Columbia. 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,

longitudinal data analysis, latent variable modeling, spatial statistics, nonparametric smoothing methods for very large data streams, 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) provides biostatistical and information science expertise in support of health research to investigators at Johns Hopkins University and other academic health centers, government agencies and private organizations. The Center currently employs two full-time doctoral level statisticians, five full-time masters level statisticians, and three full-time data management professionals as well as part-time FTE at both the doctoral and master degree levels.



The JHBC was created in 1997 within the Department of Biostatistics at the Johns Hopkins Bloomberg School of Public Health (JHBSPH). The JHBC is the practice arm of the Department. The Center provides comprehensive biostatistics and data science expertise to improve the quality of biomedical research that advances health at the Johns Hopkins Medical Institutions and beyond. 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 JHMI. JHBC faculty research has recently appeared in top medical journals including *Lancet*, *JAMA*, *BMJ*, *Circulation*, *Pediatrics*, *Neurology*, and *Radiology*. The JHBC is also an integral component of the Biostatistics, Epidemiology and Research Design (BERD) Core of the Johns Hopkins Institute for Clinical and Translational Research (ICTR). In this capacity, the JHBC works towards the advancement of the appropriate use of biostatistics and data science in the design, implementation, data analysis and interpretation of analytical results of clinical and translational research conducted at JHMI. JHBC has been providing ICTR support since its inception in 2007.

JHBC is an active partner with researchers on biostatistics questions related to the effective collection, analysis and interpretation of health research information. It assists with: 1) research study design, including sample size calculations and power analysis, 2) statistical analysis approach, 3) statistical analysis and interpretation, and 4) manuscript preparation and scientific report-writing. The JHBC Biostatistics faculty and staff are experienced in a variety of applied statistical methodologies including longitudinal data analysis; multi-level and hierarchical modeling; analysis of survival and time-to-event data; power analysis, study design and sampling methods; and multivariable regression analysis under various outcome distributions. We are proficient in the use of several standard statistical software packages including SAS, R, STATA, and SPSS.

The DISC team is comprised 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 access and support to the REDCap (Research Electronic Data Capture) web application.

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. Currently, the Department of Biostatistics has primarily-appointed tenured and tenure-track faculty members internationally recognized in their fields of research who are available for consultation as needed. JHBC is also supported by a Center Administrator and Program Coordinator who handle the financial and administrative 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. 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.

Johns Hopkins Claude D. Pepper Older Americans Independence Center (OAIC; Jeremy Walston, MD, 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, population-based 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 six cores that work synergistically to accomplish the goals of the center; 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. 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. <http://coah.jhu.edu/oaic>.

Edward R. Roybal Center at Johns Hopkins University (David L. Roth, PhD, Director): The Roybal Center for translational research at Johns Hopkins University provides visionary leadership and critical infrastructure to stimulate, facilitate, and advance translational research on the informal support resources of vulnerable older adult populations. This includes research that focuses on supporting family caregivers and strengthening the roles that family members play in managing the health problems of older adults. A unifying theme of this center is its emphasis on novel methodological approaches that make innovative contributions to the knowledge base for applied interventions. http://coah.jhu.edu/roybal_center.

Center for Computational Biology. The Center for Computational Biology, a research center in the McKusick-Nathans Institute of Genetic Medicine, includes a bioinformatics core group with Bioinformatics Engineers who are trained in a wide variety of next-generation sequence analysis methods, including the ones developed in the Salzberg lab as well as many others. The CCB is a multidisciplinary center dedicated to research on genomics, genetics, DNA sequencing technology, and computational methods

for DNA and RNA sequence analysis. CCB brings together scientists and engineers from many fields, including computer science, biostatistics, genomics, genetics, molecular biology, physics, and mathematics, with a common interest in gaining a better understanding of how genes and genomes affect biological functions. The Center has available a large-scale computing facility that it uses routinely to analyze and store results from analysis of exomes, transcriptomes, and whole-genome sequencing projects.

Institute for Computational Medicine (ICM). Because of its inherent complexity, computational models are becoming indispensable tools for understanding the perturbed structure and function of living systems in disease. The type (molecules, molecular networks, cells, tissue, organ structure and function), quantity, and quality of data that can be collected from the individual is increasing due to advances in molecular assay and imaging technologies. Availability of these data is making it possible to develop patient-specific models for surgical planning, early detection of disease, and selection of optimal therapy. This approach is becoming known as “Computational Medicine”, and has been pioneered by the faculty of the Johns Hopkins University Institute for Computational Medicine (ICM). Efforts include modeling of molecular networks (computational molecular medicine), integrative, multi-scale modeling of physiological processes from cell to organ and organ systems (computational physiological medicine), and modeling anatomic shapes and their variations layered with physiological function (computational anatomy). Although modeling approaches used in each of these areas differ, the common thread is the use of quantitative models to understand altered structure and function in disease.

The ICM faculty are closely integrated within the internationally leading School of Medicine at Johns Hopkins. Dr. Winslow has a joint appointment in the Division of Cardiology, and has collaborated with Cardiology investigators for the past 23 years. He as well as Dr. Trayanova have worked and published with many Cardiology faculties. This includes Drs. Brian O’Rourke (cardiac mitochondrial energy production), Gordon Tomaselli (cell electrophysiology and signaling), Joao Lima (cardiac structural imaging), Ronald Berger (ECG analysis), Robert Weiss (cardiac metabolism and structural imaging), Theodore Abraham (MR and ultrasound imaging), Roselle Abraham (cardiac electrophysiology), Katherine Wu (cardiac imaging), and David Kass (physiology of heart failure). Other ICM faculty have established more than 90 independent collaborations with faculty of the SOM and School of Public Health (SPH). As examples, Dr. Karchin collaborates with Drs. Bert Vogelstein, Ken Kinzler, and Victor Velculescu of the Institute for Genetic Medicine. Dr Miller has extensive collaborations with the SOM and Kennedy Krieger Institute including Drs. Susumu Mori of Radiology and Marilyn Albert of the Department of Psychiatry.

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

Courses in Biostatistics

Quantitative Methodologies 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.

A full listing of Biostatistics courses may be found at
<http://www.jhsph.edu/courses/list/?yearId=2017&department=BIOSTAT>.

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.

Short courses in computational biology

The Center for Computational Genomics offers 10 focused modules for Hopkins faculty, staff, fellows, and graduate students, as well as those outside the Hopkins community.

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. <http://coah.jhu.edu/academics/aging-training.html>. The training program sponsors pan-Baltimore events including networking events with trainees in a similar T32 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 27th year, and the Poster Showcase, its 10th.

Seminars

Weekly Seminar Series – Departments of Biostatistics and Epidemiology

The Biostatistics and Epidemiology Departments each conduct weekly-to-biweekly seminars throughout the academic year. Both series host scientists who are globally prominent in the respective disciplines and are subscribed by interested parties throughout the Baltimore-Washington area. The Biostatistics seminars regularly include “Grand Rounds” seminars featuring a specific CT or other health problem introduced by a subject area expert, communication of a statistical solution to the problem, and discussion by both substantive and statistical experts.

Yearly Symposium and Poster Session on Genomics and Bioinformatics

This Center for Computational Genomics-sponsored symposium focuses on investigators in their first years of research at Johns Hopkins, and fosters collaboration among the biologists and computationally-oriented researchers in the diverse areas of genomics and bioinformatics. A poster session and happy hour is offered after the keynote address.

Annual Practical Genomics Workshop, “Practical Genomics: From Biology to Bioinformatics”

Also sponsored by the Center for Computational Genomics, this skills-oriented workshop helps scientists maintain innovation and relevance in a fast-moving field.

This four day workshop is an intensive hands-on introduction to analyzing next-generation sequencing data using publicly available Unix and R tools. Exercises are designed to take participants through a limited number of approaches (ChIP-seq and RNA-seq) in depth while emphasizing practical concepts in experimental design, quality control, biostatistics, reproducible research, and exploratory data analysis.

CCB Biweekly Seminars

CCB organizes a biweekly seminar attended jointly by faculty in the CCB and faculty with common interests from the Department of Biostatistics, as well as weekly or biweekly meetings of the research group of the co-located faculty. In addition, CCB has been a participant in the Genomics@JHU seminar organized by the Institute for Data Intensive Engineering and Science, and aiming to bring top investigators from outside the University to present the latest Genomics research.

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 semi-annual. 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 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 recent addition to the health system of 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 hold 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.

JOHNS HOPKINS CLINICAL RESEARCH NETWORK

Johns Hopkins has developed strong relationships with regional medical institutions to create a powerful network to facilitate discovery. The JHCRN includes the five hospitals that are part of Johns Hopkins Medical Institutions, as well as four partner sites, including:

- Johns Hopkins Hospital in Baltimore (described above)

- Johns Hopkins Bayview Medical Center in Baltimore
- Johns Hopkins Suburban Hospital in Bethesda
- Johns Hopkins Sibley Hospital in Washington, DC
- Anne Arundel Medical Center in Annapolis
- Greater Baltimore Medical Center in Towson
- INOVA Health System in Northern Virginia
- Peninsula Regional Medical Center on Maryland's Eastern Shore
-

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.

Suburban Medical Center Suburban Hospital Health Care System includes among other entities the Suburban Hospital, a 240 bed acute care hospital in Bethesda, Maryland. The hospital admits about 13,000 patients each year and evaluates approximately 45,000 patients in its Emergency Department including 1600 patients in its Level II Trauma Center. There are approximately 1000 physicians on Suburban's Medical Staff including full time Intensivists and Hospitalists. There are large programs in joint replacement, cancer and cardiovascular diseases. There are approximately 100 research protocols active in CV disease and cancer. Suburban Hospital supports an active translational research program in collaboration with



the intramural program of the National Institutes of Health; the hospital is an 8 minute walk from the NIH Clinical Center

Sibley Hospital Sibley is a non-profit, full service 318 bed acute care community hospital serving the Washington, DC area since 1890. The mission of Sibley Memorial Hospital is to provide quality health services and facilities for the community, to promote wellness, to relieve suffering, and to restore health as swiftly, safely, and humanely as it can be done consistent with the best service we can give at the highest value for all concerned. The campus is also home to our assisted living residence, Grand Oaks, and The Sibley Renaissance, which houses our Center for Rehabilitation Medicine, skilled nursing care, and a residential Alzheimer's unit. Sibley has approximately 318 beds and sees 1100 new cancer cases annually. The medical oncology unit includes 5000 square feet with 3 exam rooms and 15 infusion chairs. Its research staff includes nurses, a data manager, pharmacy technicians, and a pharmacist.



Anne Arundel Health Systems (AAHS) AAHS is the parent company of Anne Arundel Medical Center (AAMC) and several other entities, including the AAHS Research Institute, Pathways Alcohol & Drug Treatment Center, and Anne Arundel Diagnostics Imaging. The 324-bed facility is located on the 60-acre Medical Park campus in Annapolis, MD. AAMC has more than 23,000 annual admissions and sees 76,000 people in the emergency room each year. The DeCesaris Cancer Institute features the AAMC Breast Center, which is accredited by the National Accreditation Program for Breast Centers (NAPBC). As part of its commitment to enhanced research and ease of contracting, Anne Arundel Health Systems formed the Anne Arundel Medical Research Institute, a clearing house for clinical research trial administration including regulatory and financial aspects.



Inova Health System The addition of Inova Health System and its five major hospitals provides yet another strength to the Network in terms of established research programs, patient population, and specialty collaborations, especially in the area of pediatrics, neurosciences, cardiovascular, oncology, and genomics medicine. The Inova Health System provides medical services for a catchment area covering Northern Virginia and Southwestern Maryland. Their clinical research programs are very mature with over 500 active protocols, including 239 treatment-related protocols, conducted by over 180 physicians. About 40% of this research is funded from commercial sources. Their largest volume of clinical trials involves pediatrics, oncology, cardiovascular, and advanced lung disease. The Inova Translational Medicine Institute was established in 2011 and will have a major focus on genomics medicine research.



Peninsula Regional Medical Center (PRMC) PRMC in Salisbury, Md., offers the widest array of specialty and subspecialty services on the Delmarva Peninsula. At over 360 acute care beds, 30 transitional care beds, and 28 newborn beds, PRMC is the region's largest, most advanced tertiary care facility and has been meeting the health care needs of Delmarva Peninsula residents since 1897. Its 3,300 physicians, staff and volunteers provide safe, compassionate and affordable care designed to exceed the expectations of the

nearly 500,000 patients who rely on the Medical Center team each year for inpatient, outpatient, diagnostic, subacute, and emergency/trauma services. It is the region's oldest health care institution with the most experienced team of health care professionals. Peninsula Regional is the sixth largest medical center in the state of Maryland by bed count, offering a full range of services, including neurosurgery, cardiothoracic surgery, joint replacement, emergency/trauma care, and comprehensive cancer care, that rival those offered in much larger metropolitan areas. PRMC has received over 100 national awards, certifications, and recognitions over the past five years for the safety and care it provides patients and the outcomes they experience.

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.

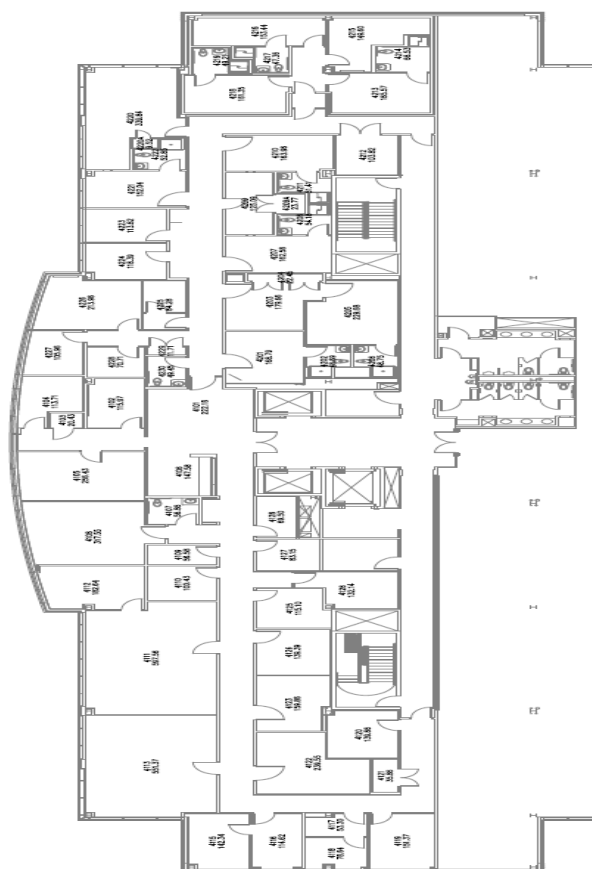
The **ICTR Administrative Offices** occupy 3,644 square feet in an office building in the historic Fells Point neighborhood of Baltimore, about 10 due blocks south of the Broadway medical campus and equidistant to Johns Hopkins Bayview Medical Center. This space is comprised of sixteen offices and twenty cubicles, plus a conference room and a reception area. All core administrative services are housed at this location, which is reachable by a university-provided shuttle bus from the medical campus. The Contracting and Billing functions of the School of Medicine Office of Research Administration (ORA), as well as the Corporate Communications offices for Johns Hopkins Medicine are also located in close proximity. This has proven useful for ease of communication with these two offices, which are respectively important for addressing issues concerning clinical research management and study start up, particularly brainstorming around processes as well as barriers; and for establishing a clear identity for this relatively new Institute.

The Principal Investigator maintains a desk in Fells Point, but keeps his main office in the Vice Deans' Suite, in the Miller Research Building on the East Baltimore Medical Campus. This gives him direct access to the Dean and CEO of Johns Hopkins Medicine, the Associate Dean for Research Administration, and the executive leadership of the School of Medicine.

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 specialists. At the Bayview campus 301 building, there is office space for the Clinical Research 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 (described more fully, below) occupy both regulated and non-regulated space within the Johns Hopkins Hospital (East Baltimore campus), and the recently built 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 (described below) 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. This is one of the primary reasons we moved in this application to an on-campus F&A rate in our budget: to more accurately reflect the use of space by the ICTR within the university, and to provide us with maximum flexibility in our future space plans. Space is no longer a direct cost on this grant.



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.

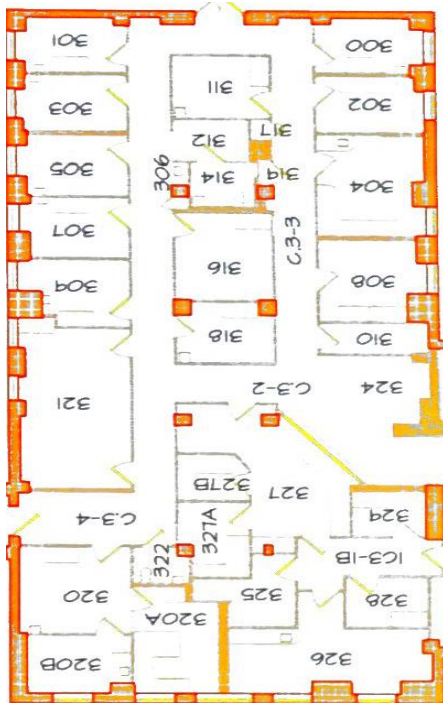
Inpatient/Overnight Services for Adult Research Participants

JHH: Osler 5 is an acute inpatient general medical floor providing up to 14 beds for overnight research. Resources include capacity for continuous cardiac monitoring and biological isolation of subjects. The unit is staffed by JHH staff nurses trained in research procedures as well as clinical practice.

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), 2 technicians (who support overnight and

outpatient visits) and 2 sleep technicians. This facility also houses space for Cardiovascular Imaging, the Exercise and Body Composition Program, and the Center for Interdisciplinary Sleep Research and Education described below. The space is shared with the JHBMC Outpatient Research Unit. (Floor plan left)

Outpatient Services for Adult Research Participants



JHBMC Outpatient Research Unit 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: Located in the Carnegie Building, this 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 2.5 research nurses, a phlebotomist and technicians who assist investigators with protocol specific evaluations (e.g., vital signs, collection/processing of specimens, administration of questionnaires, EKG's.) Experienced RN's provide nursing evaluation and observation, administer medications and provide emergent support for research projects in this specialized research setting. (Floor plan left)

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 floor plan of the state-of-the-art outpatient unit is shown to the right. The services are supported by 1.5 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.

JOHNS HOPKINS ICTR CLINICAL RESEARCH UNITS CHARGEMASTER					
			CLINICAL RESEARCH UNIT CHARGES		
			BAYVIEW	JHH CRU	PCRU
FACILITY					
bed night charge (includes nurse oversight)		700		2,100	2,100
includes meals and linens/telephones/tv					
outpatient room charge/hr		35		35	35
parking (passed to study)					
BIONUTRITION					
meals		10		10	10
consultation (per Nutrition cost plan)					
NURSING OP (see below)					
EXERCISE & PHYSICAL FUNCTION TESTING					
- All procedures can be done at JHBM. Those designated ** can be done at JHH also.				EQUIPMENT	
Exercise Session		75.00/hr			
exercise physiologist/hr		45			
**DXA - total body		100		GE prodigy DXA scanner	
- hip, spine, pelvis		100			
- combined		150			
**anthro		45		tape measure, skin fold caliper	
BIODEX		100		BIODEX system 3 machine	
EST		100		treadmill, bike, Vmax Encore	
VO2		200		treadmill, bike, Vmax Encore	
**RMR (resting metabolic rate)		100		Vmax Encore and hood	
Augmentation Index		45		sphygmator	
Pulse Wave Velocity		45		sphygmator	
EndoPAT		45		endoPAT 2000	
balance assessment		25		chair, step stool, stop watch	
functional assessment		25		BP device, cones, stop watch, step stool	
**6 minute walk test		25		BP device, cones, stop watch, pulse oximeter	
hand strength		40		hand dynamometer	
**BIA (Bioelectrical impedance analysis)		60		RJL Quantum analyzer	
sit and reach		25		sit and reach box	
CARDIOVASCULAR (only at Bayview)					
Echocardiogram					
Perfoming		200			
Analysis		100			
Carotid IMT					
Perfoming		200			
Analysis		100			
Brachial FMD					
Perfoming		200			
Analysis		100			
Ankle Brachial Index		nursing fee/per hour			
NURSING (OP)					
Phlebotomy (include Lab 1 Sample processing)		blood draw, urine			25
Nursing Level 1		Brief study visit, simple initial visit or			50
Up to 1 hour		follow-up minimal set-up, vital signs, height, weight, medication pick-up, 12-lead EKG (1)			
Nursing Level 2		standard intervention, screening or follow-up, routine set-up, vital signs, height, weight, anthropometrics, vital signs w/doppler, EKG			100
1-3 hours		at multiple time points, IV placement, subject medication, monitoring & education			
Nursing Level 3		Complex intervention, infusion <6 hours, PKs up to 4 time points, complex set-up required biopsy (fat,muscle), lumbar puncture, glucose tolerance test			200
3-6 Hours					
Nursing Level 4		Intensive intervention, infusion >6 hours, PKs greater than 4 times points, complex sampling & monitoring schedule, procedures requiring multiple nurses			400
6-8 hours					
Nursing Level 5		Visit requiring nursing in excess of 8 hours			600
8-12 hours					
SAMPLE LAB PROCESSING (JHH & Bayview)					
Lab1		specimen handling with no or minimum processing			11
Lab 2		Specimen processing of 15-45 minutes			22
Lab 3		Specimen processing of 45-75 minutes			40
Lab 4		Specimen processing of 75-105 minutes			60
Lab 5		Specimen processing >over 105 minutes			120

As of March 2018 CRU resource costs will be shared with individual projects. A detailed cost structure is included below

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 4), as well as trainees from the Study Coordinator Apprenticeship and Mentoring Program (SCAMP) that have reached their first year of training (currently 6). The coordinators home offices are located at the ICTR Fells Point office, but they perform work duties wherever is requested by the study team that hires them.

Research Nutrition Program

<http://ictr.johnshopkins.edu/clinical/clinical-resources/human-subjects-research-core/ictr-clinical-research-units-crus/services/research-nutrition/>

Offices: Offices with staff computers are located in Johns Hopkins Hospital on the adult unit (Osler 5), in the Charlotte Bloomberg Children's Center, the Pediatric unit (Bloomberg 9N) and the Bayview Medical Campus - Domiciliary Unit.

Research Kitchen and Formula room: The research kitchen is located on the adult unit (Osler 5) and metabolic kitchen/formula room is located in the Pediatric Clinical Research Unit (Bloomberg 9N). The research kitchen and formula room services all 3 hospitals with active transport of the food service to each site. In the past, research meals were also provided to the University of Maryland Medical Center. Standardized meals, specialized weighed meals for pharmacokinetic studies, feeding studies, food arrays, and double-blind placebo-controlled oral food challenges for food allergy protocols are all created and prepared in the research kitchen. Preparation of take home doses of food allergens for oral immunotherapy desensitization studies are also weighed in the metabolic formula room, in addition to any specialized metabolic formulas.



Equipment: Three analytical balance scales, one Sartorius CPA64 and four Ohaus Explorer are used for weighing out placebo and allergen dosing for oral immunotherapy studies, metabolic formulas and foods for all sites.

One CareFusion Vmax Encore 229N metabolic portable system is used for measuring resting energy expenditure. Four licenses for the Nutrition Data System for Research (NDSR) for dietary analysis of food

records and 24 hour recalls conducted by the Research Nutrition Core for various investigators across campuses and the Schools of Medicine, Nursing and Public Health as well as contracts with Geisinger Medical Center.

Several non-invasive methods are available for anthropometry and body composition assessment. Two Bioelectrical Impedance Analysis (BIA)-RJL Systems Quantum II and Quantum X measures lean body mass, body fat, intra- and extracellular water and phase angle. Four Lange Calipers used to measure thickness of subcutaneous fat. Two bone breadth calipers (Campbell 10 and 20), one segmometer and two metal anthropometric measuring tapes for measuring bone width and segmental lengths of the body.

Exercise and Body Composition Program

<http://ictr.johnshopkins.edu/clinical/clinical-resources/human-subjects-research-core/ictr-clinical-research-units-crus/services/exercise-physiology-and-body-composition/>

The laboratories are located on the Clinical Research Unit in the 301 Building at JH Bayview and is equipped with a CareFusion (formerly Viasys) 229 Metabolic and ECG system for exercise testing and



resting metabolic rate. Exercise tests, with or without assessment of oxygen uptake and related measures can be performed on a treadmill or cycle ergometer and a Biodex System 3 Dynamometer is used for isokinetic strength testing. The BIODEX system can test the major muscle groups for concentric and eccentric contractions at a wide range of speeds (degrees/second) and is also capable of passive strength testing. Attachments are available for the major muscle groups for adults and children. Two Hoist multistation strength machines are available for isodynamic muscle strength training. The exercise core also performs a variety of functional tests such as the 6-minute walk, sit and

reach, hand grip strength, and other techniques as needed for specific protocols. GE Lunar Prodigy Encore (GE Medical Systems) Dual Energy X-Ray Absorptiometry (DEXA) machine for body composition and bone density assessment (pictured above.) Software Version 13.60.033 is the current version. The DEXA is capable of whole body scans as well as focused scans for the spine, hips and forearm for protocols in which bone is of primary interest. Other body composition measures offered include BIA, circumferences measures and skinfold caliper assessments. In addition, the exercise core offers vascular assessments including pulse wave velocity, augmentation index, EndoPAT with the option of heart rate variability and the Endothelix.

Exercise Training. The exercise training facility is located in the Asthma and Allergy Center on the Bayview Campus. The facility is shared with the clinical cardiac and pulmonary rehabilitation programs. The facility is full-equipped and can have 15 subjects exercising at the same time. Major equipment includes treadmills, cycle ergometers (leg only, upper body only, and dual legs and arms), upright and recumbent steppers, Elliptical machines, Hoist multi-station strength training machines, and an assortment of handheld weights.

Center for Interdisciplinary Sleep Research and Education (CISRE)

The Johns Hopkins *Center for Interdisciplinary Sleep Research and Education* has over 30 years of clinical sleep research experience (<http://cisre.jhu.edu/>). The CISRE provides an ample array of sleep testing services. CISRE is housed on campus alongside the Bayview Clinical Research Unit (CRU), which provides a wide variety of additional testing including body anthropometry, cardiovascular, metabolic, informatics and blood processing services. CRU in turn is supported by the Johns Hopkins

Institute for Clinical and Translational Research (ICTR) and is funded by a Clinical and Translational Science Award (CTSA).

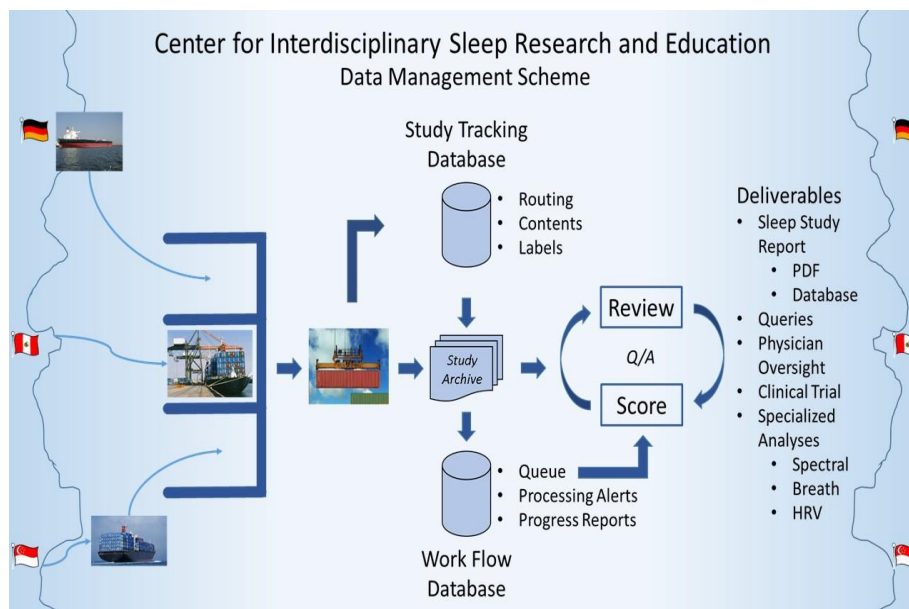
The CISRE offers facilities and infrastructure to foster collaborations with other academic institutions in a variety of areas of research, including sleep disorders, chronobiology, drug abuse, endocrine disease, neuropsychiatric disorders, obesity, cardiovascular health and pulmonary disease.

The CISRE has a 10-bed capacity, and is supported by a dedicated registered sleep technologists and an extensive network of workstations and IT infrastructure.

CISRE provides an IT backbone consisting of an extensive network of data acquisition workstations and servers, which facilitate data acquisition, analysis, tracking, databasing and archiving sleep study data. It's networking environment that provides investigators ready access to sleep recordings, sleep study reports and databased results.

CISRE's Scoring Hub consists of an AASM-accredited unit with proficiency in scoring and processing polysomnographic data (<http://cisre.jhu.edu/sleep/scoring-hub>). The Scoring Hub team is led by an ABMS-certified physician in Sleep Medicine (Dr. Alan R. Schwartz), who is responsible for reviewing all sleep studies that have been scored by the team's staff of Registered Polysomnographic Technicians (RPSGTs). At each stage of the scoring process, detailed quality assurance measures are databased. CISRE maintains the highest quality of sleep data acquisition and analysis by providing staff regular Q/A feedback and by conducting complementary inter-scorer reliability exercises on an ongoing basis.

CISRE's Data Management core provides our investigators and sponsors with immediate access to sleep recordings and prompt sleep study reports. Its versatile IT backbone combines fixed in-lab and mobile domiciliary testing suites to record, score, analyze and archive raw and summary data. Customized software offers robust, secure mechanisms for transmission of sleep recordings and summary data to and from the Scoring Hub from on-site study beds and remote locations across the globe.



Clinical Research Core Laboratory

<http://ictr.johnshopkins.edu/clinical/clinical-resources/human-subjects-research-core/ictr-clinical-research-units-crus/services/clinical-research-unit-core-lab/>

The primary function of the ICTR Clinical Research Core Laboratory is to provide technical support for sophisticated clinical research assays. The laboratory is a regional resource that supports investigators within the ICTR and investigators at 5 nearby institutions (the University of Maryland, Mercy Medical Center, the University of Pennsylvania, University of Pittsburgh, and the National Institute of Mental Health). Within this context, the Laboratory supports approved investigators by providing facilities,

technical experience and training for non-routine blood, saliva and urine biochemical analyses. The Laboratory is staffed by a Director and three full-time technicians who have extensive experience in the theory and practice of clinical laboratory assays, and in prioritizing access to laboratory resources.

The Laboratory technicians perform approximately 90 different immunoassays for the determination of proteins, peptides, hormones, and other biochemical markers. Investigators access Core Laboratory resources through iLab (https://johnshopkins.corefacilities.org/service_center/show_external/3781). The Laboratory provides standardized sample handling that minimize freeze/thaw cycles, low investigator cost and high quality control. Quality control is maintained by including in each assay run kit manufacturer's controls as well as low, medium and high value in-house controls. In addition, ED 80, 50 and 20 values as well as each standard curve is compared with historical values and "grave yard" curves. Control values are used to maintain a database of coefficients of variance for inter- and intra-assay variability. The Laboratory is GLP and CLIA compliant. The laboratory participates in the AccuTest, Inc. (Westford, MA) Digital PT proficiency testing program for FDA-approved immunoassay kit or machine measurements and utilizes a consortium of national NIH funded CTSA Core Laboratories for internal sample swapping and proficiency testing of immunoassay kits used for clinical research.

Space and Equipment: The ICTR Clinical Research Laboratory is located in Room 5A.64 of the Johns Hopkins Asthma and Allergy Center. The Core Laboratory technicians perform immunoassays and chemical assays for the determination of proteins, peptides, hormones, lipids, carbohydrates and other biochemical markers. Laboratory personnel also can perform sample processing, short term storage and shipping of research samples. This 600 ft² facility is located in the Johns Hopkins Asthma & Allergy Center. The facility houses a Mesoscale Discovery Sector Imager 2400 Workstation for multiplex ELISAs, Packard Cobra II Model 5010 Gamma Counter for RIAs, two YSI glucose analyzers, Three Cholestech lipid analyzers, two hemoglobin A1c analyzers, Beckman J6B refrigerated centrifuge, a Beckman Creatinine analyzer, Wallac Victor 2 Microplate Work Station, LabSystems Multiskan MS microplate reader, three (3) Revco and one Puffer Hubbard -80°C freezers, Corning model 320 pH meter, Bio-Rad Power Pak 3000 electrophoresis power supply, and Omnigene thermal cycler. In addition, a central facility containing a cold room, and a radioisotope processing and disposal lab are available. The laboratory is equipped with multiple Apple computers and printer.

Community Engagement and Recruitment Innovation

The Community Engagement and Recruitment Innovation group headed by, Dr Cheryl Dennison Himmelfarb is located in the School of Nursing Building. This building is on the Broadway medical campus and includes numerous conference and class rooms where meetings and classes related to the community engagement core can occur. Dr. Hae-Ra Han and Professor Lee Bone are the two other lead faculty in the group; they have their offices in the Anne M. Pinkard Building and Hampton House, respectively. These buildings are also located on Broadway Medical Campus, allowing for frequent in-person meetings among the core faculty. Johns Hopkins Information Technology provides support for each faculty member. The ICTR administrative suite with its offices and meeting rooms is home to other staff and volunteers that support the group.

There are several institutes and centers at Johns Hopkins who work closely with the Community Engagement core 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 three years. These institutes and centers have also co-sponsored 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.



Center to Eliminate Cardiovascular Health Disparities	Medicine
Baltimore Diabetes Research and Training Center	Medicine
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 DEVELOPMENT CORE

(Dr. Craig Hendrix, Core Director; Dr. Barbara Slusher and Dr. James Polli, Core Co-Directors)

Discovery and Early Development:

Medicinal Chemistry Unit (Dr. Takashi Tsukamoto, Unit Director; Dr. David Meyers, Unit Co-Director)

- **Tsukamoto laboratory:** The laboratory is consistent of 3 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 owns a dedicated Bruker 400 MHz multi-probe NMR (1H/13C/31P/19F) with sample automation capabilities operated by Bruker Topspin. The lab is also equipped with analytical and preparative LC/MS instrument, a Biotage Isolera automated chromatography system, lyophilizers, a CEM microwave system, 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.

- **Meyers laboratory:** Includes two 6-foot chemical fume hoods each equipped with water, house air, house vacuum, high vacuum, a double bank vacuum manifold and argon. Grace Reveleris flash chromatography system equipped with integrated dual-UV and ELSD detectors and fraction collector. Preparative Beckman 32 Karat HPLC equipped with a photodiode array detector and preparative reverse phase column. Biotage Initiator 2.0 microwave synthesizer equipped with automatic vial-handling Robot 8 Protein Technologies PS-3 peptide synthesizer. Minor equipment includes -20 C flammable materials storage freezer, Denver Instruments analytical balance, 5 IKA stir plates with digital temperature control, drying oven, rotary evaporators, and Radleys carousel 12 reaction station. There is also shared access to mass spectrometers (ESI and MALDI) and a variable temperature NMR (500 MHz Bruker, $^1\text{H}/^{13}\text{C}/^{31}\text{P}/^{19}\text{F}$ quad probe, autosampler); access to additional higher field spectrometers at JHU Homewood campus. Protein Technologies Prelude peptide synthesizer (Dr. Sean Taverna's lab). Preparative reverse phase LC/MS equipped with auto-sampler.

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

The CADD Center has the following equipment/computer resources: four clusters, gluster storage, backup gluster storage, tape backup, quantum mechanic server, 22 Linux workstations, 7 MAC laptops, and XSEDE 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 connected to emergency power. Resources monitored 24/7 by facilities. Gluster storage, based on the Gluster FS software, consists of 432 TB of network-accessible storage solution and an archival solution that is located at a different site and used as a data mirror in case of disaster.

Assay Development and Screening Unit (Dr. Camilo Rojas, Unit Director; Dr. Jun Liu, Unit Co-Director)

- **Rojas 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 a Beckman tabletop ultracentrifuge, UV-Visible light spectrophotometer, 96-well fluorimeter, a Fluorescence Imaging Plate Reader (FLIPR), TopCount radiometric detector, an HPLC equipped with photodiode fluorescence and radiometric detectors, a large shaking incubator, a gel drying system, speed vac concentrating system, balances, pH meters, micro-centrifuges, vortexers, sonicators, and electrophoresis equipment.
- **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.

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

- **Rais laboratory:** The laboratory has three state of the art mass spectrometric systems, (a) Triple stage quadrupole mass spectrometer, (b) Hybrid quadrupole-orbitrap mass spectrometer and (c) QTOF mass spectrometer. The Thermo TSQ Vantage triple stage quadrupole mass spectrometer system is equipped with an atmospheric pressure ionization source (electrospray ionization) coupled with a front end of Accela 1250 HPLC chromatographic system; Thermo Xcalibur software (version 2.0) is 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 96-well 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. Katarzyna Macura, Unit Director; Dr. Maureen Kane, Unit Co-Director)

- **Macura laboratory / JHU Unit** The Johns Hopkins University has a large array of different imaging modalities including CT, MRI, Ultrasound, Nuclear Medicine/PET imaging, cardiovascular imaging and a diverse number of research centers for molecular, small animal and functional imaging. PET imaging equipment includes 2 PET scanners and 2 PET/CT scanners. A GE Advance whole-body PET scanner is dedicated for research use, as is a Siemens ECAT HRRT brain-only PET system. The HRRT is a high resolution, high sensitivity PET system, supported by a powerful cluster of dedicated servers that enable advanced image reconstruction of large data sets. The HRRT has significantly better spatial resolution (2-3 mm FWHM) than typical whole-body PET systems due to its small detector size and ring diameter. In addition to the 2 PET-only systems, the division has 2 PET/CT systems: a GE Discovery LS and a GE Discovery VCT(RX). The Discovery LS will be replaced in 2012 with a new state-of-the-art whole-body system with time-of-flight capability. The Discovery VCT(RX) has 64-slice CT capability and is used for diagnostic CT protocols as well as low-dose CT for PET attenuation correction and

localization. The PET component is based on 3 cm thick LYSO crystals (enabling high sensitivity 3D acquisition with low scatter and randomness compared to BGO systems) and supports a range of flexible acquisition modes including both 2D and 3D, list-mode, dynamic and both ECG and respiratory gating. Single Photon Emission Computed Tomography (SPECT) instrumentation specifically dedicated for research includes a General Electric Millennium VG dual-head SPECT system equipped with a Hawkeye x-ray transmission CT unit which is located in the basement of the Jefferson building adjacent to the GE Discovery LS PET – CT. The thicker 111 crystal is especially suitable for medium and higher energy SPECT radiotracers, and the combined CT capability provides precise co-registered functional and anatomic localization in addition to rapid attenuation correction. In addition, we have two triple-head SPECT systems available for this project, a Trionix Triad and a Picker (Marconi) IRIX. In Nuclear Medicine, we have had a Trionix Triad triple-head SPECT system for several years. We routinely acquire high resolution brain SPECT studies with the following protocol: high resolution collimator, 40 views per head (120 total projections, 3 degrees per step), 128 transverse x 64 axial matrix (square pixels), and reconstruct with filtered back-projection with a Hanning filter with a cutoff of 1.3 cycles/cm. Acquisition is typically dynamic, with projection time adjusted depending on total acquisition for the frame (e.g., 7 sec per step for a 5 min acquisition). Additional clinical nuclear medicine equipment includes: 2 Siemens E.CAM dual-camera SPECT systems. Three new GE Millennium VG dual-head SPECT systems equipped with 5/811 NaI(Tl) crystal and Hawkeye x-ray transmission units are installed in the Nuclear Medicine clinic with one dedicated to research.

- **Kane laboratory / UMB Unit:** UMB Imaging Center has a Thermo HM550 Cryostat. Samples can be 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 system. MSI data will be acquired on a Bruker Solarix 12T Hybrid QqFT-ICR Mass Spectrometer, or a Bruker UltrafleXtreme MALDI TOF/TOF Mass Spectrometer. Images will be analyzed using the following bioinformatic software: flexImaging (Bruker) and SCiLS Lab for MALDI imaging mass spectrometry (SCiLS).

Biomarker Development: *Metabolomics* Unit (Dr. Anne Le, Unit Director)

The lab consists of cell culture hood, PCR machine, and microplate reader that can assess colorimetric as well as luminescence and fluorescence; the latest speedvac model and Labconco FreeZone Freeze Dry System, as is equipped with an automated epMotion 5070 for large scale pipetting. The lab is also equipped with the latest metabolomics technologies including the Agilent 6540 Quadrupole–Time-of-Flight (Q-TOF) mass spectrometer with Agilent 1290 HPLC and Triple-Quadrupole instruments, as well as all software for metabolic profiling, pathways and interactive analysis of genomics, proteomics and metabolomics data. Samples will be analyzed using Agilent Mass Hunter and Agilent Mass Profiler Professional (MPP) and Agilent Qualitative and Quantitative Analysis Software packages.

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

- **Cole laboratory:** The facility has four mass spectrometers, including three Thermo Orbitraps (Fusion with ETD, Q-Exactive Plus and Q-Exactive HF) and a AB Sciex Voyager DE-STR MALDI-TOF (matrix assisted laser desorption ionization with a time-of-flight). All mass spectrometers for peptides have high sensitivity (amol to fmol), high resolution (7,500 to 240,000) and high mass accuracy (sub ppm to 10 ppm error). The electrospray instruments are interfaced with two dimensional nanoflow liquid chromatographic systems (Eksigent Technologies, Thermo or Waters Corp.) or a capillary electrophoresis system (908 Devices) for on-line separation and fragmentation for identifying peptides. Off-line chromatography is also performed for fractionating complex samples and for specialized applications (e.g. quantifying proteins using TMTs, iTRAQ, SILAC, AQUA, PSAQ or enrichment for post-translational modifications) on the Core's Agilent 1100/1200 capillary chromatography systems or BioRad Mini-Prep Cell gel electrophoresis

systems. Enzymatic digestions are performed in a laminar flow clean hood. All proteomic data is stored on a mirrored 14TB NAS server in the Core's office suite where 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, 4TB NAS server for password protected transferring of large datasets and results files to investigators, and the backup mirrored 14TB NAS server with investigators proteomic data. Archive data is duplicated and stored for at least 7 years in two separate locations, one in the core and the backup copy in the Basic Science Network Office. The lab also has two-dimensional (2D) gel electrophoresis and gel imaging equipment to support many sample preparation techniques. Electrophoresis equipment includes: IPGphors (3 units) and slab gel electrophoresis units (12 mini-gel, 7x10 cm, and 4 cooled Dalt-Six, 20x24 cm) for protein separation by pI and size; a Typhoon laser scanner and Epson flatbed densitometer for image analysis. The laminar flow clean hood is also used for manual cutting out gel bands or spots. The gel electrophoresis equipment as well as the MALDI-TOF 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 (<https://johnshopkins.corefacilities.org/landing/42>).

- **Shapiro laboratory:** Equipment includes several protein purification systems (e.g. Äkta Pure HPLC, 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. Typhoon FLA 7000 Phosphoimager, Biacore3000 and T200 Surface Plasmon Resonance Instruments, MicroCal Ultrasensitive PEAQ-ITC Microcalorimeter Cell, JASCO J-810 CD spectrophotometer with fluorescence, Molecular Devices SpectraMax M5 microplate reader), Alpha Innotech gel-documentation system, Nikon E800 and Ti microscopes with NIS Elements imaging software, and shared access to department NMR facility (e.g. Varian 400 and 500 MHz) for saturation transfer difference (STD)-NMR.

Pharmaceutics and Regulatory

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 pharmaceutical 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)

The Mass Spectrometry Center is equipped with 15 mass spectrometers for investigator use. The available instrumentation is as follows: AB Sciex 5500 QTRAP Hybrid Tandem Quadrupole - Linear Ion Trap Mass Spectrometer with a Shimadzu Prominence UFLCXR, Agilent 7700 ICP-MS Inductively Coupled Plasma Mass Spectrometer, Bruker AmaZon X Ion Trap Mass Spectrometer, Bruker UltrafleXtreme MALDI TOF/TOF Mass Spectrometer, Bruker Solarix 12T Hybrid QqFT-ICR Mass Spectrometer, Thermo Q-Exactive Quadrupole-Orbitrap Mass Spectrometer with Waters NanoACQUITY UPLC, Thermo TSQ Quantum Ultra Triple Stage Quadrupole Mass Spectrometer with Dual Pump Dionex UltiMate 3000 Rapid Separation UHPLC, Thermo Orbitrap Elite Hybrid Mass Spectrometer with Waters NanoACQUITY UPLC, Thermo Orbitrap Fusion Tribrid Mass Spectrometer with Waters NanoAcquity UPLC, Thermo Exactive bench-top accurate mass, high resolution mass spectrometer, Waters ACQUITY TQD Tandem Quadrupole Mass Spectrometer with Alliance HPLC, Waters ACQUITY TQD Tandem Quadrupole Mass Spectrometer with AQUITY H-Class UPLC, Waters AQUITY TQ-S Tandem Quadrupole Mass Spectrometer with AQUITY H-Class UPLC, Waters SYNAPT G2 HDMS Q-TOF Mass Spectrometer with Ion Mobility Separation coupled with Nano ACQUITY UPLC System with HDX Technology, Waters SYNAPT G2Si HDMS Q-TOF Mass Spectrometer with Ion Mobility Separation). For protein mapping, equipment includes Precellys PeqLab 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 G2 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, Thermo Orbitrap Fusion Tribrid Mass Spectrometer with Waters NanoAcquity UPLC, Thermo Orbitrap Elite Hybrid Mass Spectrometer with Waters NanoACQUITY UPLC, or Thermo Exactive bench-top accurate mass, high resolution mass spectrometer. 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).

Biologic Products Development Program Unit (Dr. Vic Lemas, Unit Director)

Equipment includes: nine Stericult incubators, five BSCs, four LN2 storage freezers (2 for quarantined products, 2 for released products as per cGMP), four 2 - 8C refrigerators, two -20C freezers, two -80C freezers, and a Coy anaerobic chamber. A development lab (POL) is used to optimize manufacturing strategies to ensure a successful production under GMP conditions. This Program also has one walk-in warm room, a walk-in cold room (40C), two autoclaves, seven CO2 incubators, one water jet and one low temperature incubator, two refrigerated and one non-refrigerated centrifuge, three six-foot baker biocontainment hoods, one four-foot baker hood in the PCR lab for nucleic acid extraction, one four-foot baker hood reserved for vaccine preparation, a fume hood, three inverted light microscopes, four dual-chamber water baths, one regular light microscope, one Nikon fluorescent microscope equipped for photography, a dissecting microscope, a microtome, an auto diluter, two ELISA readers, two plate washers, a RID plate reader, a MiniMAG for nucleic acid extraction, Flexigene and Genius thermocyclers, one Applied Biosystems 7300 real-time PCR machine, equipment for sonification, including a soundproof cabinet, four aquariums equipped with heating circulator pumps, full size and mini gel apparatuses and power supplies, a gel dryer, seven computers, two printers, four refrigerators, one double door

refrigerator, four –200C freezers, five -700C freezers, two liquid nitrogen tanks each with 20,000 vials capacity, and several clinical centrifuges. A Pharmacia/LKB fast protein liquid chromatography system and a standard low-pressure chromatography system are available for antigen and antibody purification.

Clinical Development

Clinical Drug Development Unit (Dr. Craig Hendrix, Unit Director)

Equipment includes: automated dynamap Pro200V2 portable vital signs stations, portable Mortara ELI 150 Rx electrocardiograph recorder, Welch Allyn VideoPath high magnification culposcopy/anoscopy viewer with camera and video monitor, Welch Allyn portable gynecology examination light, two phlebotomy chairs, two examination tables, weight balance/height scale, moveable hospital bed, drug supply cabinet with temperature monitor, medication refrigerator, wireless printer, fax machine, 8 personal desktop computers, telephones, galley (pantry, food refrigerator, microwave, coffee maker).

Pharmacometrics Unit (Dr. Joga Gobburu, Unit Director)

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: NONMEM, Perl Speaks NONMEM (PsN), Piranajs, R, Rstudio Server, Rstudio Connect, Sun Grid Engine and a Fortran Compiler.

JOHNS HOPKINS ALL CHILDRENS HOSPITAL

Clinical Johns Hopkins All Children's Hospital, Inc. (JHACH), located in Saint Petersburg Florida, is one of only three freestanding children's hospitals in Florida and the only one located on the state's west coast. The hospital, founded in 1926 as the American Legion Hospital for Crippled Children, has grown over the past near-century from a small community hospital into a major pediatric referral center in the Southeast region of the United States. It is a non-profit entity which provides tertiary level medical care in virtually all of the pediatric medical and surgical subspecialty areas for a routine direct catchment area of seventeen Florida counties, home to 1.3 million children. Nearly 70% of patient is provided to indigent pediatric populations.

In 2010, All Children's opened a new ten-floor, 738,000 square foot, state-of-the-art facility. This facility has 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 transplant unit. In addition, there are 12 state-of-the-art operating suites, an emergency center and a diagnostic imaging department. In addition, the 3rd floor of JHACH houses Bayfront BabyPlace, via a strategic partnership with Bayfront Health. This partnership is strengthened by a JHACH-employed Obstetrics practice. Babyplace consists of 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 the BabyPlace.



JHACH is adjacent to and connected with a five-floor Outpatient Care Center, which houses individual subspecialty and general pediatrics clinics, multidisciplinary clinics, diagnostic services, the Department of Pathology and Laboratory Medicine, physician offices, and the simulation education laboratory. Also located in the Outpatient Care Center is JHACH's employed-physician practice All Children's Specialty Physicians (ACSP). ACSP is a group-practice plan that includes more than 175 physicians in 24 pediatric medical and surgical programs.

Through a network of strategically located off-site care centers, JHACH brings diagnostic, rehabilitation and subspecialty care services to communities throughout its service area, which includes federally-designated underserved areas and populations. JHACH operates a network of ten regional outreach specialty care centers over a 150 mile reach, extending from Citrus County in the North to Ft. Myers in the South. In addition, JHACH's Kids Home Care offers home health services designed to meet the special medical and developmental needs of children at each stage of development, from infants through teens. The Johns Hopkins All Children's Cancer and Blood Disorders Institute provides clinical care and research trials for children, adolescents, and young adults in west and west central Florida and is the only pediatric affiliate of Moffitt Cancer Center, an NCI Comprehensive Cancer Center. JHACH also coordinates with Connect to Protect Community Coalition: a multi-site community mobilization intervention to reduce HIV/AIDS incidence and prevalence among urban youth.

In 2011, All Children's became a member of the Johns Hopkins Health System, and re-branded as All Children's Hospital Johns Hopkins Medicine. This was not simply an affiliation, but rather, a comprehensive integration. As such, All Children's became the Southern pediatric campus of Johns Hopkins Medicine, and in 2015, the hospital completed its rebranding as Johns Hopkins All Children's Hospital (JHACH). The integration into Hopkins has led to a strengthened emphasis and expanded infrastructure for mission pillars of education, research, quality/safety, and advocacy, which also serve to strengthen All Children's original core mission of clinical excellence. Currently, JHACH is the home to over 7,000 inpatient admissions, 45,000 emergency room visits, and 200,000 on-campus outpatient visits annually, and nearly 150,000 outpatient visits at its outreach centers each year.

The Department of Pathology and Laboratory Medicine (37,486 sq. ft.) is a complete tertiary level resource center, occupying the 4th floor of the JHACH Outpatient Care Center building, which is directly attached to the main hospital via pedestrian bridge and computerized tube transport system. The Department processes more than one million specimens each year, and supports both clinical and research activities. The Laboratory is accredited by the College of American Pathologists, and is certified by the State of Florida, the College of American Pathology, The Clinical Laboratory provides examinations and testing in the following areas: Anatomic and Clinical Pathology, Biochemical Genetics, Clinical Molecular Genetics, Cytogenetics, Chemistry, Diagnostic Immunology, Electron Microscopy, Flow Cytometry, Hematology, Histocompatibility (HLA), Immunohematology, Microbiology, Parasitology, Serology and Virology. Tests not performed in-house are sent to approved reference laboratories. Laboratory services are available to inpatients, outpatients and referral clients. Staff are trained to obtain biological samples and perform laboratory testing on patients of all ages (newborn through adult), especially neonates, infants and small children. Phlebotomy services are designed to meet patient and family needs and expectations--including physical, psychological, social and cultural--in a timely manner with highest quality and specimen integrity. Patient specimens are collected 24 hours a day for laboratory testing.

JCAHB Research: The JHACH research infrastructure consists of the All Children's Research Institute, a non-profit entity comprised of multiple pediatric research-related cores, departments, and offices, the JHACH Office of Human Subjects Research (OHSR), and any local project-specific resources derived from research grants and contracts. The Chief Research Officer for the All Children's Research Institute

is Neil Goldenberg, MD, PhD, who also serves as JHACH director research. The Institutional Official for OHSR is Daniel Ford, MD, Vice-Dean for Clinical Investigation at the Johns Hopkins University School of Medicine. Each of these roles involve close oversight and/or cooperation with Jonathan Ellen, MD, President and CEO of JHACH, who also serves as Johns Hopkins University School of Medicine Vice-Dean for JHACH.

The establishment of All Children's Clinical and Translational Research Organization in 2012 was a key step in the shared vision for investigator-initiated pediatric multicenter trial leadership and coordination. Outpatient research visits are conducted within the main hospital and the Outpatient Care Center, and a self-contained inpatient Clinical Research Unit is slated to open in June 2017, co-localized with the Post-Anesthesia Care Unit in the Hospital. All human subjects' research activities are executed within a portfolio of auditable Standardized Operating Procedures, in compliance with Hopkins research policies and federal/international guidelines (GCP, ICH).

Now comprised of over 40 individuals, the Johns Hopkins All Children's research cores, departments, and offices are each led by a core Manager and/or Director. These include the: Department of Research Administration (Pre-Award and Post-Award personnel, Accounting, and Legal Counsel for Research Compliance and Contracting); Research Operations Core (Clinical Research Coordinators, Clinical Unit-Based Research Nurses, Project Managers, Research Assistants, and the Research Operations Core Director); Database Design and Data Management Unit of the Health Informatics Core (consisting of Database Architects/Data Managers, Data Specialists, and Program Administrator); Epidemiology and Biostatistics Unit of the Health Informatics Core (comprised of Epidemiologists and Biostatisticians); Regulatory Affairs/Quality Assurance Core (Regulatory Affairs/Quality Assurance Manager, Regulatory Submission Specialists, and Legal Counsel for Research Compliance and Contracting); Investigational New Drug (IND)/Investigational Device Exemption (IDE) Support Core (Manager and Coordinator); Investigational Drug Services Core (Investigational Drug Pharmacist; pharmacy technician); the Johns Hopkins All Children's Pediatric Biorepository (Scientific Director, Manager, Specimen Technologists, Research Phlebotomists, and Program Administrator); and the Johns Hopkins All Children's Molecular Determinants Core, focused on mass-spectrometry-based multi-"omics" science for biomarker and metabolite discovery and validation (Scientific Director, Manager, Technologists, and Program Administrator). All core staff have their own computer, which requires a Log-in ID and password for access and the standard Microsoft Package computer software. The computers are connected to the Hospital's protected information technology network and servers, and have e-mail and internet access.

Database design for investigator-initiated clinical/translational research studies is typically developed and implemented in a REDCap platform. Statistical analytic software licenses used in the Health Informatics Core include SAS, STATA, SPS, R, and other software packages. JHACH's Electronic Medical Record (EMR)-derived Clinical DataWarehouse is supported by a Clinical Decision Support team and Chief Medical Informatics Officer. Query/report requests of the DataWarehouse for research and pre-research are centrally managed, with appropriate limitations to access/transmission of protected health information as pertinent to the type of research and the specifications within its IRB approval. JHACH DataWarehouse-derived reports can be aggregated with like reports from a Johns Hopkins Hospital EMR-derived dataset, in order to facilitate inter-campus analyses and/or external validation studies. An I2B2-like, PHI-free, end-user-based query solution for cohort finding is scheduled to go live at JHACH in Summer 2017. A single email server for JHACH and JHU supports on-site and off-site faculty members, allowing for transparent movement of information. Remote teleconferencing and videoconferencing is regularly conducted between the campuses as well as with collaborators outside of Hopkins.

Work performed by the Department of Research Administration on federal grant proposals is overseen by the Office of Research Administration at Johns Hopkins University, which has a very robust infrastructure that manages an average of 1500 total federal awards annually. Similarly, from a regulatory

perspective, the Johns Hopkins All Children's Office of Human Subjects Research (OHSR, or "IRB office") is a local office within the overall OHSR at the Johns Hopkins University School of Medicine. The JHACH IRB is 1 of 7 Johns Hopkins University School of Medicine IRB panels, and functions as the HIPAA Privacy Board at JHACH. The Johns Hopkins University School of Medicine IRB serves as the overall responsible IRB for all studies conducted at JHACH.

Construction is nearly complete on the new, stand-alone, state-of-the-art, 225,000 sq. ft. Johns Hopkins All Children's Research and Education Building, which will house: all aforementioned research-related Cores; the Johns Hopkins All Children's Institute for Brain Protection Science, Cancer and Blood Disorders Institute, Maternal Fetal and Neonatal Institute, and Heart Institute, including associated basic science laboratories; a vivarium; conferencing facilities; simulation laboratories; other educational facilities; and administrative offices for research and education faculty.

JHACH Pediatric Biorepository: Accredited as a Biorepository in 2014 by the College of American Pathologists, the Johns Hopkins All Children's Pediatric Biorepository is located adjacent to the hospital in the OCC. With an approximate footprint of 1,000 square feet, the Biorepository has current capacity for approximately 500,000 specimens in dedicated storage equipment remotely monitored 24/7 using NIST-certified TempTrak probes. All storage equipment is connected to critical power outlets, which are capable of supplying 21 days of emergency backup power through the JHACH dedicated Central Energy Plant in the event of power failure. The Biorepository also maintains liquid nitrogen reserves capable of maintaining required storage temperatures in the complete absence of power. All storage equipment is maintained in an environmentally controlled facility behind two sets of secured doors, accessible only by badge entry for Biorepository staff and senior management.

Additionally, the Biorepository uses the STARLiMs software system from Abbott Bioinformatics for operations, inventory control, and data management. STARLiMs is maintained and backed-up on a routine basis by the JHACH IT department. Downtime is minimized by contracted, 24/7 vendor support service and by maintaining separate development/test/production environments on devoted servers. STARLiMs is FDA 21CFR Part 11 capable from a systems-perspective, and the Biorepository's SOPs in regard to its use are designed to assure Part 11 compliance.

Current freezers and bioprocessing equipment are further itemized as follows:

Freezers: -86°C Hamilton Sample Access Manager (SAM) Robotic Freezers (n=3), -86°C ultralow freezer upright), -86°C chest freezers (n=2), LN2 Taylor Wharton 20k Freezers (n=2), -20°C upright freezer (reagent storage and staging of PAXgene tubes), 4°C Refrigerator (reagent storage), MVE Cryocart (transient storage for transport between freezers)

Bioprocessing Equipment: ChemagicSTAR Liquid Handling Automated Units (n=2, configured for DNA and RNA extractions), Nanodrop 2000 (UV spectrophotometry nucleic acid QC), Agilent TapeStation (DIN/RIN nucleic acid QC), Fume hood, Biological safety cabinet (level 2), Hereaus X3R Temperature Controlled Centrifuge (NIST calibrated) (n=2)