RESOURCES AND ENVIRONMENT

Entries in this section are divided by sections of the Research Plan, then by institution. Resources that are not specific to a particular section of the Research Plan are listed first under the **Overall** heading.

Contents

OVERALL

UNIVERSITY OF CHICAGO

University of Chicago

The University of Chicago, one of the nation's leading private universities, was founded by in 1892 by John D. Rockefeller. The University consists of four graduate divisions (Biological Sciences, Humanities, Physical Sciences, and Social Science), six professional schools (Pritzker School of Medicine, Divinity School, Graduate School of Business, Harris Graduate School of Public Policy Studies, Law School, School of Social Sciences Administration), the Institute for Molecular Engineering, and the College. There are 2,274 faculty members. Eighty-nine Nobel Laureates have been faculty members, students, or researchers at the University of Chicago. There are currently 171 members of the American Academy of Arts and Sciences and 44 members of the National Academy of Sciences on the faculty. The University has had past and present 34 recipients of a MacArthur Fellowship and 15 recipients of the National Medal of Science, and many faculty members who serve as advisors to governmental and policy-making bodies.

Biological Sciences Division (BSD)

The BSD is the largest of the University's four graduate divisions. The Division includes 23 academic departments, 13 interdisciplinary committees for graduate education, 14 externally funded centers of research, 5 major institutes and numerous ancillary support units. In the Division of Biological Sciences, the undergraduate and graduate programs in the Biological Sciences and the Pritzker School of Medicine are combined in a single academic and administrative unit, providing a favorable environment for research and the training of researchers through extensive support and encouragement of collaborations between translational and basic science faculty. There are 899 (281 basic science and 579 clinical, 26 clinical scholars, and 13 undifferentiated) faculty members and 351 postdoctoral trainees, 921 residents and fellows as well as 127 additional Research Associates (similar to Research Professor track at other universities) engaged in full-time research, teaching, and medical care within the Division. The BSD is the largest single component of the University of Chicago.

The BSD maintains a strong tradition of multidisciplinary and interdepartmental interaction, which augments its educational and research endeavors. The BSD not only contains the traditional academic departments found in most medical schools but also a number of research institutes (e.g., Grossman Institute for Neuroscience, Quantitative Biology, and Human Behavior, Institute for Biophysical Dynamics, Institute for Genomics and Systems Biology, Institute for Integrative Physiology), centers (UC Comprehensive Cancer Center, Diabetes Research and Training Center) and unique interdepartmental committees structured along programmatic rather than departmental lines. The BSD provides outstanding facilities and environment for graduate and postgraduate education and research including the recently erected Gordon Center for Integrative Science and the Knapp Center for Biomedical Discovery. The unique organization of the Pritzker School of Medicine within the BSD benefits both the students and faculty by offering opportunities for interdisciplinary research and collaboration between the basic science and clinical faculty, and for the faculty to teach in the Division and the medical school. The vast majority of Pritzker students engage in research during medical school, either as part of a formal degree program or in summer research programs, many obtaining a second graduate degree (PhD or MS) before graduating from medical school.

University of Chicago Medical Center

University of Chicago Medicine currently houses all of the hospital and clinical areas of the campus which include The Center for Care and Discovery, a state-of-the-art hospital with a focus on cancer, digestive diseases, neurosciences, advanced surgery and high-tech medical imaging, burn care, and transplant care; Bernard A. Mitchell Hospital dedicated to emergency medicine; Comer Children's Hospital, devoted to pediatric and maternal care; Duchossois Center for Advanced Medicine (DCAM), a state-of-the-art ambulatory-care facility with

the full spectrum of preventive, diagnostic, and treatment functions; and the University of Chicago Pritzker School of Medicine, one of the nation's premier medical schools. The UCM patient care system also includes physician offices in several Chicago locations, the suburbs, and northwestern Indiana and affiliations with several hospitals including LaRabida Children's Hospital (staffed by University of Chicago pediatricians), NorthShore University Health System and other hospitals. The UCM has a full range of specialty and primary care for adults and children, including the following notable programs: cancer, endocrinology, gastroenterology, geriatrics, heart, kidney disease, neurosciences, orthopedics, respiratory disease, surgery, transplantation and women's services. To provide outstanding patient care, investigate the cause and treatment of disease, and educate physicians and scientists, the medical center forms the clinical arm of the University of Chicago Division of the Biological Sciences. Special programs include: The Brain Research Institute, The Center for Clinical Cancer Genetics, The Center for Global Health, The Center for Personalized Therapeutics, The Great Lakes Regional Center of Excellence (GLRCE) for Biodefense and Emerging Infectious Diseases Research, The Gwen Knapp Center for Lupus and Immunology Research, Howard Hughes Medical Institute (for research in molecular biology and molecular genetics), Inflammatory Bowel Disease Center, The Institute for Biophysical Dynamics, The Institute for Genomics and Systems Biology, Joseph P. Kennedy, Jr. Mental Retardation Research Center, The Ludwig Center for Metastasis Research, The MacLean Center for Clinical Medical Ethics (considered the leading ethics training program in the United States), National Cancer Institutes-designated Comprehensive Cancer Center, National Institutes of Health-funded Clinical and Translational Science Award (Institute for Translational Medicine), National Institutes of Health-funded Clinical Resource Center (among the first such centers nationwide), and The Tang Center for Herbal Medicine Research.

Center for Care and Discovery (CCD)

The Center for Care and Discovery (CCD) opened in February 2013 and is dedicated to providing the most advanced health care to patients of today and tomorrow. The $700 million, 10-story state-of-the-art hospital focuses on cancer, digestive diseases, neurosciences, advanced surgery, high-tech medical imaging, burn care, and transplant care. The facility is designed for family-centered care and improved communication among all members of the patient's care team. The CDD brings together the best minds in research and medicine aided by the latest in technology. More than a building, it offers patients new and innovative medical therapies and an exceptional place for healing. Features of the hospital include: 240 private, light-filled patient rooms spacious enough to accommodate visiting family members, a Sky Lobby on the 7th floor -- with floor-to-ceiling windows and panoramic views -- that houses central reception, family waiting areas, a chapel, 24-hour dining areas and other public spaces, 21 operating rooms (with space for up to 28) designed to accommodate hybrid and robotic procedures, 52 intensive care beds, 7 advanced imaging suites for interventional procedures, and the latest in nurse-patient communications and remote health monitoring.

Comer Children's Hospital

The University of Chicago Medicine Comer Children's Hospital is a tertiary care teaching hospital dedicated to preserving the health of children through patient care, education, and research into the causes and cures of childhood diseases. Comer Children's Hospital is a major referral center operating 155 beds. The state-of-the art $130-million seven-story facility provides an ultra-modern yet child- and family-friendly setting for all inpatient children's health services at the University of Chicago Medicine campus. In addition, it includes one of the country's largest and most advanced newborn intensive-care units (47 Level-III beds, 24 Level-II beds). The hospital forms the center of a regional perinatal network that provides nine area hospitals with consultation as well as transport services for approximately 16,000 births, more than one-third of them considered high-risk. The network is committed to reducing fetal and infant mortality throughout the surrounding urban, suburban, and rural communities. In August 2016, a new Family Birth Center was opened in Comer. The new facility features 9 Labor/Delivery/Recovery rooms, 5 Triage Rooms, 5 Antepartum Rooms, 2 dedicated C-Section Operating Rooms, 2 Recovery Suites, and 2 Natural Birth Rooms. Dedicated physicians, nurses, and staff provide high quality mother-baby care. They offer nationally known programs in gynecologic oncology, minimally invasive gynecologic surgery, urogynecology, and reproductive endocrinology and infertility. Inpatient gynecologic

care is provided. They also offer in vitro fertilization (IVF) and other assisted reproductive care services at the Center for Reproductive Medicine and Fertility in downtown Chicago.

Duchossois Center for Advanced Medicine (DCAM)

The Duchossois Center for Advanced Medicine (DCAM), a six-story, 525,000 square-foot building, brings together most of the medical campus's diagnostic and outpatient treatment services. The building includes: 329 exam rooms, 90 rooms for outpatient procedures, including eight operating rooms for ambulatory surgery, two helical CT scanners that allow fast, detailed imaging and 3-D reconstruction, three state-of-the-art echoplanar MRI scanners, PET/CT scanner for cancer diagnosis and staging, a fully digital chest X-ray machine, a dedicated breast imaging center with computer-assisted diagnosis, direct digital linkage between radiology's X-ray image archives and clinics, and radiation therapy clinical systems and technology that includes four linear accelerators and two wide-bore CT simulators for precise dose planning and delivery. All four linear accelerators are capable of providing intensity modulated radiation therapy (IMRT). Two of the four linear accelerators can also perform image-guided radiation therapy (IGRT) as well as stereotactic radiosurgery (SRS). Both of the CT simulators are wide-bore units that can comfortably scan patients positioned with treatment set-up accessories, as well as plus-sized patients. State-of-the-art treatment planning software can fuse images from PET, CT, and other diagnostic modalities to facilitate precise planning. The DCAM provides the best possible setting for the healthcare of the future, bringing the latest medical technology and scientific know-how to each patient in the most convenient, efficient, and comforting environment imaginable.

University of Chicago Pritzker School of Medicine

The University of Chicago's Pritzker School of Medicine matriculated its first class in 1927. From the beginning the medical school has benefited from its relationship with the University as a part of the Division of the Biological Sciences. This relationship offers opportunities for interdisciplinary research and collaboration between the basic sciences and clinical staff, and for faculty to teach in both the Division and the medical school. Moreover, the medical school is an integral part of the University as it is set physically within the Division. This provides both students and faculty with easy access to the rest of the campus and its programs of study. Pritzker was #11 in the USNWR 2016 rankings for research intensive medical schools.

Argonne National Laboratory and the Marine Biology Laboratory at Woods Hole, MA

The University of Chicago is the steward of two major research institutions which are closely tied to strategic and programmatic vision of the Division of Biological Sciences – Argonne National Laboratory located in the western suburbs of Chicago and the Marine Biological Laboratory (MBL) at Woods Hole, MA. Both institutions provide training and learning opportunities to our members, particularly in the areas of microbial ecology and the gut microbiome, computational platforms for integration and analysis of large datasets, and innovative "-omic" technologies (metabolomics, proteomics, metagenomics, transcriptomics, and computational modeling). MBL has many educational and workshop meetings that are offered to University of Chicago personnel at a substantial discount. The STAMPS course ("Strategies and Techniques for Analyzing Microbial Population Structure"; for microbial bioinformatics, for instance, has been attended by several DDRCC full and associate members. (http://stamps.mbl.edu/index.php/Main_Page)

Institute for Molecular Engineering

The Institute for Molecular Engineering, established in 2011 by the University of Chicago in partnership with Argonne National Laboratory, is a transformational academic unit exploring the intersection of science and engineering. Building upon the University of Chicago's mission of cross-collaboration and cutting-edge research, IME's mission is to lead science and engineering research and education in new directions, solve technological problems of global significance, and continually inspire creative applications of molecular-level science. Assembling a team of world-class researchers across a broad range of science and engineering disciplines, the institute conducts research at the intersection of chemical, electrical, mechanical, and biological engineering as well as materials, biological, and physical sciences. The Institute's work exploring innovative technologies in

nanoscale manipulation, nanofabrication, and design at a molecular scale has the potential for societal impact in such areas as energy, health care, and the environment. This exciting new field involves the incorporation of synthetic molecular building blocks into functional systems that will impact technologies from advanced medical therapies to quantum computing. The institute's partner, Argonne National Laboratory, brings leading scientists and engineers and world class facilities to the endeavor, including the Advanced Photon Source, the Argonne Leadership Computing Facility, and the Center for Nanoscale Materials. The institute is the largest new academic program that the University has started since the founding of the University of Chicago Harris School of Public Policy in 1988.

Chicago Tri-institutional Center for Chemical Methods and Library Development

The mission of the Chicago Tri-Institutional Center for Chemical Methods and Library Development (CTCMLD) is to address the fundamental challenges of modern high-throughput organic synthesis and to provide major advances that will significantly facilitate the development of small-molecule libraries for broad biological screening. The Chicago CMLD is jointly supported by the NIH/NIGMS (P50 GM086145) and the Chicago Biomedical Consortium with support from the Searle Funds at the Chicago Community Trust (Lever Award). It bridges seven research groups from the three leading institutions in the Chicago area including University of Chicago, Northwestern University and University of Illinois at Chicago. The CTCMLD brings together exceedingly complementary expertise in organic synthesis, including Dr. Kozmin, Dr. Yamamoto and Dr. Rawal at the University of Chicago, Dr. Scheidt at Northwestern University and Dr. Gevorgyan at the University of Illinois at Chicago. In addition, the Chicago CMLD provides an effective mechanism for the cross-disciplinary integration of the core synthetic effort with the surface engineering expertise of Dr. Mrksich at Northwestern University and the cheminformatics expertise of Dr. Liang at the University of Illinois at Chicago.

Gwen and Jules Knapp Center for Biomedical Discovery (KCBD)

Opened in 2009, the 10-story Knapp Center for Biomedical Discovery provides 330,760 square feet of research space for groundbreaking initiatives and a state-of-the-art translational research programs in children's health, cancer, diabetes, digestive diseases, computational medicine, and other medical specialties. KCBD houses laboratories, offices and cores of the Digestive Diseases Research Core Center (DDCRC), the UC Comprehensive Cancer Center (UCCCC), the state-of-the-art computational and DNA sequencing facilities, the Institute of Genomics and Systems Biology (IGSB), the NIDDK P30 Diabetes Research and Training Center as well as the Kovler Diabetes Center, various Pediatrics Research laboratories, a gnotobiotic and mouse vivarium, and advanced imaging, mouse genetics, and core Genomics facilities.

Gordon Center for Integrative Science (GCIS)

The GCIS, completed in 2005, dramatically expanded space for research and teaching, and has been the home for many pre and post-doctoral trainees. Encompassing 480,000 gross square feet, the state-of-the-art laboratories of GCIS house 80 senior scientists and 700 investigators and students. The building is connected below ground to Cummings Life Sciences Center, the Kovler Laboratories, the Medical Center complex, and Crerar Library. Above ground, the facility is connected to Knapp Center for Biomedical Discovery and Knapp Biological Learning Center. Of the entire building, approximately 279,000 square feet are dedicated the biological sciences, with the remaining portion dedicated to the physical sciences. The building houses the Department of Biochemistry and Molecular Biology, the Howard Hughes Medical Institute, the Institute of Biophysical Dynamics, the Ben May Department for Cancer Research, the Materials Research Science and Engineering Center, the James Franck Institute and the Chemistry Department. In addition, it houses the newly developed graduate program in Biophysics. This initiative was cosponsored by the Divisions of Biological Sciences and Physical Sciences. Researchers from historically distinct, yet potentially complementary areas (e.g. biological and physical scientists working in fields ranging from condensed-matter physics and synthetic chemistry to complexity theory and cancer biology) benefit from increased interchange of ideas and ease of collaboration in this new facility. Faculty and students develop high-impact projects that are able to cross the boundaries between individual disciplines.

Cummings Life Sciences Center

The Cummings Life Sciences Center (CLSC) houses advanced biological research laboratories for the Departments of Molecular Genetics and Cell Biology, Microbiology, and Human Genetics are housed in this 11-story facility completed in 1974. The building has recently undergone major renovation and upgrading of each floor in a multi-million dollar project supported by the University. CLSC is located between the Medical Center complex, the Kovler Laboratories, the Crerar Library, and GCIS (just minutes from each, connected by underground tunnels).

Hull Court Complex

The Hull Court Complex is located a block away from the Knapp Center, is made up of four buildings: Zoology, Erman, Anatomy, and Culver. The Hull Court facility is a combined 134,000 gross square feet and houses the Departments of Organismal Biology and Anatomy, and Ecology and Evolution. The Department of Statistics is located next to the Erman Building.

Donnelley Biological Sciences Learning Center/Greenhouse

Donnelley Biological Sciences Learning Center / Greenhouse is a Learning Center that encompasses 124,000 gross square feet of space devoted to interactive teaching laboratories, classrooms, lecture halls, and specialized facilities for computer-simulated biological experimentation, and a rooftop research greenhouse. The facility is connected above ground to KCBD and the adjoining GCIS. The Learning Center underscores the University's commitment to Life Sciences. In addition, the Pritzker School of Medicine and the Office of Graduate Student Affairs are located in this building.

Kovler Laboratory Building

Kovler Laboratory Building is a 35,000 gross square foot building that primarily houses shared core facilities functions for the University of Chicago research community, including its cGMP Laboratory described below.

Shared Research Facilities

The BSD has a strong commitment to shared research facilities (cores) housing state-of-the-art technologies available to all research faculty, staff and students on campus. Each core facility is managed by a full-time professional Technical Director with oversight by a Faculty Director. The Technical Director and his/her staff oversee the day-to-day operation and also provide user training.

The BSD recognizes that core facilities are extremely valuable partners in our research efforts and require continued and significant investment. Two Divisional entities exemplify our commitment: 1) an active standing faculty committee (the Research Resources Oversight Committee) which serves as an institutional “board of directors” and meets monthly to advise the Dean on institutional investment of financial and space resources in the facilities, implement his recommendations, and review facility operations and 2) a centralized administrative support unit within the BSD Office of the Dean (the Office of Shared Research Facilities) which serves as the home department for the facilities. This operation is funded entirely by Divisional resources and provides operational management support, highly efficient fiscal management, HR support, grant support, and coordinated strategic planning for the facilities. In addition to these Divisional units, each facility is served by a Faculty Oversight Committee that addresses user satisfaction and requests for development of new services. Combined, this oversight structure provides expert supervision and responsiveness to faculty demanded services and innovations. Many of the existing BSD Cores were established with Divisional resources and continue to be underwritten with BSD funds which provide for new equipment, operational support for newly developed cores, dedicated information systems for data management and administrative support for the facilities. In addition to financial resources, the BSD has developed a strategic space plan to house shared resources. This continued investment in the facilities will ensure the facilities will remain at the forefront of the technologies they offer.

Cytometry and Antibody Technology (CAT)

The Cytometry and Antibody Technology (CAT) core facility was formed in 2012 out of the merging of the Flow Cytometry facility and the Frank Fitch Monoclonal Antibody Facility. The Scientific Director of the core is Dr. Anne Sperling, who has held the position for the last 14 years, and the Technical Director is Mr. David Leclerc, who has been with the core for a total of 11 years. The CAT contributes to the research efforts at the University of Chicago by providing cutting-edge technology for the measurement of cells and their products, the high quality monoclonal antibodies to maximize the benefits of that technology and expert research technologists to operate the instruments, and offer training and consultations on the proper protocols and practices. The facility is constantly exploring new development in the field of imaging and flow cytometry to ascertain the tools that will best benefit the research community. Currently, the facility houses A) five benchtop analyzers including two 4 lasers, 15 detectors BD Fortessa benchtop analyzers, one of which is equipped with and high throughput system allowing for the sampling of 96-wells plate, two BD LSRII, one equipped with 4 lasers and 12 detectors, the other with 3 lasers and 8 detectors, and a BD Accuri C6 instrument; B) three cell sorters including a BD FACSAria Fusion equipped with 5 lasers and 18 detectors and two BD FACSAria equipped with 4 lasers and 15 fluorescent detectors; C) an Amnis ImageStream Mark II for imaging flow samples; and D) our most recent acquisition, a Fluidigm Helios CyToF, which is a mass cytometer that can measure over 40 parameters on each cell. In addition to flow cytometry services, the CAT facility provides monoclonal antibody production, purification, and conjugation services. Further, the CAT maintains a hybridoma bank that provides large quantities of purified antibodies to the UChicago community at cost. Finally, the CAT provides site licenses for flow cytometry software and training in the usage of the software on site.

Genomics Core Facility

The Genomics Core Facility (GCF) is committed to providing University of Chicago biomedical researchers (ranging from experts in the field of genomics to those unfamiliar with whole genome and bioinformatics approaches) access to state-of-the-art on-campus genomics resources (data generating and data analysis). The GCF consists of two interactive data generating subunits, “Next Generation Sequencing and Microarrays” and “DNA Sequencing and Genotyping,” and collaborates with the Bioinformatics Core Facility. More specifically, the Core provides state-of-the-art microarray, DNA sequencing, and genotyping platforms with specialized databases for storing, managing, and manipulating both clinical information and diverse types of genetic and genomic data. Services are for biomedical researchers, as well as experts seeking sophisticated hardware, software, programming solutions, database solutions, or interdisciplinary collaborations. All genomic and bioinformatics analyses are completed at the highest possible speeds.

<u>Services</u>

- Next-Generation Sequencing (Lifetech SOLiD and Illumina)
- Microarray Services (Illumina, Affymetrix and Agilent)
- Sanger Sequencing (including plasmid preparation) and non-array based genotyping
- Real-time PCR services
- Agilent Bio-Analyzer validation of sample quality (RNA, next-generation libraries)

Human Immunologic Monitoring Facility

The Human Immunologic Monitoring-cGMP Facility provides service to clinical cancer investigators to prepare clinical-grade products, and to measure immunologic endpoints and other pharmacodynamic parameters in subjects participating in clinical trials. The facility serves as a specialized laboratory to perform scientific analyses that include: 1) evaluating changes in immune response parameters in response to immunotherapeutic interventions; 2) monitoring biologic effects of other pharmacologic agents using lymphocytes or other hematopoietic cell subsets as a surrogate tissue; and 3) preparing clinical-grade products, such as cancer vaccines, for administration to patients. The Facility also has flexibility to develop new assays when needed for specific scientific questions.

Services

- Preparation of peptide-based cancer vaccines
- Vialing of cGMP-grade peptides and quality control
- Isolation of specific cell subsets from PBMCs
- Isolation of T cell subsets from viably frozen tumor biopsies
- mRNA isolation and qRT-PCR analysis of gene expression profiling data in the tumor microenvironment
- Preparation of RNA sample from cells or tumor biopsies for microarray analysis
- Preparation of tissue samples for immunohistochemistry
- DNA, RNA, and microRNA isolation from in vitro stimulated T cells
- In vitro priming for antigen-specific CD8+ T cells
- ELISPOT for IFN-γ and other cytokines
- Peptide/tetramer or dextramer analysis
- Flow cytometric staining for specific T-cell subsets and activation markers
- PHA-induced T cell proliferation
- NK cell cytolytic activity
- Intracellular FACS analysis for cytokines and/or other proteins
- ELISA assays for specific factors in serum, plasma, and other body fluids
- Western blot analysis for specific signal transduction intermediates
- Data analysis, assistance in grant proposals, budget preparation

Transgenic Mouse/Embryonic Stem Cell Facility

The Transgenic Mouse and Embryonic Stem Cell Facility provides investigators with genetically manipulated mice through transgenic technology or embryonic stem (ES) cell manipulation. The Facility provides a comprehensive set of technical services and has a fully operational construction and gene targeting service.

Services

- Transgenic mouse production from founder through F1 Stage
- ES cell technology mouse production (e.g., knockouts, knockins, conditional knockouts)
- ES cell gene targeting and culturing
- Embryo rederivation
- Mouse embryonic fibroblast (MEF) cell production
- Timed pregnancies of various strains and lines of mice
- Various breeding services and genetically engineered mouse model line maintenance
- DNA preparation from ES cell lines
- Design and construction of transgenic or ES cell targeting vectors
- PCR and Southern blot analysis of existing ES cell lines and constructs
- Training in the breeding and handling of mice, isolation of genomic DNA from mouse tissues, and genomic DNA analysis through Southern blot hybridization

Pharmacology Core Facility

The Pharmacology Core Facility provides comprehensive lab services to support investigators conducting clinical and preclinical drug development studies. The Facility's Analytical Unit measures drug concentrations in patient specimens from clinical trials, and analyzes and models pharmacologic data. The Biofluids Unit integrates research phlebotomy, sample processing for studies requiring multiple and time-sensitive sampling, urine collection, sample storage, and tracking and archiving resources. The Pharmacology Core Facility complements the existing Human Tissue Resource Center (HTRC) and developing Epidemiology and Research Recruitment Core (ERRC) to provide a full range of consenting, biobanking, and analytic services.

Services

- Development and implementation of analytical assays for measurement of drugs and metabolites in biological fluids
- Pharmokinetic study design and writing assistance for clinical protocols
- Pharmacokinetic/pharmacodynamic analysis
- Research phlebotomy and intravenous cannulation
- Sample processing and urine collection
- Specimen storage, tracking, and shipping
- Research-related electrocardiograms on sponsor-provided machines

Integrated Small Animal Imaging Research Resource

The Integrated Small Animal Imaging Research Resource (iSAIRR) is a synergistically integrated infrastructure that offers a broad spectrum of imaging modalities and techniques for in vivo imaging of small animals and ex vivo imaging of tissue/organ specimens. The Facility's goal is to provide UChicago investigators with state-of-the-art, quantitative multi-modality imaging technologies to advance in-vivo molecular and physiological research of a broad range of disease and cancer models to accelerate pre-clinical development of novel therapeutics. Currently, iSAIRR subcores feature magnetic resonance imaging and spectroscopy (MRIS); optical imaging; micro-positron emission tomography, single photon emission computed tomography, and computed tomography (microPET/SPECT/CT); and veterinary technology (IVT) support.

Services

- Consultation to assist users in planning and designing experimental procedures and animal imaging protocols
- Instrument and procedural training
- Processing of acquired raw data to produce reconstructed/processed images
- Collaboration with the (Image Computing, Analysis, and Repository (ICAR) Facility to formulate special image analysis tasks
- Magnetic resonance imaging and scanning of tissues, cells materials, and animal models of cancer and ex vivo surgical specimens to provide information on 3D anatomy, hemodynamic parameters, tumor oxygenation, energy metabolism, metabolic markers, calcium dynamics, etc.
- Development and testing of new imaging contrast agents and new imaging methods
- Hands-on optical imaging (fluorescence and bioluminescence) or optical imaging services to assess gene expression, protein-protein interactions, tumor growth, vascularization, etc.
- CT, PET, and SPECT imaging of small live animals, tissues, cells, materials, ex vivo specimens, mummified or other specimens, including high-resolution detailed 3D anatomy by CT, quantitative metabolic imaging by PET, various functional/physiologic/molecular imaging using radiotracers by PET and/or SPECT
- Animal preparation and handling, induction and maintenance of anesthesia, performance of animal surgical procedures, physiological monitoring and recording during imaging sessions, injection of imaging probes/drugs/other interventions, physiologic sampling and measurements, catheter implantation, and inoculation of tumor cell lines

Integrated Microscopy Core

The Integrated Microscopy Facility functions as a supervised, user-based, hands-on core by providing state-of-the-art microscopy imaging capabilities to investigators through microscopy instrumentation, image analysis tools, and expert training and assistance. The Facility strives to provide high-quality optics and equipment that most labs do not possess, including confocal and state-of-the-art two-photon and STED superresolution spectral microscopes. Available techniques provided by the Facility include classic color histological stain imaging, contrast generation in unstained cells, and fluorescence technologies that allow for applications ranging from

localization of multiple targets to readouts of biochemical or physiologic parameters in either fixed or living preparations.

Services

- User training on microscopes and software
- Light microscopes with brightfield and fluorescence optics, including high-end objectives and technologies (color, phase contrast, differential interference contrast [DIC], multiparameter fluorescence including multiratio imaging and laser-based total internal reflection fluorescence microscopy [TIRFM])
- Digital image capture using high-resolution B/W and color charge-coupled device (CCD) cameras, high-sensitivity CCD cameras, and high-speed electron-multiplying CCD (EM-CCD) cameras
- Full-service digital slide scanning service for color histology and four-color fluorescence
- Access to high-grade objective lenses and specialized filters and optics
- Confocal microscopy including Leica two-photon and spectral systems (high-resolution, high-sensitivity, and high-speed image capture), and STED-CW superresolution microscopy
- Support systems for live sample maintenance and imaging
- Data analysis workstations (including Imaris and Huygens Pro deconvolution programs), storage, back-up, oversight, and maintenance
- Assistance in feasibility studies, grant applications technique/technology development, and compilation of data for presentations and publications
- New product demonstrations

Human Tissue Resource Center

The effective procurement, storage, distribution, and analysis of human biospecimens are of critical importance to the research mission of University. The Human Tissue Resource Center (HTRC) provides investigators with a centralized infrastructure to optimize the efficiency and costs related to research involving human biospecimens. The Core Facility provides a coordinated, centralized, and dedicated program for the procurement, processing, dispersing, and assessment of all types of biospecimens. The HTRC comprises four integrated subcores: biospecimen bank (BSB), laser capture microdissection (LCM), digital pathology, and histology services.

Services

- Biobanking of solid tissues, lymphocytes, and bodily fluids including saliva, urine, whole blood, plasma, serum, and derivatives
- Pathological verification and analysis of tissue samples
- Histological services including routine tissue formalin fixation, processing, paraffin embedding, microtomy, H&E staining, and immunostaining
- Tissue microarray (TMA) fabrication
- Laser capture microdissection (LCM)
- Quantitative image analysis of immunohistochemistry on conventional and tissue microarray sections, including quantification of nuclear, membranous, and cytoplasmic staining, rare event detection, TMA analysis, microvessel density counting, and histological pattern recognition

Animal Microsurgery Center

The Animal Microsurgery Center or AMC has been developed and affiliated with the Department of Surgery. This core provides strategic leadership; serves as a liaison to academic departments, professional organizations, and administrative units of the University; manage operations, staffing, and program development of the Center; helps set strategic goals; disseminates mouse and rat surgical techniques; trains laboratory and clinical research personnel in surgical procedures in the rodents; and collaborates with Animal Resource Center to oversee the establishment of goals and operating procedures, practices, and guidelines for the Center. The AMC provides investigators with mouse and rat surgical models, including:

- Transplantation models, including heart (first and secondary), kidney, pancreas, small bowel, liver, skin and islet
- Ischemic model: kidney, liver and heart
- Bariatric surgical procedures, including gastric banding, vertical sleeve gastrectomy, Roux-en-Y gastic bypass, DJB, biliopancreatic diversion with duodenal switch
- Cardiovascular and metabolic models: myocardial infarction, aortic hypertension, A&V catheterizations
- Cancer and immunological models: Barrett's esophagus, tumor implantation
- General procedures: IV injection, splenectomy, nephrectomy, catheterization, blood glucose tests (GTT) and diabetic models
- Develop surgical techniques and approaches according to the requirement by investigators

Biomolecular NMR Core

The Biomolecular NMR Core supports biochemical, biophysical, metabolomics research in the Biological Sciences Division at the University of Chicago. The facility houses two 600 MHz and one 500 MHz NMR spectrometers, which are properly equipped for most modern solution state NMR experiments. This includes a high sensitivity, cryogenically cooled probe on our Varian INOVA 600 spectrometer, single axis gradients and pulse shaping on all spectrometers, variable temperature capabilities (-50˚C to 150 ˚C), and automatic tuning and matching on our Bruker AVANCE IIIHD 600 and Bruker AVANCE III 500. Our automation capabilities include a 60 sample robotic sample changer (Bruker SamplExpress) and a Gilson sample preparation robot.

In addition to our state-of-the-art NMR spectrometers, we also provide expert assistance and training in solution state NMR spectroscopy. We can help you chose the experiments you need to run, teach you how to set up and optimize them, and assist with data processing and interpretation. We have an array of advanced processing software and computation facilities to assist with spectra interpretation. Our facility can help you solve the structure of large biological molecules, perform drug binding studies, identify protein-protein interaction sites, monitor biochemically important motions, or identify metabolites in a complex biofluid.

cGMP Laboratory

Cellular & Tissue-based Processing cGMP located in Kovler Laboratory is directed by Dr. Michael Millis. The purpose of the facility is to manufacture cell-based products and clinical grade reagents for treatment of patients, thus supporting investigators in meeting requirements set by the FDA for cell, gene and tissue translational therapies for Phase I, II and III human clinical trials. The cGMP facility provides a clean-room environment in which to transition research from the laboratory bench to clinical phase trials. This subcore was developed in 2001 to accommodate the growing number of clinical trials that require highly manipulated cellular products for patient treatment. The cGMP facility is registered with the FDA in accordance with 21 CFR part 1271. This registration complies with federal regulations that require clinical facilities engaged in production of cellular products follow strict guidelines to minimize microbial contamination and manufacture cellular-based products that are sterile and potent for their intended purpose. The facility is capable of providing a range of services dedicated for supporting cellular based therapies including vaccines for patient treatment.

Advanced Electron Microscopy Facility

A primary mission of the Advanced Electron Microscopy Facility is to develop techniques for preserving cellular structure with the highest degree of reliability. These techniques involve different methods for rapidly freezing our samples in order to halt structural and biochemical activity in a very short timeframe, thus preserving structure in the "live" state. Once the sample is preserved in the "live" state, it is then possible to study the ultrastructure of these samples using not only basic Electron Microscopy imaging techniques, but also state-of the-art techniques such as: 1) 3-D electron tomography, and 2) immuno-cytochemistry.

Center for Electron Paramagnetic Resonance (EPR) Imaging in Vivo Physiology
The Center for Electron Paramagnetic Resonance (EPR) Imaging in Vivo Physiology at the University of Chicago, is a National Institutes of Biomedical Imaging and Bioengineering and NIH supported technology development resource. The aim of the Center is the development of new imaging technologies sensitive to the functioning of the normal and diseased tissues of living animals. The main focus of the Center is accurate and efficient imaging of molecular oxygen concentration in tissues. The Center's imaging technology exploits the unique, quantitative sensitivity of the EPR spectrum of soluble, injectable spin probes to crucial aspects of the fluids in which life processes evolve. The Center develops EPR instrumentation, spin probes and imaging methodologies. We use very low frequency EPR technology to maximize the depth in animal tissue to which the technique is sensitive. We have developed a wide range of methodologies to extract this information including pulse, continuous wave and Rapid Scan methodologies.

IBD NanoBiology Facility
The IBD NanoBiology Facility is a new interdisciplinary core research facility for the development and application of advanced nanoscale microscopy measurement techniques to biological and biophysical systems. In addition to atomic force microscopy (AFM) scanning probe instruments, we are actively developing nonlinear confocal time-resolved fluorescence microscopies for Fluorescence Lifetime Imaging (FLIM), Fluorescence Energy Transfer (FRET), and Fluorescence Correlation Spectroscopy (FCS) in single molecular, cellular, and bulk regimes. These methodologies are excellent for noninvasive determination of phenomena such as binding, quenching, energy transfer, ion concentrations, pH, protein conformations, etc. We are also developing a Coherent Anti-Stokes Raman Scattering (CARS) confocal microscope that is sensitive to molecular vibrations, thereby enabling tag-free truly noninvasive imaging and chemical identification due to contrast mechanisms based on intrinsic molecular properties both in vitro and in vivo

University Computing Organization
The centralized University Computing Organization (UCCO) provides facilities and services to meet the needs of the faculty, students and staff. This is achieved by maintaining a system that incorporates individual workstations, departmental mainframes, standard operating and networking systems, as well as access to increased computing capabilities when necessary. The organization if comprised of several departments that are each responsible for service in a different area including Academic and Public Computing, Networking and Large Scale Computing, Administrative and Library Information Systems, and the Campus Computer Stores. UCCO provides support for instructional computing, research applications, public clusters and user support, as well as network services such as electronic mail, Internet, BITNET and access to high quality laser printers. The computer resources currently available include the principal investigator's PC (state of the art processor and essentially unrestricted memory and located in the investigator's office) with full access to the campus networks, and a wide range of state of the art software for data management and statistical analysis (i.e. SAS, STATA, Minitab, and S-Plus).

High-throughput Next Generation DNA Sequencing
Collaborations between the University of Chicago and Argonne have promoted considerable advances in developing and analyzing data from high-throughput molecular-based approaches to study microbial community structures, centered on the application of next generation sequencing (NGS) approaches, which fall under the rubric of the IGSB. The massively parallel capabilities of these platforms (Illumina) have targeted the variable regions of 16S rRNA for deeper and more cost-effective analysis of microbial communities, particularly in detecting minor changes between biological samples, and have also been applied to shotgun metagenomics.

The Institute for Genomics and Systems Biology's Next Generation Sequencing Core (IGSB-NGS) at Argonne National Laboratory is a state-of-the-art facility for ultra-high throughput sequencing. The NGS Core maintains both Illumina HiSeq2000 and MiSeq next generation DNA sequencing platforms. The Illumina HiSeq2000 generates over 6 billion reads at 150 bp in length per read resulting in over 600 Gb worth of data across sixteen

lanes available per run. The Illumina MiSeq generates over 24 million reads at 150 bp in length per read resulting in over 4.5 Gb worth of data available per run (over a single lane). Applications on both the Illumina HiSeq2000 and MiSeq include: shotgun metagenome sequencing; rRNA-based amplicon library sequencing; and genome sequencing and resequencing.

High-throughput Genome Analysis Core

The IGSB's High-throughput Genome Analysis Core (HGAC) is a state-of-the-art facility for ultra-high throughput sequencing and large scale microarray processing. The Core is housed in Argonne's Computing, Environment and Life Sciences (CELS) directorate, providing world class computation power, software, and expertise critical to the acquisition, analysis, and interpretation of the unprecedented volume of genetic information being generated on next generation genomic platforms. The core provides resources and services to University of Chicago users, Argonne National Laboratory users, and to the broader scientific community. HGAC is involved in a broad range of scientific research from the sequencing of metagenomic samples to defining transcription factor binding sites through tiling microarrays and next generation sequencing.

Proteomics Core Facility

The Proteomics Core Facility, located in 161 CLSC and directed by Dr. Stephen Kron, is a proteomics and informatics facility dedicated to the characterization of proteins and peptides. To provide the researchers at the University of Chicago with the latest technologies in mass spectrometry and proteomics, the facility has implemented a regional core model. This facility utilizes the state-of-the-art mass spectrometry resources at two neighboring universities in the Chicago metropolitan area; the Proteomics Core at Northwestern University and the Proteomics and Informatics Services Facility (PISF) at the University of Illinois at Chicago. Mass spectrometry instrumentation available includes: Northwestern Proteomics Core (Thermo Orbitrap-Velos with ETD). The PISF facility at UIC currently has (Thermo Orbitrap-Velos with ETD), (Thermo FT-LTQ Ultra (7T magnet) with ETD), (Thermo LTQ-ion trap), (Agilent 6420 Triple Quad), (ABSciex 5500 Triple Quad), (ABSciex 4700 MALDI-TOF/TOF), and an (ABSciex Voyager DE-Pro MALDI-TOF). The University of Chicago Proteomics Facility offers a full range of services from simple MW determination to protein identification and quantitation. This facility handles everything from sample preparation, expediting samples to the various reference labs, MS data retrieval, proteomics data processing, informatics and spectra analysis. This facility provides proteomic project consultation ranging from the routine, shotgun bottom-up proteomics to the advanced, PTM identification and quantitative proteomics (SILAC, 18O, iTRAQ).

<u>Available instruments:</u>

- ABI 4700 Maldi TOF/TOF MS
- Maldi Based, Non-chromatographic research grade instrument.
- Capable of TOF (linear and PSD) and TOF/TOF (CID mode) operation.
- Suitable for High Throughput Operation (Offline LC-MALDI)
- Protein ladder sequencing, protein ID, protein expression, biomarker discovery, protein chip based analysis.

Biophysical Core Facility

Biophysics directed by Dr. Tobin Sosnick and located in W102 Center for Integrative Science, is to provide unimpeded access to state-of-the-art and well maintained biophysics equipment, integral to the research community at the University of Chicago. The equipment allows measurement of thermodynamic properties including stability using CD spectrometry, and binding constants using analytical ultra-centrifugation, and ITC calorimetry. Secondary structure content can be studied by CD spectrometry which also can monitor conformational transitions. Over-all size and shape can be determined from rotational correlation times measured using light scattering or time-resolved fluorescence anisotropy.

Brain Research Imaging Center
Brain Research Imaging Center is located in the AMB, Q-300 suite of the Medical Complex, houses a research-dedicated Philips Achieva Quasar Dual 16 Channel 3T MRI scanner. The 3T facility delivers cutting edge whole-body imaging and spectroscopy with real time control of RF transmission, gradient switching, data acquisition and triggering. The 3T facility has the necessary auxiliary equipment for brain functional MRI (fMRI), including the devices for presenting visual and auditory stimuli to people undergoing fMRI scans and the devices for recording their behavioral and physiological responses. The 3T facility plays an important role in the work of a number of departments and crosses University Divisional boundaries with impact on both the Biological and Social Sciences. Associated with the 3T facility is an excellent group of researchers working to develop magnetic resonance imaging methods and apply them to the whole University research community.

Electron Microscopy Facility
Electron Microscope, Cryopreservation and Tomography facility is a joint BSD/PSD facility co-directed by Dr. Joseph Austin and Dr. Norbert Scherer. Users have access to an FEI Tecnai F30 scanning/transmission electron microscope. The facility is located in ESB23 in the Center for Integrative Science. The group provides preparation and viewing services for transmission electron microscopy. Physical Science services include: phase-contrast TEM imaging which provides information on materials structures at atomic resolution; diffraction contrast imaging which is used for morphology and defect investigation; STEM Z-contrast imaging which presents information not only on crystal structure but also on chemical composition at atomic resolution; electron diffraction that can be used for crystal structure and orientation investigation; elemental analysis using X-ray energy-dispersive spectrometry; and tomography for 3D structure determination. Biological Science services include: tissue embedding; sectioning; immunogold-labeling; negative staining; and imaging. A special strength of the facility is EM tomography of samples prepared by high-pressure freezing allows accurate three-dimensional reconstruction of biological samples at 5 – 7 nm resolution. This method is proving to be indispensable for understanding how molecular structures are linked to cellular architecture and function. An added benefit will be the capacity to perform high-quality immunoelectron microscopy of rapidly frozen samples.

Functional Genomics Facility
The Functional Genomics Facility provides resources for investigating gene function with a focus on applying microarray and oligonucleotide technology. Individuals from the University of Chicago and other institutions contribute a broad scope of talents to the robust interdisciplinary environment necessary for pursuing modern biomedical and molecular genetics research. As a service facility the FGF provides expertise and equipment for all phases of array- and chip-based research, ranging from sample preparation through to data analysis and management. As a research facility, the FGF pursues various research and development projects, including oligonucleotide array design.

Human Tissue Resource Center/Biobank
The development of new immune-based therapies, such as cancer vaccines and novel cytokines, and the elucidation of the mechanism of action of currently available treatments, require careful monitoring of scientific endpoints to determine the optimal biologically active dose and schedule of these agents. The purpose of the Human Immunologic Monitoring Facility is to perform such assays in the context of clinical trials in human patients. This service enables a range of clinical researchers, who may not themselves have the expertise or laboratory commitment to carry out these assays, to measure immunologic endpoints in participating study subjects.

Institute for Biophysical Dynamics Nanobiology Core
The Institute for Biophysical Dynamics Nanobiology Core provides atomic force microscopy, CARS microscopy, and nearfield optical microscopy capabilities and assistance.

MRIS Imaging Facility
The MRIS Imaging Facility contains a 4.7T magnet for imaging and model systems to investigate mechanisms of disease and aid in the design of methods which can later be implemented on clinical systems. In addition, the facility provides an important teaching resource, aiding graduate students, residents and postdoctoral fellows to develop a thorough understanding of all areas of biomedical research and provides a powerful new research tool for investigators throughout the University campus.

NMR Facility
NMR Facility. High-resolution nuclear magnetic resonance (NMR) spectroscopy provides detailed information on the three-dimensional structure, dynamics, and interactions of biological macromolecules in solution. This facility houses two 600MHz and one 500MHz NMR spectrometers that are capable of performing most demanding solution NMR experiments for proteins and nucleic acids.

Protein Peptide Core Facility
The Protein Peptide Core Facility provides advice and services pertaining to: Peptide Synthesis, Protein Sequencing, Mass Spectrometry, Amino Acid Analysis.

Scientific Visualization and Image Analysis Core Facility
The Scientific Visualization and Image Analysis Core Facility is a shared facility designed to provide high speed and parallel processing capabilities and hardwired 3D visualization and virtual reality capabilities to researchers at UChicago.

IT Services and Emerging Technologies and Communications

IT Services is the central IT organization for the University of Chicago, providing data center services, networking services, enterprise applications, web and mobile application development, academic and research support, end user support, and technology consulting for the campus community. We are a group of approximately 300 technology professionals, including developers, project managers, business analysts, security pros, support specialists, and consultants, among many others. Units in the organization report to the Chief Information Office of the University. Clients of IT Services include all major schools and divisions, the university medical center, all administrative units, as well as dozens of institutes and labs.

Emerging Technologies and Communications is a division of IT Services and comprises approximately 30 staff, including front end developers, application programmers, project managers, strategists, and consultants. The group reports to the Sr. Director for Emerging Technologies and is managed by an Assistant Director and 4 functional Managers. The team operates under a recharge model, recuperating overhead costs through project fees. Projects include general website development, custom web application development, mobile development, cloud service implementation and management, technology consulting, business analysis and information architecture, and general project management.

University of Chicago Library Resources

Brief Overview of the Biomedical Collection
Since the merger of the University of Chicago science libraries with the John Crerar Library in September 1984, the John Crerar Library at the University of Chicago is considered the central location for the biological sciences and medical collections. Rare biomedical materials, manuscripts, and archives are housed in the Special Collections Research Center, located in Regenstein Library. The biomedical/medical sciences collections include scientific research and scholarly publications in the basic and clinical biomedical sciences, and publications and other information resources useful in an academic medical center and clinical care institution. Print and digital collections of journals, books, and other information resources are developed to support the research, instructional, and clinical and patient care interests of faculty, medical students, residents, fellows, and staff of the University of Chicago Biological Sciences Division (BSD), the Pritzker School of Medicine, and

the University of Chicago Medical Center. The Library provides a steadily increasing number of electronic journals and, as funds allow, their electronic backfiles, as well as other electronic resources and Internet-based clinical information services developed by biomedical publishers, professional societies, and various vendors. Dr. Michelle Bass of the Crerar Library will support the ITM in bibliometrics.

John Crerar Library Journal Collection
Total number of science journals and current print/electronic ratio – 25,000 (estimate). Ratio 20/80 (estimate). Total number of biomedical journals and current print/electronic ratio—15,860 (estimate)—includes electronic serials received but not purchased that are freely accessible. (/Ratio 10/90)

The Joseph Regenstein Library Collections
The Joseph Regenstein Library is home to over 4.5 million print volumes focusing on subjects in the humanities and social sciences, as well as business, divinity, and area studies. Regenstein's bookstacks are freely browsable by the University of Chicago community. Currently the Library has 92 print subscriptions in philosophy; and approximately 434 electronic titles that are indexed in various social science indices related to philosophy.

The D'Angelo Law Library Collections
The D'Angelo Law Library has collections of over 700,000 volumes in print and other formats, including the primary laws of the United States and all fifty states, foreign, comparative and international law, legal commentary on a variety of topics, and resources in other disciplines of interest to law researchers. The University of Chicago Library subscribes to hundreds of electronic indexes and full-text databases available to library users on campus.

Interlibrary Loan
The Interlibrary Loan Service is made available without charge for University of Chicago faculty and students for any materials the Library doesn't own. University of Chicago faculty members are eligible for access and borrowing privileges at all libraries on Northwestern's Evanston campus, as well as the libraries of the University of Illinois-Chicago. Faculty can also access the library collections of several Hyde Park seminaries. The University of Chicago is a member of the Center for Institutional Cooperation (CIC), which allows faculty to use libraries at Indiana University, the University of Wisconsin-Madison, and several other institutions.

RUSH UNIVERSITY

Rush University Medical Center

General Description. Rush University Medical Center (RUMC) is an academic medical center comprised of Rush University (Rush Medical College, College of Nursing, College of Health Sciences and the Graduate College), Rush University Medical Center (600 operating beds), Rush Oak Park Hospital (176 operating beds), Johnston R. Bowman Health Center for the Elderly (79 operating beds), and four affiliated hospitals. RUMC has extensive programs in patient care, education, research, and community service. RUMC is affiliated with a number of Chicago-area hospitals and patient care institutions, including Cook County Hospital and Health System, which is adjacent to Rush. The Rush academic network includes 16 colleges and universities in six states. RUMC is the apex of a comprehensive health delivery system designed to serve some 1.5 million people both through its own resources and through its affiliation with community health care institutions in Illinois and Indiana. It is a focal point for merger between the basic scientist and clinician in a multi-disciplinary arena. The traditional setting of intense interaction between scientist and clinician inherent within the administrative structure of the RUMC is underscored by the fact that clinical faculty and basic science faculty are equal members of a single faculty. Collaboration between the clinician and basic scientist is the norm within the environment.

Purpose. The vision of RUMC is to be "the leading academic health system in the region and nationally recognized for transforming health care." To achieve its vision, RUMC is dedicated to "providing the best care for the individuals and diverse communities served through the integration of patient care, education, research and community partnerships." Core values to achieve the mission include innovation, collaboration, accountability, respect and excellence.

Research Mission. Research at Rush is dedicated to the pursuit of outstanding biomedical research to advance knowledge and optimize patient care.

Office of the Associate Provost for Research

RUMC is committed to fostering centers of excellence that combine clinical, basic and population science to study areas of importance to the community. Several programs have been created to support and encourage RUMC investigators involved in more than 1,600 research studies, including trials of new medical and surgical therapies.

Under the direction of the Associate Provost for Research, RUMC's research infrastructure includes, but is not limited to, people, processes, and policies regarding research management, scientific cores, and other institution-wide research tools, resources, and plans.

Clinical Research Administration Division

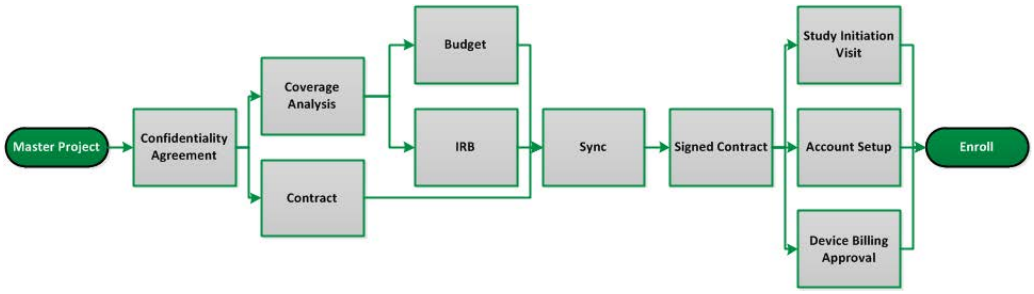
The Clinical Research Administration Division (CRAD) within the Office of Research Affairs facilitates the financial and operational aspects of clinical research across the campus at Rush. This team partners with and supports the Cancer Clinical Trials Office (see further details below). The CRAD team supports investigators in the following ways:

- Clinical Research Finance Support
    - Coverage Analysis Development
    - Medicare Submissions for Investigational Devices
    - Contract Negotiation in partnership with Legal
    - Budget Development and Negotiation*
    - Industry Sponsor Invoicing
    - Synchronization (Sync) Process
- Clinical Research Core Support
    - Clinicaltrials.gov application support
    - Monthly Education Sessions
    - Regulatory Coordinator*
    - Research Nursing Support*
    - Study Coordinator Support*

*These resources are limited, but growing.

Clinical Research Finance

Clinical Research Finance facilitates the timely execution of coverage analysis, clinical trial budgets, sponsor agreements, and sponsor invoices. This process includes the review of Confidentiality Agreements and Clinical Trial Agreements, creation of Coverage Analysis and assistance with budget negotiation. They complete an internal review of all study documents prior to institutional endorsement to ensure our informed consent documents for research subjects is in agreement with what was negotiated with the study sponsor. Once a Clinical Trial Agreement has been executed, they initiate the set-up of the research study account that is executed by Corporate Finance, and they create sponsor invoicing grids to ensure timely invoicing and payment for all industry sponsored research. The key steps in the study start-up process (this is not all-inclusive) are depicted in the diagram below.



Sponsored Programs Administration

Sponsored Programs Administration (SPA) within the Office of Research Affairs (ORA) provides assistance to faculty and staff in obtaining and managing sponsored awards that support research activities. SPA is charged with reviewing and approving proposals submitted to all sponsors, for interpreting, negotiating, and accepting grants and contracts for sponsored programs funded by federal and state agencies, foundations and other public agencies, and providing guidance to assure proper stewardship of funds that are received. In addition, SPA prepares and negotiates sub-awards for collaborative research.

Their mission is to provide superior guidance and support to faculty, staff, and administration in the pursuit of funding and collaborations for research, education and outreach.

Rush Research Portal

The Rush Research Portal (RRP) located at https://rrp.rush.edu/researchportal is a better way to manage all aspects of the research submission process. All new studies will be submitted electronically through the RRP. IRB studies that were active prior to September 17, 2007 (legacy studies) have been uploaded into the system.

One of the many benefits of the RRP is it is accessible via the Internet, allowing a streamlined approach to the submission, review and approval of research projects, even if the necessary people are not physically here at Rush. The system will notify department approvers, IRB staff and/or other study staff as the project advances through the system. This process eliminates the need to submit 13 paper copies of studies to the IRB.

New components to the RRP are available. Coverage Analysis, Grants and Contracts can now be created and submitted through the RRP. This will allow an even more efficient process linking the IRB study, Coverage Analysis, Grants and Contracts in one central location. A Clinical Trials Management System is currently being implemented and should be going live in the near future.

Additionally, all users are required to complete their mandatory training prior to having their study reviewed by the IRB. The mandatory training is accessible through the Rush Leap On-Line system.

Division of Innovation and Technology Transfer

The Innovation and Technology Transfer (I&TT) division within the Office of Research Affairs (ORA) is responsible for managing the intellectual property assets generated by research and educational activities at Rush. The I&TT division seeks to guide early stage innovation through the various stages of the academic technology transfer process by providing services that include evaluation, protection, marketing, and licensing of intellectual property.

The I&TT division protects faculty interests while advancing discoveries toward commercial development. A high-performance team with a broad range of expertise provides a full suite of support services to ensure Rush inventions reach their fullest potential. The I&TT division assists Rush faculty by:

- evaluating research results and inventions for patentability and navigating it through the patenting process
- protecting intellectual property while preserving academic priorities, interests and values
- effectively transferring discoveries and inventions from the laboratory into commercial development
- helping form collaborations with industrial partners for new sources of research sponsorship
- negotiating license agreements to ensure the development and commercialization of technologies

The I&TT division is passionate about its role at Rush and continues to endeavor to ensure Rush has a strong impact on the next generation of biomedical technologies that will improve patient lives.

Research Cores

All the scientific cores have pricing structures that are advantageous for Rush investigators and will therefore allow greater productivity per grant expenditure than comparable external facilities operated by neighboring universities or commercial laboratories. With rare exceptions, investigators can receive training to operate these facilities independently, thereby reducing the labor charges associated with larger projects.

MicroCT/Histology Core

MicroCT is a non-destructive, x-ray based means of constructing three-dimensional images of objects with natural or contrast-enhanced radio-opacity. The laboratory has been used by intramural and extramural researchers for ex vivo three-dimensional imaging of bone, cartilage, nerve, vascularity, and various biomaterials by PIs from Rush and several universities across the U.S. There are two scanners in the lab. The microCT40 (Scanco Model 40) has a nominal best resolution of 6 □m with a real resolution of ~9 um (45-70 kVp); reconstructed image matrix of either 1024 x 1024 or 2048 x 2048; field of view up to 37 mm and maximum scan length of 7 cm. The microCT50 (Scanco Model 50) has a nominal best resolution of 0.5 µm with a real resolution of ~1 µm (40-90 kVp) and a maximum scan length of 16 cm and field of view of 48 mm. Reconstructed image sizes can be as large as 8190 x 8190. Both instruments have an open VMS operating system; complete imaging software for data acquisition, online/offline reconstruction, 3D visualization and animation, and 2D and 3D trabecular bone histomorphometry, database for tracking specimen processing and archiving. Images can be exported in DICOM and TIFF formats and the histomorphometric data can be readily downloaded to spreadsheets. The histology part of the core provides support for preparing ground or thin sections from plastic-embedded, undecalcified bone specimens (often containing a metal implant), as well as paraffin sections from decalcified specimens. The lab also has the ability to perform histochemistry and immunohistochemistry.

Flow Cytometry Core

<u>Instrumentation</u>

The Rush University Medical Center flow cytometry core facility currently operates four Becton-Dickinson instruments: one dual-laser FACSCalibur, one three-laser FACSCanto II, one three-laser BD-LSR II analyzer and one four-laser BD LSRFortessa. The FACSCalibur flow cytometer is an end user-operated instrument with two lasers, permitting measurement of four fluorescent and two light-scatter parameters. Trained users prepare and acquire/analyze their own samples using a Macintosh G4 computer and either CellQuestTM or FlowJo software. The FACSCanto II flow cytometer is an operator-assisted instrument with three lasers (405 nm, 488 nm, and 633 nm), permitting measurement of eight fluorescent and two light-scatter parameters. The LSR-II flow cytometer is a three-laser (405 nm, 488 nm, and 633 nm) instrument capable of measuring up to twelve parameters (10 fluorescent and 2 light-scatter), and is operator-assisted. The LSRFortessa flow cytometer is a four-laser (405 nm, 488 nm, 561 nm, and 640 nm) instrument capable of measuring up to eighteen parameters (16 fluorescent and 2 light-scatter), and is operator-assisted. Trained users bring prepared samples to the facility and are assisted on their acquisition/analyses using the PC-based FACS DiVa or analyses using Macintosh-based FlowJo software. Multiple analysis workstations are available for the purpose of post-acquisition

analyses. These workstations offer both PC- and Macintosh-based analysis and are installed with software for both FlowJo and FACS DiVa software. The facility staff will train investigators in the use of data analysis software programs for the purpose of data reanalysis or graphics production.

Services

- Immunophenotyping
- Cell viability/apoptosis
- Intracellular protein staining
- Multiplex assays for detection of cytokine and chemokines
- Cell tracking and proliferation
- Cytotoxicity
- DNA or RNA analyses

Proteomics Core

The Rush Proteomics Core (RPC) provides a comprehensive range of services for the design, execution and analysis of proteomics research. Applications include the identification of proteins and antigens, serum profiling and discovery of novel disease biomarkers, analysis of post-translational modifications, characterization of protein-protein interactions, and identification of molecular pathways involved in health and disease. The RPC supports the research of both junior and senior investigators and assists clinical/translational researchers in conducting laboratory procedures. RPC services include:

(1) Consultation on experimental design, post experiment analysis and guidance on the most appropriate experimental platform for specific research objectives and data interpretation.

(2) Training for self-service and performance of procedures as needed. RPC personnel participate in several graduate-level courses to introduce basic proteomics methodology to students and young investigators.

(3) Protein chemistry services include sample preparation from simple and complex mixtures including serum, cell lines and tissue, as well as extraction of diverse proteins from human and animal sources, using standard isolation, enrichment and solubilization methods. The RPC develops protein fractionation protocols and provides assay development as needed. Proteins are separated and detected using one- and two-dimensional gel electrophoresis and one- and two-dimensional HPLC, Western blot, and image acquisition and bioinformatics analysis.

(4) Production and purification of recombinant proteins is performed using E. coli. The recombinant proteins will be purified up to 95 % purity using multi-stage purification processes including affinity, size exclusion and ion exchange columns per the investigator request.

(5) ELISA assay for biomarkers, hormones, proteins and lipids from many biological fluids. RPC can perform any commercially available ELISA assays for precise measurements of biological components.

The facility also provides bioinformatics support using analytic software for gels and Western blots (BioRad), biomarker discovery algorithms, protein database searches, and analysis of data from glass microarrays, as well as data analysis for the Affymetrix gene chip platform. An in-house Linux system is routinely used to analyze and store data. Bioconductor, based on the R statistical program, is used for microarray and proteomic data analysis, and we have the ability to write R programs for custom method development. Most of the NCBI tools for genomic data analysis are installed, including several Blast programs and sequence retrieval/analysis programs. The Core is also linked to the nearby University of Illinois Research Resources Center (RRC) for additional resources such as a Fourier transform mass spectrometry.

Biomarker Development Core (RBDC)
The Biomarkers Core provides a cost-effective means to evaluate protein biomarkers (such as cytokines, growth factors, and autoantibodies) in any biological specimen, including serum, plasma, synovial or cerebrospinal fluids, urine, tissue or cell lysates, and conditioned media. All evaluations can be performed with either absolute or relative quantitation, and will be performed using the Luminex xMAP immunobead platform by highly-experienced experts trained by the Luminex Corporation. This platform permits simultaneous quantification of up to 500 analytes from low microliter volumes of sample. Early disease detection and monitoring of disease progression and treatment response are principal applications. Commercial kits are available for a wide array of potential analytes by multiple partners of the Luminex Corporation. Services range from performance and analysis of existing assays by facility personnel to custom assay development/validation for virtually any protein. Further, we can also work in concert with the Rush Proteomics Core toward identification of novel biomarkers and their translation to the Luminex platform for validation purposes and routine evaluations.

microRNA and Gene Expression Core
The microRNA and Gene Expression Core is intended to facilitate research on the molecular pathogenesis of disease leading to drug target development, molecular diagnosis, and molecular monitoring of treatment efficacy. MRGEC is equipped with the Applied Biosystems HT7900 RT-PCR, which accommodates 384-well plates and has fully robotic automatic loading capability. DataAssist data analysis software is used. Supporting apparatus such as a NanoDrop DNA/RNA/protein spectrophotometer and a full range of electrophoresis equipment, together with the BioRad GelDoc XR gel analysis and documentation system, are also available. The services provided by MRGEC covers all aspects of miRNA and gene expression analysis, from DNA/RNA/miRNA preparation, to microarray miRNA and gene profiling, functional annotation analysis, and validation studies. It facilitates research at all levels, from clinical diagnostic studies to cutting-edge basic, discovery research. The MRGEC facilitator and staff provide consultations to help researchers, especially newcomers to genetics and molecular biology studies. The spectrum of support ranges from investigator training in operation and troubleshooting of the apparatus to experimental design/optimization. MRGEC encourages collaborations with researchers, and will provide support to researchers during their grant application and help enhance their grant components of miRNA and gene expression studies.

Live Animal Imaging Core Facility

Program Statement and System Capabilities.
The IVIS Lumina II imaging system allows monitoring of cellular activity (quantitative) through bioluminescent or fluorescent reporters in live mice or rats. This system can be utilized to identify tumor development in studies aimed at dissecting the molecular genetics of several types of cancer using mouse or rat models. The imaging system allows the use of a smaller cohort of animals for the research as animals do not need to be sacrificed to ascertain the presence of tumor lesions. The system offers non-invasive longitudinal monitoring of:

1. disease progression (e.g., tumor progression and metastasis)
2. tumor response and recurrence
3. cell trafficking and gene expression patterns in living animals
4. drug metabolism genes due to either the parent molecule or its metabolites.

A potentially greater use of this imaging system is in translational research involving therapeutic trials using animal models for disease. It is hypothesized that compounds with demonstrated efficacy on tumors developed 'in situ' in animal models will have a higher success rate after translation to the clinic, as these scenarios will more faithfully recapitulate the conditions under which human tumors grow. The ability to image tumors 'in situ' rapidly and with high sensitivity using the IVIS imaging system, and the correlation between tumor size and the amount of emitted light, indicate that the IVIS imaging system provides a mechanism to rapidly evaluate potential therapeutic compounds. The imaging system can be likewise applied to any other disease state in which disease burden can be quantified (e.g. the number of bacteria in the systemic circulation). Other important ap-

plications include: infectious disease, inflammation, gene therapy, stem cell biology, cardiovascular diseases, immunology and transplantation biology.

System Specifications

The system comprises a light-tight imaging chamber, a high-sensitivity cooled charge coupled device (CCD) camera, a cooling system for the camera, and proprietary software (Living Image) that controls all of the system components. The IVIS Lumina II allows imaging of up to 5 mice or 2 rats and can also accommodate Petri dishes or micro-titer plates for in vitro imaging. The system is equipped with up to 21 filter sets that can be used to image reporters that emit from green to near-infrared. Access to the system is by login of registered users, the list of which is maintained by the core facilitator.

IM Research and Drug Discovery Imaging Core

The IM research CORE facilities consist of multiple state-of-the-art imaging, liquid handling, high-throughput, and other analytical equipment. The list of equipment includes High-Content Screening (HCS) Systems, Electron Microscopy (TEM/SEM), Confocal Microscopy, Live-Cell Imaging, and Flow Cytometry. The facilities housing the equipment were entirely renovated in 2013 and early 2014 and occupy space on 1st and 7th floor of the Cohn building.

High-Content Screening (HCS) Systems: The Core will oversee the operation of a Perkin Elmer's Opera HCS System, which offers the ultimate in high throughput, speed and resolution – making it the ideal solution for flexible, scalable assay development and robust screening. The Opera system utilizes Acapella high content imaging and analysis software and offers solutions for apoptosis, calcium flux, cell cycle, cell differentiation, cell migration, cell proliferation, cell shape changes, cytoskeletal rearrangement, cytotoxicity, fluorescence in situ hybridization (FISH), lipid droplet analysis, neurite outgrowth, protein expression, receptor activation, RNAi screening, signaling pathway analysis, and transcription factor. The HCS facility also has Perkin Elmer's JANUS automated workstation - a liquid handling platform that provides real-time and future adaptability for augmented throughput, plate capacity and dynamic volume range. It includes a gripper 'pick and place' robotic arm for automatic 'on the fly' switching of heads for optimal precision pipetting and performance. JANUS with proprietary Modular Dispense Technology (MDT) NanoHead dispense heads enhance assay miniaturization with 384-tip processing down to 50 nL with C.V.s less than 13%. Also in the HCS facility, a BioTek plate washer is available for washing cells in 96- and 384-well plates.

Electron Microscopy: The Core Facility can provide researchers access to a scanning electron microscope with transmission electron microscopy (TEM) capabilities. Services include critical point drying and gold coating of EM samples. The Zeiss Sigma HDVP Electron Microscope is a high definition imaging system capable of producing ultra-high resolution images with a resolution of up to 1nm. This scope features both high vacuum and variable pressure modes, and is equipped with five different detectors including: a secondary electron detector, a back scatter detector, an in-lens detector, a variable pressure secondary electron detector, and a scanning transmission electron microscopy detector to image TEM tissue sections. This instrument has an acceleration voltage range of 1kV-30kV and scan speeds up to 50ns per pixel. The SmartSEM software is capable of 4-D imaging, elemental mapping, remote viewing, and is user friendly, offering a number of customizable preferences unique to each user. Atlas Imaging software is also included, and enables automatic site to site scanning for mosaic compositions. The room has been outfitted for magnetic interference cancellation, electrical stability, and vibration reduction.

Confocal and Live Cell Microscopy: The Core will run a Confocal Facility, which is equipped with a Zeiss LSM 700 including two spectral channels and a live cell imaging workstation. The confocal microscope is based on an Axio Observer Z1 motorized inverted microscope with four laser excitation lines from four solid-state diode lasers: 405nm, 488nm, 555nm, and 635nm. The instrument is equipped with a motorized scanning stage with controller. It also has the Zeiss Definite Focus controller for extremely precise focus control during long-term conditions where focus drift is a problem. The Live Cell Imaging microscope is based on a Zeiss Axio Observer

D1 inverted microscope and is equipped with an XL-3 Incubator heated stage fitted with a CO2-supplied cover plate. This incubation system enables precise temperature control for the entire instrument and there is a heated stage insert for additional temperature control and CO2 supply at the specimen stage for extended imaging experiments. The instrument uses the Zeiss ZEN Windows-based software, which is user-friendly and logical.

The IM Research CORE facilities are available for use by the RUMC community. Access to the facilities is restricted by swipe card access, which is only granted to approved, trained users and staff. A 3-hour training and certification program is required for all users and is available through the IM Research CORE Facilities Coordinator.

Biological Safety Level 3 Laboratory

The BSL3 facility (JS 1183) is a negative pressure biohazard containment facility that consists of an anteroom (90 ft2) and laboratory (430 ft2). The facility was totally renovated in 2011 to conform to current Biosafety in Microbiological and Biomedical Laboratories (CDC-NIH, BMBL, 2007) standards for handling RG3 agents, large volume isolation of RG2 agents, as well as new and uncharacterized pathogens when found or genetically modified human pathogens as described in the current NIH OBA current guidelines covering "Recombinant or Synthetic Nucleic Acid Molecules." The facility would be invaluable as a support laboratory during a bioterrorism event and RUMC's response. The facility would also be useful for BSL2+ risk level experiments such at the propagation of drug resistant Mycobacterium tuberculosis. The facility is recertified annually to meet current CDC/NIH requirements. The facility is connected to RUMC emergency power and is designed to maintain containment and security during emergency conditions. All exhaust from the BSL3 is HEPA filtered before it is vented to the outside. A Steris pass-through steam sterilizer between the vestibule and main laboratory is equipped with appropriate biosafety collar, one-way pass through control, and backup steam generator. The main laboratory consists of two work areas. On area has two biological safety cabinets (BSC), one 4 foot and one 6 foot, the other area has a single 6 foot BSC. The BSCs are certified annually by an outside contractor. Each area has a dual chambered 37°C CO2 incubator. Additional shared equipment includes a 4°C refrigerator (24 ft^3), a -30°C freezer (24 ft^3), a -80°C freezer (20.4 ft^3), three high capacity table top centrifuges (two refrigerated), three micro-centrifuges (two refrigerated), two microscopes, and a Coulter AcT10 cell counter. The refrigerator, the two freezers, the incubators, and the room are equipped with micro-sensors that continuously monitor temperature and wirelessly transmit their data to a centralized computer as part of a Siemens Checkpoint System, which automatically alerts specified people to any problems. The BSL-3 Laboratory is available for use by the RUMC community. Access to the BSL-3 facility is restricted by swipe card access which is only granted to approved, trained staff. A 4-hour training and certification program is available and required of all users.

Comparative Research Center

RUMC is committed to excellence in patient care, education and research. In its commitment to excellence in these areas, the institution acknowledges the need for continued use of animals in teaching, research and testing, and the undeniable link of animal research to the advancement of biological and medical knowledge. Information and experience that are gained through the use of animals has improved, and will continue to improve, the quality and length of human and animal life.

RUMC is committed to the judicious and humane care and use of animals in teaching, research and testing. The use of animals at Rush is a privilege granted through the Institutional Animal Care and Use Committee (IACUC), with moral, scientific and legal obligations for humane care and treatment of the animals.

RUMC will comply with all applicable provisions of the Animal Welfare Act, other federal statutes and regulations relating to animals and any state statutes and regulations related to animals. As the institution receives federal funding and has an approved "Assurance of Compliance with Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals," all persons will strictly adhere to the provisions of the PHS pol-

icy and the Rush PHS assurance. As the PHS policy covers all vertebrate animals, the institution's policies and procedures will apply to all vertebrate animal use, regardless of the funding source. Rush is also guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Teaching," detailed in the PHS policy. All animal care and use will follow the Guide for the Care and Use of Laboratory Animals (Guide). In situations where the regulations enforcing the Animal Welfare Act are specific and more restrictive than the PHS policy, these regulations will take precedence over the PHS policy.

Comparative Research Center (CRC) is located in state-of-the art facilities in the RUMC, Cohn Building and occupies approximately 23,300 gross square feet. The CRC is responsible for implementing the Rush Animal Care and Use Program and managing animal care facilities in accordance with the Guide. The Center's functions include procurement, care and maintenance of all animals used in research, teaching and testing, and the provision of professional advice to research and teaching staff.

Periodic assessment of the effectiveness of the CRC is provided at multiple levels by numerous sources including, but not limited to: semiannual program review and inspection of the facility by the Institutional Animal Care and Use Committee; annual performance reviews of CRC personnel; annual unannounced inspections by a USDA Veterinary Medical Officer; triennial site visits by the AAALAC International Council on Accreditation; and annual reporting to the USDA, Office of Laboratory Animal Welfare (OLAW) and AAALAC.

Biospecimen Freezer Facility

RUMC has a centrally-located, 2500-square foot freezer facility. The facility includes a mixture of cryogenic storage units, -80°C mechanical freezers (many with liquid nitrogen backup cooling), -20°C freezers, and refrigeration units for large tissue samples. At present, 59 units are operating, but this number will increase to 114 units and the foot print will expand to 5400 square feet when the second phase of the facility opens in 2014. Units are digitally monitored to give automatic notification of temperature excursions or mechanical failure to both maintenance personnel and to the response tree established by the investigator. Access to the facility is electronically controlled and monitored. This facility provides improved security for specimen collections including an Alzheimer's brain tissue library, and preserves space in the investigators' laboratories.

RUMC Library

The library of Rush University is centrally located on the main campus with a large collection of paper and electronic books, journals, and audiovisual tapes. The ongoing journal subscription includes approximately 7000 electronic titles and includes full desktop access to the Nature family of journals. Over one hundred medical databases including MEDLINE via PubMed and OVID, Scopus, PsycINFO and CINAHL provide comprehensive access to medical citations. Databases accessed through the Library homepage link to the Library' electronic full text journals through our Get It! linking software. Other online resources include UpToDate, Access Medicine and MD Consult. There are over 40,000 print books and access to 4000 books online. The online catalog includes all items, print and electronic, in the collection. Reference services include on-demand workshops on bibliographic and other tools, free consultations, comprehensive literature reviews, and assistance with NIH Public Access Policy compliance. All electronic materials may be accessed from off-campus via a free proxy account. Interlibrary loan requests are processed via ILLiad or I-Share. I-Share gives both electronic and in-person access to 76 participating libraries including the University of Illinois at Chicago's Library of Health Sciences two blocks away. In addition, Rush students have access to the University of Illinois libraries, including its medical library that is immediately adjacent to the Rush campus.

LOYOLA UNIVERSITY

Loyola University Health Science Division (LUHSD) is an academic medical center comprised of the Stritch School of Medicine, Marcella Niehoff School of Nursing, LUCHSD Graduate College, and LUHS. The clinical faculty are full and part time employees of both LUHS and have faculty appointments in LUHSD. There is a

partnership between LUHS and HSD with the clinical faculty being both employees of LUHS and with faculty appointments in LUHSD.

Loyola University Health System

LUHS is part of Trinity Health, one of the largest Catholic Health Systems in the United States. The Health System includes:

- Over 1,000 physicians and 6,000 employees;
- Two hospitals – Loyola University Medical Center (559 beds) and Gottlieb Memorial Hospital (255 beds);
- More than 30 ambulatory care sites in the west and southwest suburbs;
- 2,100 trainees including residents, medical and nursing students, allied health professionals, chaplains, and paramedics;
- Over 60 clinical and academic affiliations with hospitals and physicians; and
- Treating more than 30,000 inpatient admissions, 68,000 emergency room visits, and 820,000 physician visits annually

The embodiment of the partnership between LUHS and the HSD of Loyola University Chicago is the 61-acre Academic Medical Campus in Maywood that fosters an environment of collaboration that encourages innovation, embraces diversity, respects life and values human dignity. The Maywood Campus, located 13 miles west of Chicago's Loop, includes:

- Loyola University Medical Center, a 559-licensed bed hospital that houses a Level 1 Trauma Center, a Burn Center and the Ronald McDonald® Children's Hospital of Loyola University Medical Center;
- The Cardinal Bernardin Cancer Center;
- The multidisciplinary clinics and treatment services of the Loyola Outpatient Center;
- The Center for Heart & Vascular Medicine;
- Stritch School of Medicine;
- Marcella Niehoff School of Nursing
- The biomedical programs of the Loyola University Chicago Graduate School
- The Center for Simulation Education; and
- The Center for Translational Research and Education.

Loyola's Gottlieb Memorial Hospital campus in Melrose Park includes the 255-licensed bed community hospital, a Professional Office Building housing 150 physician clinics, Loyola Center for Metabolic Surgery and Bariatric Care, the Geriatric Behavioral Health Unit and the Loyola Cancer Care & Research Center.

LUHS is a member of Trinity Health, one of the nation's largest Catholic health systems. Trinity Health has 90 hospitals and hundreds of continuing care facilities, home care agencies and outpatient centers in 21 states and 95,000 employees.

Loyola University Health System Clinical Excellence

Loyola is a nationally recognized leader in providing quality, tertiary care in heart disease, cancer, bone marrow transplant, organ transplantation, orthopedics, and neurological disorders. Loyola is one of Chicago's leading academic medical centers and is nationally ranked by U.S. News & World Report. Loyola University Medical Center's physicians are members of the faculty of Loyola University Chicago Stritch School of Medicine. Loyola University Medical Center has the highest case mix index in the State of Illinois, meaning we care for the most acutely ill patents in the state. Loyola University Health System has received recognition from U.S. News and World Report's Best Hospitals and it has elite Magnet designation from the American Nurses Credentialing Center.

LUHS Mission

We, Loyola University Health System, a regional health ministry of Trinity Health, serve together in the spirit of the Gospel as a compassionate and transforming healing presence within our communities. Loyola University Health System is committed to excellence in patient care and the education of health professionals. We believe that our Catholic heritage and Jesuit traditions of ethical behavior, academic distinction, and scientific research lead to new knowledge and advance our healing mission in the communities we serve. We are committed to going beyond the treatment of disease. We also treat the human spirit.

Research Facilities

Dedicated research space for LUCHSD investigators is located at the center of the medical campus, in two adjoining buildings: the newly opened Center for Translational Research and Education (CTRE) and the Cardinal Bernardin Cancer Center (CBCC).

The newly constructed CTRE has 227,000 sq. ft. designed to facilitate collaborative translational research and education. This LEED Gold facility includes open wet laboratory and laboratory support space with adjoining offices, workstations, conference and collaborative spaces as well as dry/desktop research space to support public health, informatics, computational, clinical, and nursing research. There are large and small conference rooms on each floor and a large auditorium on the first floor. Research facilities within the CTRE include: a comparative medicine animal vivarium, genomics, imaging, proteomics, a viral vector core, and a small animal model development core. There is dedicated office space for the Clinical Research Office (CRO) personnel including offices for the CRO medical director, sponsored research nurse director, biostatistics director, regulatory director, biobank manager, and finance personnel with additional cubicles for nurses, research coordinators, bio-statisticians, and technicians. The CRO biobank with adjacent laboratory space is located on the first floor of the CTRE in close proximity to the new clinical research space that has a reception area, 3 exam rooms, a specimen handling room, and bathroom dedicated to the support clinical research. Administrative space is available for the Office of Research Services, IRB and contracting offices. The CTRE is connected by an enclosed walkway to the CBCC, which consists of approximately 26,000 sq. ft. of wet laboratory, clinical cancer center space and adjoining office/administration space for investigators focusing on oncology research. The CBCC also has additional conference/lecture rooms. Other key research support in the CBCC includes a fluorescence activated cell sorting (FACS) facility and a GMP-certified cell therapy center and a cancer clinical trials office.

Research Organization

LUCHSD is committed to the long term goal of reaching across organizational boundaries to promote centers of excellence that combine clinical, basic and population science to study areas of public health importance. To integrate our research teams, improving patient access to clinical trials, facilitate public-health-based research and optimize the impact of these efforts areas of research strength at Loyola are organized in to thematic research institutes jointly directed by both a basic and a clinical researcher. The current institutes include:

Burn and Shock Trauma Institute

The Burn and Shock Trauma Institute (BSTI) is a unique community of basic scientists and clinicians devoted the study of traumatic injury. As multidisciplinary research institute, our programs include both clinical and laboratory research relevant to trauma injury and burns. Our scientists investigate the body's reaction to injury, alcohol and infection, with the hope that their findings may someday lead to innovative therapies for trauma and burn patients.

Cardiovascular Institute

The Cardiovascular Institute (CVI) consists of a basic research division as well as the Department of Thoracic and Cardiovascular Surgery and the Department of Medicine's Division of Cardiology. The mission of the CVI is to support basic and clinical research and training in the cardiovascular sciences.

Infectious Disease and Immunology Institute
The Infectious Disease and Immunology Institute (InDII) consists of a large group of researchers and clinicians dedicated to understanding interactions between microbes and the immune system. By establishing collaborations among basic and clinical scientists studying microbes and the immune system the goal is to translate the knowledge gained for the treatment, control and prevention of diseases caused by human infectious agents.

Oncology Institute
The Oncology Institute within the Cardinal Bernardin Cancer Center supports basic and clinical research focused on elucidating the underlying mechanisms of cancer. The Institute provides the infrastructure to coordinate and integrate a truly multi-disciplinary approach to cancer research and our clinical programs.

Institute of Public Health
The Institute of Public Health is a reflection of LUC's dedication to maintaining a scholarly environment that supports the mission of reducing the global burden of preventable disease, improving international health, and decreasing health disparities arising from racial, ethnic, socio-economic, gender, environmental or other factors. This is accomplished via education of students, conducting nationally/internationally recognized research that identifies and minimizes or eliminates factors that contribute to the burden of preventable disease and health disparities and working within local and global communities to improve health and reduce disparities.

Biobanking Services
The Clinical Research Office (CRO) Biobank provides a range of services related to clinical sample procurement, processing, storage and distribution. Central to its function is the IRB-approved CRO-Biorepository which provides a well-controlled, fully compliant, centralized location for patient sample storage and distribution for clinical research, including genomic or proteomic studies. The Biobank is overseen by a clinical faculty member, a basic science faculty member and has a dedicated technician. The facility currently has four -80°C freezers as well as two -20°C freezers, a 4°C refrigerator, and a liquid nitrogen tank. To assure samples are safe, all the freezers are monitored by a Smart-Vue alert system and have a CO2 back-up system. There are also two back-up freezers available in the building. Standard operating procedures are in place to ensure samples are handled/processed appropriately. Specimens are then tracked by the sample management software Freezerworks via a barcode system which provides a real time electronic inventory of samples and a link to user defined sample information. Demographic and phenotypic data are collected and linked to stored samples using RedCap. All data and specimens are de-identified and coded with a unique 12 digit Smart ID based on donor variables making it consistent across studies. The CRO-biorepository serves as an "honest broker" for distributing samples and associated de-identified clinical data for IRB approved protocols under a standard User Agreements. Confidentiality is protected under an NIH Certificate of Confidentiality (HG-2013-01, expiration 10/16/2022). Currently the biorepository has stored 4,000 specimens including blood, urine, tracheal aspirates and solid tissue. There are over 30 IRB approved protocols contributing samples to the repository and 9 currently withdrawing samples. Related Biobank services include protocol specific sample processing (e.g. DNA/RNA extraction, blood separation and aliquoting), coordination with pathology for tissue acquisition, as well as consent and clinical coordination training for study personnel.

Comparative Medicine Facility
The Comparative Medicine Facility, an AAALAC accredited animal facility located in the CTRE. The Comparative Medicine Facility is directed by a full-time veterinarian and provides all support for the housing and care of laboratory animals.

Fluorescence Activated Cell Sorting Facility
The Fluorescence Activated Cell Sorter (FACS) facility provides flow cytometric and cell sorting services. The FACS facility is equipped with a FACSCantoll®, a FACSFortessa®, a FACSAria Ill®, an AutoMACS® Pro Separator, an Amnis lmageStream MKll, Mac and PC workstations loaded with the data analysis software FlowJo and IDEAS, a biological safety cabinet, and a POLARStar Omega® plate reader.

Genomics Facility
The Genomics Facility provides comprehensive services to support high-throughput experimentation. The Genomics Facility supports a variety of experimental platforms across biomedical research including gene expression (microarrays, RNA-seq, microRNA-seq), variant analysis, epigenetics, whole-genome sequencing, and microbiome research.

Imaging Facility
The Imaging Facility includes a transmission electron microscope (Philips CM120) equipped with a BioSprintM 16MP digital camera, and two confocal microscope systems. 1) A Zeiss LSM-510 inverted confocal microscope equipped with a motorized scanning stage, live cell C02 incubation chamber with heated stage, and FRET capabilities. A 1.4 megapixel cooled extended spectral range RGB digital camera is available for LM work. 2) A Leica SP5 multi-photon microscope. The system is equipped with both a standard high spatial resolution and a resonant fast scanning laser scanning; up to 7 visible lines, a 4-W Coherent IR tunable femtosecond IR laser, as well as a pulsed 405 UV laser are installed. Emission detection is by 3 regular, 2 FLIM (fluorescent lifetime imaging) capable detectors, 2 NDD detector, transmission, and 2 APD style detectors capable of FCS (fluorescent correlation spectroscopy). The system also contains a cooled CCD for bright field Deconvolution epi-fluorescence. The facility includes all ancillary equipment needed to process samples and a workstation for computer-based image processing and analysis.

Proteomics Facility
The Proteomics Facility houses three mass spectrometers and a fully equipped two-dimensional differential in gel electrophoresis system (2D-DIGE). The mass-spectrometers allow for quantification of known targets by MRM-based approaches using either analytical- or nano- triple quad mass-spectrometers (Thermo), or discovery based analysis using MALDI-TOFF (Shimadzu) approaches. An off-gel system is also available for preprocessing of samples. The 2D-DIGE equipment includes equipment for simultaneous processing of up to 8 individual sample groups, a Typhoon+ scanner, and Decyder software analysis package (GE Health Sciences).

Small Animal Model Development Facility
The Small Animal Model Facility provides investigators with resources for creating and studying animal models. With special expertise in cardiovascular physiology and pathophysiology, the techniques are exportable to multiple other lines of investigation. The facility includes a fully equipped surgical suite with a Zeiss ophthalmic surgical/operative microscope; Omano dissecting microscope; rodent ventilators and anesthesia instrumentation; state-of-the-art, high-frequency, high-resolution imaging (Vevo 2100); admittance-based pressure-volume catheters (Scisense); STARR pulse Ox system; rodent treadmill; telemetric instrumentation for monitoring ECG and blood pressure; and metabolic cages.

Viral Vector Facility
The Viral Vector Facility provides a comprehensive range of resources and services for gene construction and transfer purposes, including recombinant protein construction and purification expertise. The Vector Facility constructs and purifies recombinant adenovirus, adeno-associated virus, and lentivirus for in vitro and in vivo use.

Tissue Processing Facility
The Tissue Processing Facility provides tissue processing and embedding, staining, technical assistance or training for histological preparation, cryostat usage or sectioning, paraffin sectioning, and immunohistochemistry.

NORTHSHORE UNIVERSITY HEALTH SYSTEM

NorthShore University Health System Research Institute Facilities

NorthShore is a not-for-profit corporation principally formed to provide quality healthcare services for the communities it serves. The organization's primary service area includes Chicago's "north shore", northern suburbs, and its environs. The core mission of NorthShore is to preserve and improve human life. This mission is achieved through the provision of superior clinical care, academic excellence, and innovative research. NorthShore is a comprehensive, fully integrated, healthcare delivery system that serves the greater North Shore and northern Illinois communities. NorthShore includes four Hospitals – Evanston Hospital, Glenbrook Hospital, Highland Park Hospital, and Skokie Hospital. Also located at NorthShore is the NorthShore Foundation, and the NorthShore Medical Group. The system employs about 10,000 people and has approximately 2,100 affiliated physicians, including the NorthShore Medical Group, an 800-plus physician multi-specialty group practice with over 100 office locations. In support of its primary mission of patient care, the corporation engages in a wide range of academic activities. As the principal teaching affiliate for The University of Chicago Pritzker School of Medicine, NorthShore is dedicated to excellence in medical education and research. Additionally, NorthShore is the only Illinois organization to receive the American Nurses Credentialing Center's Magnet designation as a healthcare system, an honor that recognizes "quality patient care, nursing excellence and innovations in professional nursing practice."

In 2003, NorthShore was the first institution to deploy Epic Systems' electronic health record system across inpatient and outpatient care. Since then, NorthShore has won numerous awards for its comprehensive, nearly paperless, system-wide clinical information systems deployment. Awards include being one of the first two institutions to reach Health Information Management Systems Society Level 7 certification, being in the Top 15 Teaching Hospitals in the Nation by Truven Health Analytics (formerly Thompson Reuters) a record 16 times, more than any hospital in the country, and being named "Innovator of the Year" for 2013 by *Health Informatics*.

The NorthShore University HealthSystem (NorthShore) Research Institute operates more than 140,000 square feet of research space at two main locations: Evanston Hospital and the Evanston-Northwestern Research Park.

On the Evanston Hospital campus, the NorthShore Research Institute operates 33,000 net square feet of research space primarily in the Coon Research Center of the Women's Hospital and the Charles R. Walgreen, Jr. Building. The laboratories in these facilities are staffed by physicians, research scientists, research technicians, postdoctoral fellows, and students. In addition to fully equipped wet laboratories, the Evanston Hospital campus houses the Center for Medical Genetics, the Center for Comparative Medicine (CCM), the Center for Advanced Magnetic Resonance Research (CAMRR) and the NorthShore Clinical Trial Center (CTC). The Center for Medical Genetics comprises a team of genetic counselors, physicians, and researchers available to assist both physicians and patients in identifying the need for genetic services and in providing medical management recommendations. The CCM is an 8,000 net square foot AAALAC accredited animal facility with housing and procedural space for various species from mice to pigs. The CAMRR is a 10,000 square foot facility dedicated to imaging research. The CAMRR currently has a Siemens Avanto 1.5 Tesla Magnetic Resonance Imaging (MRI) and a Siemens 3T Skyra Fit and space for a third imaging unit to be installed in the future. The CAMRR has a team of physicists, engineers and computer scientists that translate the most advanced MR imaging techniques into clinical practice, particularly in cardiology, cancer and stroke. The CTC is an approximately 1,000 square foot area dedicated to supporting clinical trials. It has a team of staff to assist investigators with submitting and running clinical trials, and includes a laboratory specifically designed to support the needs of clinical research.

In the Evanston-Northwestern Research Park, NorthShore Research Institute operates two research facilities. The park is home to the 87,000 square foot Research Institute Building which currently includes 24,000 net

square feet of modern, wet laboratory space, 23,000 net square feet of dry laboratory/office space, NorthShore Research Institute Administrative Offices, a conference facility and a 5000 net square foot, barrier facility for rodents. The Research Park building is the home for several important Centers and Cores including the NorthShore Genotyping Core, the Center for Psychiatric Genetics, the Center for the Study of Complex Diseases, the Ambulatory Primary Care Innovations Group (APCIG) and the Center for Individualized Medicine. The Center for Psychiatric Genetics is equipped with state of the art genotyping and DNA sequencing equipment and conducts some of the largest and most comprehensive genetic experiments in the field. The Center for the Study of Complex Disease serves as resource to NorthShore faculty and staff by providing essential dynamic system modeling services for projects focusing on underlying mechanisms, treatment of disease and quality improvement. APCIG develops, tests, and disseminates novel strategies for improving the quality of care for primary care patients in ambulatory settings in collaboration with leaders in specialist medicine, inpatient medicine, and clinical operations. CBRI supports a matrix of multi-disciplinary teams reporting across NorthShore (e.g. Enterprise Data Warehouse team, Epic Optimization team, Research Institute) to drive forward the Center's unique approach to innovating across the full continuum of care. CBRI's scientists and staff collaborate across topics in basic bioscience, medicine, health systems, and public health, using methods from computational biology and imaging, biostatistics, personalized genomics, medical informatics and health services research.

The other Research Park facility, just next door, houses the Center for Basic Magnetic Resonance Studies, a 9000 square foot center for conducting preclinical imaging studies in cells and small animals. This imaging center has wet laboratories and offices that support the center which has three state of the art magnetic resonance (MR) instruments, a Bruker Biospec 4.7 Tesla, 40-cm bore, horizontal axis MR unit, a Bruker Avance 600WB, 89-mm bore, vertical axis MR unit, and a Bruker Biospec 9.4 Tesla, 305 mm bore, horizontal axis magnet.

ILLINOIS INSTITUTE OF TECHNOLOGY

Armour College of Engineering (ACE)

The mission of Armour College of Engineering (ACE) today remains preparing engineering students to be the innovators and entrepreneurs that will shape the future. In order to facilitate a collaborative educational approach ACE launched Armour R&D. Students are given the opportunity to explore topics of high priority and relevance throughout their undergraduate degrees. These themes include water, health, energy, and security. Students will have the opportunity to further explore these topics with the Program for Undergraduate Research in Engineering (PURE), Mentoring, Innovation and Development (MIND), and Student-led projects. The Inter-professional Program (IPRO) was developed at IIT and consists of student teams from the junior through graduate levels, representing the breadth of the university's disciplines and professional programs that work to solve a real-world problem.

A diverse student body provides an environment where students can draw from each other's unique experience to tackle problems that affect the world. Armour College of Engineering's has over 2,300 students, of which 48% are from foreign countries. Engineering is a field dominated by males, but ACE is proud to share that 25% of students are female.

Pritzker Institute of Biomedical Science and Engineering

The Pritzker Institute is an umbrella organization that enhances the biomedical science and engineering research activities on the IIT campus. The Medical Imaging Research Center (MIRC), the Center for Integrative Neuroscience and Neuroengineering research (CINNR), the Engineering Center for Diabetes Research and Education (ECDRE), the Center for the Molecular Study of Condensed Soft Matter (UCOSM), and the Biophysics Collaborative Access Team (BioCAT) are some of the Centers and activities that operate under the Institute. Each of the Centers has a Director and is described in more detail elsewhere on this page. The Pritzker

Institute develops and coordinates relationships and programs with traditional science and engineering departments within IIT, as well as outside institutions, especially, Argonne National Laboratory, Rush Presbyterian Medical Center and the University of Chicago.

The Pritzker Institute of Biomedical Science & Engineering has a Ti-E Inverted microscope equipped with fluorescence and brightfield capabilities, an Axiovert 200 inverted microscope equipped with confocal, fluorescence, phase-contrast, DIC, and brightfield imaging capabilities, a computer controlled UV-Vis plate reader with cuvette option for ELISA, activity assays utilizing chromogenic substrates, a computer controlled fluorescence reader for assays utilizing fluorogenic substrates, 2 Class II laminar flow hoods, water jacketed temperature and CO2 controlled incubators for cell culture, Beckman-Coulter Multi-sizer 3 for evaluation of cell (primarily platelets) counts and size distributions, Malvern Zetasizer™ Light Scattering Instrument, NanoTracker (JPK Instruments, Berlin, Germany) Optical Tweezers/3D Particle Tracking for evaluating mechanical properties of cell adhesion, Mitutoyo series LSM-3100, model LSM-3403V for mechanical testing of the materials and a Carl Zeiss Microimaging Cryostat for tissue sectioning, and an in-line phase sensitive x-ray imaging system.

Illinois Institute of Technology Research Institute (IITRI)

IITRI was founded in 1936 as the research arm of the Illinois Institute of Technology (IIT) and operates as an independent, not-for-profit preclinical contract research organization and research institute. Current facilities include over 125,000 square feet of laboratory space in one location on the IIT campus in Chicago. Areas of specialty include preclinical safety and toxicology, inhalation toxicology, biodefense, and infectious disease studies, as well as extensive experience evaluating the efficacy and preclinical safety of cancer therapeutics.

IITRI has a long history of providing preclinical safety and toxicology testing services to sponsors from the pharmaceutical, biotechnology, consumer products, and chemical industries, as well as to the US Government. They have been performing GLP safety studies since the regulations were put in place in 1979, and during this time have performed thousands of GLP studies. They offer complete IND-enabling programs to take a drug candidate through IND filing with the FDA.

IITRI is also a significant provider of inhalation toxicology services, and has been performing these studies for over 40 years. A particular strength of IITRI's program is their knowledge of aerosol science and the ability to generate and characterize well-controlled test atmospheres with various complex test articles.

IITRI established the cancer research program in 1957 to evaluate the efficacy, mechanisms of action and preclinical safety of cancer therapies and chemopreventive agents. IITRI is a leader in cancer drug discovery and development with over 250 publications in the area, and they are the leading preclinical contractor to the NCI.

Finally, IITRI provides research and development services to support the US Government's efforts to defend against the growing threats of bioterrorism and emerging infectious diseases. The IITRI laboratory and vivarium space is able to assess the efficacy of medical countermeasures, decontamination materials and biosensors against pathogenic agents of interest, and they are one of only two non-government laboratories that operate a Department of the Army approved Biological Surety Program.

The Institute for Food Safety and Health – Center for Nutrition Research

Established in 2011, the Institute for Food Safety and Health (IFSH) at Illinois Institute of Technology (IIT) is a world-class food science research institute that produces knowledge-based outcomes in the areas of food safety, food defense, and nutrition for stakeholders in government, industry, and academia. IFSH's collaborative research model facilitates innovation in the food industry through the assessment and validation of new and novel food safety and preservation technologies, processing and packaging systems, microbiological and chemical methods, health promoting food components, and risk management strategies.

The Center for Nutrition Research (CNR) conducts human nutrition and clinical studies to determine the health benefits of foods and food components in a variety of specialty areas.

CNR facilities include:

Applied Chemistry Laboratory
This 1,000 sq. ft. applied chemistry lab supports research in nutrition and chemical contaminants, including investigations into the properties of food matrices related to the content and profile of antioxidant compounds and their effect on human health, as well as food safety related contaminant issues, such as acrylamide, melamine, pesticides and mycotoxins in food that may help improve food processing mitigation strategies. IFSH member Agilent Technologies is a collaborative partner in the renovation and has outfitted the lab with several pieces of equipment.

Facility highlights

- Four large bench areas with three new and modern hoods for additional chemical and extraction processing
- Agilent rapid resolution liquid chromatograph (RRLC) with 6460 triple quadrupole (QQQ) mass spectrometer (MS); Agilent 1100 HPLC with 6500 time-of-flight mass spectrometer (TOF-MS); two Agilent 1100 HPLCs with diode array and fluorescence detection; Agilent 7890 GC with 5975 single quadrupole MS; and Agilent 7890 GC with 7000 triple quadrupole MS, for pesticide, mycotoxin, drug residue and phenolic antioxidant research.
- Agilent 7000 inductive coupled plasma-mass spectrometer (ICP-MS), 7696A sample prep workbench and bioanalyzer, for analysis of heavy metals and other elements, fatty acid profiling and species identification of fish.
- Varian ICP with optical emission (OE) spectrometer, for nanotechnology research
- Shimadzu GC-MS with CTC headspace autosampler, for use in proficiency testing and FERN initiatives

Analytical Chemistry Laboratory
This chemistry laboratory has state-of-the-art equipment such as UV, Fluorescence, GC, GC-MS, HPLC, HPLC-MS/MS, ELISA, electrophoresis and DSC. In addition, through the Illinois Institute of Technology, lab technicians have access to circular diachronic and X-ray crystallography for protein structure determination. This equipment is also used to support nutrition research projects and the chemistry group has extensive capability and expertise in analytical assessment of nutritional compounds, including vitamin C, vitamin A and the carotenoids, vitamin E and the B vitamins.

Novel Food Processing Technologies Processing Bay
The novel food processing technologies bay has a 24-L Avure high pressure processing unit which can reach pressures upto 813 MPa and temperatures upto 131 °C. Multiple Ultraviolet light units (annular tube, coiled tube, thin film laminar reactor, cidersure reactor) are also available. Several pulsed light systems (1.8 Hz, 3 Hz, 100 Hz systems, and a handheld pulsed light unit) are also available in the novel food processing technologies laboratories. Two cold plasma units (a conveyor belt system and a fluidized bed reactor) are available for microbial inactivation studies. Multiple high power ultrasound applicators are also available in the laboratory. Moreover, COMSOL Multiphysics 4.1 software is also available for modeling and simulation.

High Pressure Processing Laboratories
A new fully self-contained processing bay for high pressure processing (HPP) research is located within the main pilot plant. New HPP-based research into pressure enhanced sterilization (PES) technologies, such as pressure assisted thermal sterilization (PATS), is conducted in this area using state-of-the-art equipment from Avure Technologies. The processing bay has been added to the select agent license, allowing critical biological validation of this proven food safety technology.

Protein and Allergens Laboratories
This fully equipped chemistry laboratory is used for protein digestion and allergenicity studies.

INFORMATICS

UNIVERSITY OF CHICAGO

Center for Research Informatics

The Center for Research Informatics (CRI) is a 40-person group, directed by ITM Informatics Director Samuel Volchenboum, MD, PhD, dedicated to providing resources to University of Chicago faculty to enable biological research. The CRI is comprised of four service lines: (1) systems, which includes high-performance computing, storage, backup, and virtualization, (2) application and platform development, (3) data warehousing, and (4) bioinformatics. All computing resources for the CRI are located in the state-of-the-art University of Chicago Kenwood Data Center. This new, 4600-square-foot data center was designed with redundant architecture and has been tested to withstand extended power outages without system or service interruption. CRI servers are physically secure in this continuously staffed and monitored facility. Kenwood Data Center is divided in two sections to more efficiently accommodate the requirements for both purely computational (i.e., high-performance computing) and business-critical systems. It is equipped to house systems that may fall under certain federal guidelines, including the Health Insurance Portability and Accountability Act (HIPAA) and the Federal Information Security Management Act (FISMA).

High-Performance Computing Resources
The CRI owns, operates, and has priority access to a high-performance computing (HPC) cluster comprised of 38 standard memory compute nodes (2.2 GHz, 2304 total cores, 256 gigabytes RAM per node) and 2 large memory compute nodes (2.27 GHz, 80 total cores, 1 terabyte RAM per node). The HPC contains over 100 software applications for bioinformatics analysis, commercial, and open-source compilers for software development, and is integrated with Galaxy (a web-based portal for biomedical analysis). Analysis can also be performed on two Large Memory Servers (32 cores and 768 GB RAM per server) that contain high-resolution graphics hardware (Nvidia Tesla K40s) for statistical visualization.

Other IT Resources
The CRI has its own Virtual Infrastructure with 18 physical servers running VMWare ESX connected to a Dell Compellent storage array that is used to provide researchers with the ability to access Web, Application, and Database Servers. The CRI provides 1.2 petabytes of file storage (an EMC Isilon storage cluster) with available space to be provisioned for group shares assigned to BSD investigators. The storage systems are backed up to a SpectraLogic T950 tape library using an IBM Tivoli Storage Manager (TSM). IBM TSM is also used for data archiving functionality, where research data are archived on a SpectraLogic nTier Verde disk-based storage array and on tape in the SpectraLogic T950 tape library. REDCap REDCap is a free, web-based, and user-friendly electronic data capture (EDC) tool for research studies. The CRI maintains a REDCap instantiation for the Biological Sciences Division and is currently hosting over 1000 projects. REDCap is a HIPAA-secure data collection tool that can be used to meet 21 CFR-part 11 requirements. Databases can be quickly developed and customized for studies' needs. REDCap is useful for collecting and tracking information and data from research studies, scheduling study events (e.g., patient visits), and conducting surveys and collecting patient-reported outcomes.

Bioinformatics
The CRI's Bioinformatics Core is comprised of nine PhD biostatisticians with extensive experience in computational programming and genomics analyses. The group has a special interest in next-generation sequencing technologies and has developed several customized proprietary pipelines for data analysis. The group has pri-

ority access to the CRI's extensive array of hardware resources. This group will interact with the biostatistics department to manage the genomic data from the 16S rRNA analysis from the proposed study as outlined in the proposal.

Applications and Platform Development

The CRI's Applications Team has extensive experience developing platforms and tools for clinical trial management, including software to enable the enrollment and tracking of patients and their samples. The CRI maintains all data according to local and federal HIPAA standards. All CRI activities are performed under the supervision of the BSD Research Data Governance structure.

The Clinical Research Data Warehouse (CRDW)

Under the leadership of then-CRI-director Robert Grossman, an international leader in big data management and analytics, the CRDW group built the first and currently only UCMC institutional Clinical Research Data Warehouse (CRDW). Sources of CRDW data include Epic EMR, Sunquest lab system, and Centricity billing system. Both Sunquest lab data and Epic EMR data are included in the Clarity data warehouse, which is refreshed weekly, while Centricity billing data is refreshed monthly. The CRDW team will be adding several new data sources in the near future, including the Social Security Administration's Death Master File (DMF) for more accurate reporting of patient vital status. In additional, data from the University of Chicago Physician's Group (UCPG) will be included to provide CPT procedure data for Professional fees. The CRDW contains information on over 632,017 patients, representing 228,709 inpatient encounters and 5,636,587 outpatient encounters. Included in the CRDW is information on 14,650,759 ICD9 Diagnosis records, 30,041,926 procedure records, 17,078,753 medication order records, 8,494,274 insurance payor records, and 100,381,634 laboratory records.

Center for Research Informatics IT Infrastructure & Services

Data Centers

Research computing resources for the Center for Research informatics (CRI) are located throughout the University of Chicago and the medical center data centers. The Kenwood Data Center is the primary data center for CRI's research computing resources. University of Chicago staff, BSD researchers, facility and collaborators have access to all research computing resources at all data center facilities.

Kenwood Data Center

The 6045 Data Center is located in Hyde Park on the University of Chicago campus at 6045 S. Kenwood Avenue. The Data Center is designed and tested to withstand extended power outages without system or service interruption. CRI servers are physically secure in a locked, well ventilated facility fitted with an electronic alarm system. As the primary data center for CRI computing resources, the Kenwood data center supports business critical systems and is equipped to house systems that may fall under certain federal guidelines, including Health Insurance Portability and Accountability Act (HIPAA) and the Federal Information Security Management Act (FISMA).

Data Center Features:

- Managed by the University of Chicago
- TIER 2 Uptime institute rating
- 10 -15 KW per cabinets
- Monitored 24/7 by staff

1155 Data Center

The 1155 Data Center is located Hyde Park at 1155 E 60th Street center. The data center provides raised floor space for University of Chicago IT Services. CRI uses this facility for off -site backup of computing resources and data.

Features:

- Managed by the University of Chicago
- TIER 1 Uptime institute rating
- 5 KW per cabinet
- Monitored 24/7 by staff

Prudential Data Center:

The Prudential Data center is located downtown Chicago at 130 E. Randolph Street. Computing resources previously offered by the Initiative for Bioinformatics (iBi) and the Academic Research Group (ARG) are now offered through the CRI. The Prudential Data Center has reached end -of life status with no new development or updates. A primary focus of the CRI Systems and Security team over the past year has been the migration of users' data and computing resources from outdated equipment in the Prudential Data Center to the newer, better -equipped Kenwood Data Center.

Features:

- Managed by CRI and CBIS
- TIER 1 Uptime institute rating
- 5 -10 KW per cabinet
- Monitored remotely by staff

Darien Data Center:

The Darien Data center is located in Darien at 7955 S. Cass Ave. This is the primary data center for clinical applications and hospital systems. Currently used by the CRI to house the Clinical Research Warehouse and other research systems with clinical diagnosis requiring 24x7 technical assistance and support.

Features:

- Managed by CRI and CBIS
- TIER 2 Uptime institute rating
- 10 -15 KW per cabinets
- Monitored 24/7 by staff

CRI Infrastructure and Resources

The CRI Systems and Security team maintains the computing infrastructure that supports not only the CRI's activities, but also research for faculty across the BSD. The CRI provides researchers with comprehensive computing resources that include:

- High Performance Computing clusters for general use by staff, faculty and students
- Large memory servers for memory intensive analytics
- Ultra -high density Network Attached Storage for lab shares and research data
- Secure private cloud with individualized virtual servers on Windows or Linux platforms
- Individualized physical servers for websites and custom ion built applicat
- Galaxy web -enabled biomedical data analytics tool integrated with the CRI's HP
- Centralized and automated data backup system for nightly backups of all critical data
- High capacity tape library backup system and data encryption
- Redcap web ed software solution for designing clinical and translational research databases

High Performance Computing:

The CRI manages four High Performance Computing clusters for general use by staff, faculty and students at Prudential and in Kenwood and two specialized computing system for Linux and Windows based applications

with more than 350 bioinformatics and software packages including SPSS, SAS, S-Plus, Matlab, R, Adobe CS4, Stata, Mathmatica.

Prudential Data Center Clusters and Systems

- Computational Core Cluster - ibicluster.uchicago.edu
- Big Memory Cluster - ibibmem.uchicago.edu
- Window Specialized system - brdfbigw.uchicago.edu
- Linux Specialized system - brdfbigl.uchicago.edu

Computational Core Cluster - IBICLUSTER

This is the production high performance computing cluster used by staff, facility and students throughout the University of Chicago and BSD.

Technical Specifications:

- Processors per Node: 2 Intel Xeon E5430
- Processor Speed: 2.66 GHz
- Cores per Processor: 4
- RAM per Node: 32 GB
- Shared Scratch Storage: 14.4 TB
- Operating System: Red Hat Enterprise Linux 5
- Scheduler/Resource Manager: Sun Grid Engine
- Interconnect: Infiniband (DDR)

Big Memory Cluster - IBIBMEM

This cluster is intended for projects that require a large memory footprint for memory intense processing.

Technical Specifications:

- Processors per Node: 2 AMD Opteron 252
- Processor Speed: 2.6 GHz
- Cores per Processor: 1
- RAM per Node: 16 GB
- Shared Scratch Storage: 14.4 TB
- Operating System: Red Hat Enterprise Linux 5
- Scheduler/Resource Manager: Sun Grid Engine
- Interconnect: None

Window Specialized system - BRDFBIGW

Windows 64 –bit cluster with software packages including SPSS, SAS, S-Plus, Matlab, R, Adobe CS4, Stata, Mathematica, etc.

Technical Specifications:

- Processors per Node: 8 AMD Opteron 8220
- Processor Speed: 2.8 GHz
- Cores per Processor: 2
- RAM per Node: 256 GB
- Shared Scratch Storage: 14.4 TB
- Operating System: Windows server 2003 64-bit
- Scheduler/Resource Manager: None
- Interconnect: None

Linux Specialized System - BRDFBIGL
Linux system with more than 350 bioinformatics and software packages available for users that need to run Linux based research applications.

Technical Specifications:

- Processors per Node: 8 AMD Opteron 8220
- Processor Speed: 2.8 GHz
- Cores per Processor: 2
- RAM per Node: 256 GB
- Shared Scratch Storage: 14.4 TB
- Operating System: Red Hat Enterprise Linux 5
- Scheduler/Resource Manager: None
- Interconnect: None

Kenwood Data Center Clusters

- Research Core Cluster – bios.cri.uchicago.edu
- Large Memory System – lmem -cri.uchicago.edu

Research Core System - BIOS
This is the new general -purpose cluster that went live in November of 2012 and
putational Core cluster in Prudential.

Technical Specifications:

- System: 32 Dell C6145s compute nodes
- Processors per Node: 4 AMD Opteron 6274
- Processor Speed: 2.2 GHz
- Cores per Processor: 16
- RAM per Node: 256 GB
- Shared Scratch Storage: 60 TB
- Operating System: Red Hat Enterprise Linux 6.2
- Scheduler/Resource Manager: MOAB/TORQUE
- Interconnect: Infiniband (QDR)

Large Memory System – LMEM
This cluster is intended for projects that require a large memory including software packages SPSS, SAS, R, Adobe, Stata, etc. This system went live in November of 2012 and will replace the current Linux Specialized System in Prudential.

Technical Specifications:

- System: 1 Supermicro 5086B -TRF
- Processors per Node: 8 Intel E7 -8870
- Processor Speed: 2.4 GHz
- Cores per Processor: 10 cores per processor
- RAM per Node: 1 TB
- Shared Scratch Storage: 50 TB
- Operating System: Red Hat Enterprise Linux 6.2
- Scheduler/Resource Manager: None
- Interconnect: None

Research Computing Storage

There are three categories of storage available in Kenwood: Home, Lab -Share and Scratch. Home directories and lab shares data is located on a 700 pTB 20 PB The home NAS, which can scale u directories and lab -share storage is available from all compute nodes an cloud infrastructure through a 1GB/s connection. Scratch space in Kenwood is hosted on CRI's HPC direct access storage, which is accessible through 40GB/s Infiniband (QDR) from all compute nodes.

Ultra-high density NAS

- Contents: Home and Project directories
- Isilon OneFS cluster filesystem
- 7200 RPM 3.5" SATA -2
- 756 TB raw capacity
- Nightly backup schedule

Direct access storage

- Contents: Home and Project directories
- GPFS file system
- 10K RPM 3.5"
- 70 TB raw capacity
- Not backed up

Private Cloud Infrastructure

The CRI manages a VMWare Virtual Server Infrastructure used to support individualized and shared virtual machines for various departments within the University of Chicago and BSD. The infrastructure can be partitioned into multiple servers such that each server has the appearance and capabilities of running on its own dedicated machine. Each virtual machine (VM) server can run its own operating system (Windows or Linux), which is assigned its own hostname and may be independently administered, configured, and rebooted without impact on other VM servers. The CRI private cloud has the capacity to support up to 1500 (VMs) on Windows or Linux platforms.

Technical Specifications:

- VMWare 5.1 VCloud Security Suite
- 2 M1000e blade enclosure
- 10 PowerEdge M710HD with Intel(R) Xeon(R) CPU X5660 @ 2.80GHz
- 10 PowerEdge M620 with Intel(R) Xeon(R) CPU E5 -2650 0 @ 2.00GHz
- Dell Compellent Enterprise Storage SAN with 100 TB tiered virtualized storage

Data Backup

CRI uses IBM Tivoli Storage manager for automated nightly data backup of critical system configurations, VMs and research data. All data is copied to tape, encrypted and stored off es1e5at Data Center.

Technical Specifications:

IBM System x3850 X5, 65G Mem, 24 CPU

- Spectra Logic T950 library
- LT04 and LT06 tape drives

Data Security and Compliance

The CRI is the primary computing resource for BSD researchers working with electronic protected health information (ePHI). For this reason, it is essential that our infrastructure and security policies comply with relevant federal guidelines, including HIPAA. To this end, the Research Informatics Compliance Review Commit-

tee, made up of IT security professionals from other IT organizations across the University, spent several months drafting, editing, and approving a set of policies and procedures for data protection. This committee is also responsible for conducting regular audits to ensure compliance to these important standards. The CRI Systems and Security group manages all security aspects of the infrastructure using next generation security technology while following best practices such proper password management, system patching and regular review of system configuration settings against leading security practices such as those established by the Center for Information Security.

Technical Specifications:

- Palo Alto next -generation firewall 10- GB/s throughput
- IBM Security QRadar SIEM 1000 events per second
- Qualys Vulnerability Management system for 1500 hosts
- CIS Configuration Assessment Tool (CIS -CAT)

Data Centers

Research computing infrastructure and resources for the Center for Research informatics (CRI) are primarily located in the Kenwood Data Center which is located in Hyde Park on the University of Chicago campus. The Data Center is designed and tested to withstand extended power outages without system or service interruption. CRI servers are physically secure in a locked, facility fitted with an electronic alarm system. The data center is divided in two sections, each designed for different use cases: POD-A (2500 sq ft) and POD-B (2100 sq ft). POD-A is designed to house mission-critical workloads and meets the Uptime Institute's Tier 2 rating. POD-B is designed for compute-heavy High Performance Compute (HPC) with a power draw of up to 25kW per cabinet. As the primary data center for CRI computing resources, the Kenwood data center is managed by the University of Chicago, is monitored by staff 24/7, and is equipped to house systems that may fall under certain federal guidelines, including Health Insurance Portability and Accountability Act (HIPAA) and the Federal Information Security Management Act (FISMA).

The **1155 Data Center** is also located in Hyde Park on the University of Chicago campus, which is 4144 sq ft and managed by the University of Chicago. The CRI utilizes this facility to house the tape library that is used for data backups.

The **Darien Data Center** is located in Darien, IL. This is the primary data center for clinical applications and hospital systems. Currently used by the CRI to house the Clinical Research Warehouse and other research systems with clinical diagnosis requiring 24x7 technical assistance and support.

Bioinformatics Facilities

The Bioinformatics Core at the Center for Research Informatics offers services and expertise designed to allow BSD investigators to take full advantage of available high-throughput technologies. The aim of the Core is to provide the following services:

- Bioinformatics analysis of high-throughput biological data using well-defined analysis pipelines
- Direct consulting with bioinformaticians within the Core for specific/custom-made analysis or pipelines. The core facility consists at the moment of nine PhD level FTEs with skills and abundant experience in bioinformatics.
- Training on the use and applications of publicly and commercially available bioinformatics software and tools, enabling investigators to develop bioinformatics expertise within their laboratories.

The Bioinformatics Core has developed a suite of pipelines for data analysis from microarray and several Next Generation Sequencing (NGS) technological platforms, including ChipSeq, RNA-seq, and Exome Sequencing (both paired-end and single-ended) analysis. Supported tasks include read quality control, mapping, recalibration for exome sequencing, analysis of differential expression using RNA-Seq, etc.

High Performance Compute Resources

The bioinformatics core facility at the CRI has access to a High Performance Computing (HPC) Cluster comprised of 36 standard memory compute nodes (2.2 GHz, 2304 total cores, 256 gigabytes RAM per node) and 2 large memory compute nodes (2.27 GHz, 80 total cores, 1 terabyte RAM per node). There is also one Large Memory Compute System (80 cores running at 2.4 GHz) available. The HPC contains approximately 100 advanced data analysis software modules for bioinformatics, including those for NGS and microarray analysis and the CRI Galaxy instance (a web-based portal for biomedical analysis that is integrated with the CRI's HPC environment).

Other IT Resources

The CRI has its own Virtual Infrastructure with 18 physical servers running VMWare ESX connected to a Dell Compellent storage array. The CRI provides1.2 petabytes of File Storage (an EMC Isilon storage cluster) with available space to be provisioned for group shares assigned to BSD investigators. The storage systems are backed up to a SpectraLogic T950 tape library using IBM Tivoli Storage Manager (TSM). IBM TSM is also used for Data Archiving functionality where research data is archived on a SpectraLogic nTier Verde disk based storage array and on tape in the SpectraLogic T950 tape library.

IBM Cognos Analytics

In an effort to provide more self-service mechanisms for filling data requests, the CRI is rolling out IBM's Cognos business intelligence tools. The CRDW team will use Cognos's enhanced data analytics capabilities exclusively to pull data from the data warehouse and present it to end-users. We see the full-service model continuing to serve researchers with limited technical knowledge, while also growing the number of data requests fulfilled through the self-service component for technically proficient users. While the initial rollout phase will focus on replacing the existing homegrown CRI reporting functionality with Cognos, the overall goal is to create an intuitive and sustainable reporting environment for BSD researchers. As a result, researchers will benefit from shorter wait times for obtaining research data, which will translate into greater output of research and publications. In addition, the CRDW team will spend less time on the manual operations of filling data requests and more time on high-end research support.

Epic Clarity Enterprise Reporting System

Clarity®/Analyst® is a well-established clinical information system with warehousing physician order entry and extensive analytics capabilities. [www.epicsystems.com/Software/Foundation.php]. Our clinical databases are interrelated and integrated under the newly created Informatics Infrastructure, led our Chief Informatics Officer Robert Grossman PhD, enabling easy access to clinical data for tracking care and outcomes.

Beagle Supercomputer

The Beagle supercomputer is housed at ANL and is managed jointly by the UC Computation Institute (Ian Foster, Director) and UChicago BSD. Beagle is a Cray XE6 supercomputer with 726 compute nodes connected with the Cray Gemini interconnect. Each compute node has two Opteron 6100 processors, with 12 CPU cores per processor for a total of 17,424 CPU cores. Each compute node also has 32GB of memory, for a total of 23.3 TB of memory. The Gemini interconnect is configured in a 3D torus, which provides 85.3 GB/s of bandwidth to each node. Beagle provides 640 TB of high performance disk storage for computations.

Center for Data Intensive Science

The Open Science Data Cloud (OSDC)

The Open Science Data Cloud provides the scientific community with resources for storing, sharing, and analyzing terabyte and petabyte-scale scientific datasets. The OSDC is a data science ecosystem in which researchers can house and share their own scientific data, access complementary public datasets, build and share customized virtual machines with relevant tools necessary to analyze their data, and perform the analysis to address their research questions. It is a comprehensive solution for making scientific research faster and

easier. The OSDC is operated through the Center for Data Intensive Science (CDIS) at the University of Chicago in collaboration with the Open Cloud Consortium (OCC), which is a 501(c)(3) not-for-profit corporation.

The Open Science Data Cloud and related OCC clouds contain several petabytes of research data and have provided services for over 700 research projects since it started its operations in 2010. In 2014 there were 328 active allocations to researchers from 101 universities and research organizations from 14 countries that actively used these science clouds (Some of the researchers have had allocation for multiple years and some have had accounts on multiple of our science clouds). The OSDC ecosystem has numerous resources to serve the diverse needs of the research community.

Public Data Commons

The OSDC has 1PB of public data in a wide variety of disciplines. These datasets are freely available and can be downloaded over the internet or high performance networks for analysis locally. All recipients of OSDC resource allocations can also compute directly over the data in the Public Data Commons directly without having to download them locally.

General Compute Resources

The OSDC currently offers one general purpose compute cloud: Sullivan. This is for researchers without datasets that need to be analyzed in a protected environment (like human medical data or patient records). Researchers awarded allocations on Sullivan have access to their own private directory for storage and compute cores for analysis. Projects and labs awarded multiple allocations can request shared directories to facilitate group work.

Hadoop Resources

The OSDC offers two Hadoop resources for selected projects: OCC-Y and Skidmore. Unlike our Public and Protected resources which utilize the Tukey Webconsole, users granted allocations on Hadoop resources interact at the command line.

Protected Compute Resources

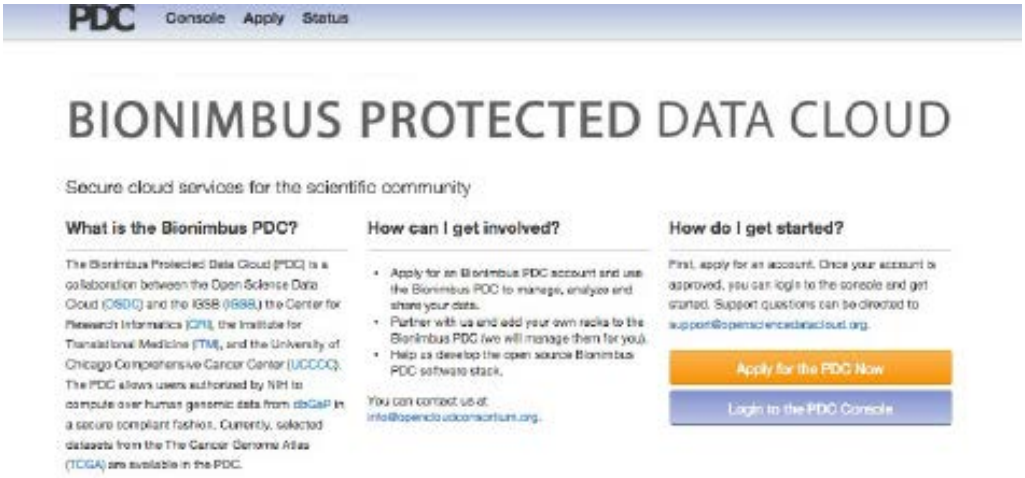
The OSDC currently offers two protected cloud computing resources for analyzing sensitive datasets (such as human medical data or patient records), the Atwood PDC and the Bionimbus PDC, operated at a FISMA moderate security level. There are additional legal requirements for access to these resources. The Bionimbus PDC is designed for researchers that have been granted access to the TCGA dataset and is currently used primarily for analysis of that data. Because it relies on eRA Commons for identification, it has a separate application process. More information about the Bionimbus PDC and Atwood PDC follows.

Bionimbus Protected Data Cloud

The Bionimbus PDC is a private cloud open-source cloud-computing infrastructure that has been operational since March 13, 2013. It is used for managing and sharing large amounts of genomic, clinical, and other data in a secure and compliant manner. The Bionimbus PDC is architected to be a secure self-service portal that enables researchers to set up their own virtual machines to access the data in the Bionimbus Data Commons, which currently includes selected data from the Cancer Genome Atlas (TCGA)

It is currently a Trusted Partner of the National Institutes of Health (NIH) and serves several different research projects, including the International Cancer Genome Consortium (ICGC) Pancan Project. More precisely, the Bionimbus PDC is operated under a subcontract (Subcontract 13xS021) between the University of Chicago and Leidos Biomedical Research Inc., in collaboration with the OCC.

Since deployment in 2013, the Bionimbus PDC has supported more than 122 allocation recipients from over 24 different research projects and 29 different institutions. Each month, the Bionimbus PDC provides over 1.4 million core hours to researchers.



Software and Services

The Bionimbus PDC currently provides Infrastructure as a Service or IaaS. With this service model, users can launch one or more virtual machines, install software and bioinformatics, access data from the Bionimbus PDC data commons, upload their own data or third party data, and perform whatever analysis they would like.

The current Bionimbus PDC software stack is based upon OpenStack for IaaS and Ceph for block and object storage. All the software that we develop is open source and uses the Apache license. The main software component of the PDC is OpenStack, which provides the services to start, stop, and monitor virtual machines, as well as related services, such as authentication and authorization services. The Bionimbus PDC uses Ceph for its storage; Ceph provides both object storage with a S3-compatible API and block storage, which is used by OpenStack.

The Bionimbus PDC also supports specialized high performance transport services so that large datasets can be moved efficiently over wide area high bandwidth networks in an encrypted format. The Bionimbus PDC middleware is called Tukey and includes services for interoperating with eRA Commons and dbGaP.

Networking and Connectivity

The Bionimbus PDC currently has a 10Gbps connection to the commodity Internet and a 80 Gbps connection to Internet2. It also uses a high performance data transport protocol called UDT (udt.sf.net), which can translate encrypted data at over 6 Gbps in a single flow. Multiple flows can be used to improve the performance.

Security and Compliance

The Bionimbus PDC currently operates under FISMA Moderate and follows the NISST Special Publication 800-63 Rev 2 with regard to authentication and authorization. The Bionimbus PDC uses NIH's eRA Commons for authentication and Access Control Lists (ACL) are created so that data can be restricted to: a) the depositor; b) to individuals that have been granted access to it; or c) to the public. The Bionimbus PDC interoperates with dbGaP at lease once per day and accesses a list of dbGaP users and the datasets they are authorized to access. Using this information ACL's can be set so that only those that have been authorized by dbGaP are provided access to controlled access data managed by the Bionimbus PDC.

Atwood Protected Data Cloud

The Atwood Protected Data Cloud is a private cloud with open source cloud-computing infrastructure to share and manage large amounts of data in a secure and compliant manner. Atwood supports faculty and research

projects at the University of Chicago. Atwood provides scalable storage and compute resources with co-located data, informatics applications, and tools. Numerous researchers throughout the University of Chicago Biological Sciences Division rely on Atwood for their projects, specifically in the departments of Health Studies, Medicine, Pediatrics, and Human Genetics.

The Atwood PDC currently provides Infrastructure as a Service (IaaS). With this service model, users can launch virtual machines, install software and bioinformatics, access data from the Atwood PDC data commons, upload their own data or third party data, and perform whatever analysis they would like.

The current Atwood PDC software stack is based upon OpenStack for IaaS and GlusterFS for storage. All the software is open source and uses the Apache license. The main software component of the Atwood PDC is OpenStack, which provides the services to start, stop, and monitor virtual machines, as well as related services, such as authentication and authorization services. The Atwood PDC also supports specialized high performance transport services so that large datasets can be moved efficiently over wide area high bandwidth networks in an encrypted format.

The Atwood PDC currently has a 10Gbps connection to the commodity Internet and a 80 Gbps connection to Internet2. It also uses a high performance data transport protocol called UDT (udt.sf.net), which can translate encrypted data at over 6 Gbps in a single flow. Multiple flows can be used to improve the performance.

The Atwood PDC currently operates under FISMA Moderate and follows the NISST Special Publication 800-63 Rev 2 with regard to authentication and authorization. The Atwood PDC has restricted authentication and Access Control Lists (ACL) are created so that data can be restricted to: a) the depositor; b) to individuals that have been granted access to it; or c) to the public.

Research Computing Center

The Research Computing Center is a unit under the UC Office of the Vice President for Research and National Laboratories, which also manages ANL and FNAL. The shared computing portion of the cluster has 345 compute nodes, of which 329 nodes containing a total of 5376 CPU cores are connected via 40Gbps Infiniband, 3 nodes with 48 CPU cores are connected via Gigabit Ethernet, 10 nodes with 176 cores contain nVidia GPU accelerators, and 3 nodes with 48 cores have extra memory up to 1 TB. The CPU cores are in 2.6GHz Intel Sandybridge Xeon CPUs, each with 6 cores. The RCC cluster currently has 96TB of high speed scratch storage, 1.4 PB of high capacity near-line storage and a 900 TB tape library for archiving and backup.

Computation Institute and Bioinformatics Resource

The mission of the Computation Institute (CI) of the University of Chicago and Argonne National Laboratory is to address the most challenging problems facing advanced high performance computation, in order to promote and facilitate problem-driven research across all disciplines. The CI leverages and enhances strength in both theoretical and applied math and computer science across the University and Argonne. Ian Foster was recently appointed Director and Jonathan Silverstein, Associate Director of CI. Among the Institute's members are more than 100 mathematicians, physicists, astronomers, linguists, geneticists (including Drs. Cox and White), geophysicists, neuroscientists, statisticians, political scientists, and legal scholars, as well as computer scientists. The CI is home to several large scale high-profile projects related to this application including the TeraGrid [www.teragrid.org], the Chicago Biomedical Consortium Proteomics Repository, and the National Microbial Pathogen Data Resource [www.nmpdr.org].

International Leadership in Grid Technologies

UC and Argonne National Laboratory researchers possess deep expertise in Grid infrastructure deployments (e.g., TeraGrid, Open Science Grid, caBIG), and applications (e.g., NMPDR, fMRI). We note that these technologies, developed by Computation Institute members, underpin the two major NIH resource federation initiatives, caBIG [cabig.nci.nih.gov] and BIRN [www.nbirn.net]. CI Director, Ian Foster, led the development of Grid

computing. By providing scalable, secure, high-performance mechanisms for discovering and negotiating access to remote resources, the Grid is allowing scientific collaborations to share resources on an unprecedented scale and for geographically distributed groups to work together in ways that were previously impossible (3). Two notable efforts from Foster's research group are their involvement in the integrated bioinformatics warehouse maintained by the Computational Biology group at Argonne; and their role in integrating Globus Toolkit 4, Web-standard workflow protocols, and data identifier and security mechanisms into the caGrid infrastructure of caBIG. The caBIG and caGRID are components of the large scale collaboration sponsored by the National Cancer Institute for collaborative cancer research. In ongoing work on caGrid, CI faculty are actively engaged in integrating Globus Toolkit 4 as the standard fabric on which all caBIG services for data retrieval and analysis.

Biomedical databases and informatics resources that support Clinical Research at the University of Chicago include:

- Velos Clinical Trials Management System: Velos eResearch is a web-based tool that supports the management, administration, and execution of clinical trials.
- Epic's Clarity Enterprise Reporting System: Clarity®/Analyst® is a well-established clinical information system with warehousing physician order entry capabilities. [www.epicsystems.com/Software/Foundation.php]
- LabVantage Biospecimen Manangement System: This is used by the Human Tissue Resource Center to track and manage biospecimens.
- Translational Research Initiative in the Department of Medicine (TRIDOM) is designed to build research infrastructure for the Department of Medicine and the BSD. Through TRIDOM, DNA, plasma, serum samples, and phenotype data are collected on approximately 3000-5000 patients per year. The TRIDOM database is managed by the Department of Medicine.
- Most recently, after a four-year collaborative development effort among three universities and the Searle family, the Chicago Biomedical Consortium has been established. The Mission of the CBC is to stimulate collaboration among scientists at Northwestern University, the University of Chicago, and the University of Illinois at Chicago that will transform research at the frontiers of biomedicine. It is a large-scale collaborative research effort focused on systems biology, leveraging proteomics, informatics, and imaging.

The informatics infrastructure and databases are, of course, interrelated and integrated under the newly created Informatics Infrastructure led our Chief Informatics Officer Robert Grossman PhD.

RUSH UNIVERSITY

Bioinformatics Core

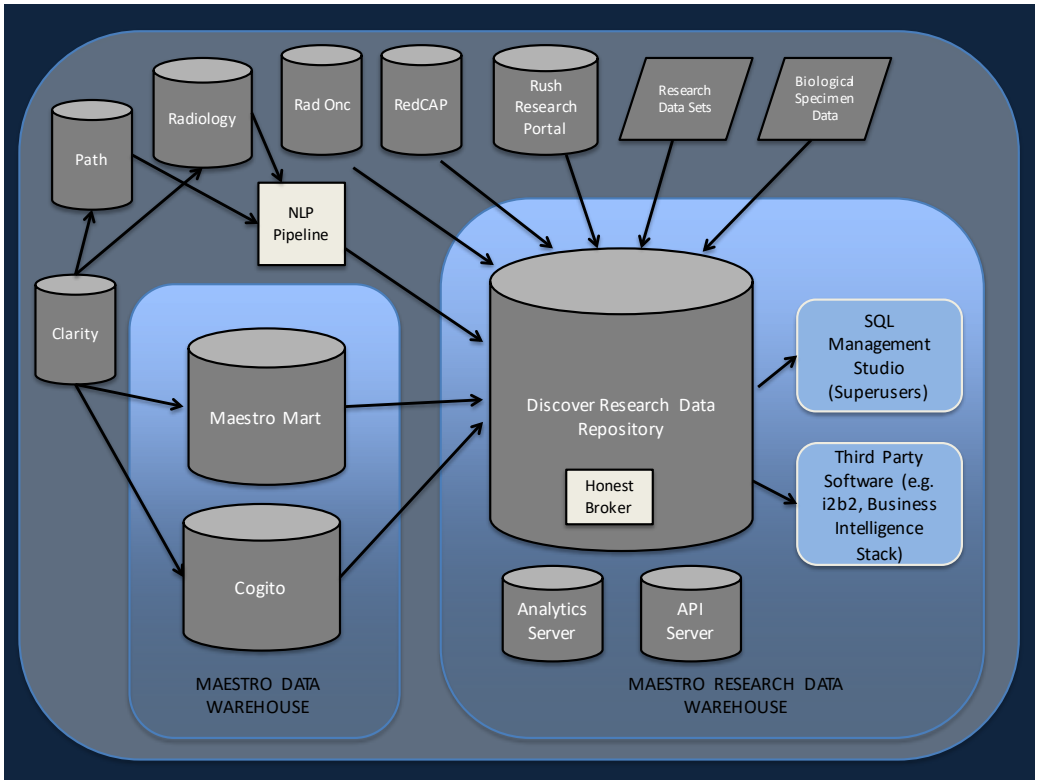
The Rush Bioinformatics/Biostatistics Core supports biostatistics and informatics needs for RUMC, including data extracts from the electronic record, development of data collection instruments, and clinical database development; bioinformatics pipelines and analysis; statistical design, and analysis; and innovative application development. The Core provides access to data for researchers from the electronic record and can also incorporate external data sets for linkage and/or analysis.

Rush has been a national leader in the implementation and integration of systems across the enterprise. The implementation of EPIC, deployed at Rush and Rush Oak Park and across hospital, emergency departments, and outpatient practices, has enabled Rush to achieve the Stage 6 HIMSS designation (achieved by only 5% of health systems) and gives a holistic, integrated view of patient care in one electronic system. The Core is well integrated within both Hospital Information Systems and Clinical Research, and overseen by the Chief Research Information Officer.

Data sources

RUSH maintains an Enterprise Data Warehouse comprised of clinical and administrative data derived from our EPIC Electronic Medical Record and associated clinical IT systems. This single source EDW supports all clinical, research, and operational needs and contains administrative data for greater than 10 years and clinical data back to 2007. RUMC currently uses Epic for nearly all clinical and revenue cycle applications across the enterprise, including inpatient, ambulatory, ED, operating room, oncology, pharmacy, registration/scheduling, professional billing, facility billing and patient portal activities. RUMC has extensively customized Epic to support quality measurement, decision support, and interactions with our patients through the patient portal implementation. The patient portal application is available to serve as a means of communication with, assessing the health outcomes of, and recruiting patients for participation in studies.

Extracts from the electronic record are curated and housed in the RUSH DISCOVER Repository Data Mart. Derived from the global knowledge management infrastructure of Rush (called Maestro), DISCOVER houses data sets and hosts views from data domains within the Rush enterprise, and protects data through governance processes and the function of an honest broker. Investigators are offered the ability to have a hosted environment for their data, with access to their data through self-service tools (see below). Data are de-identified through the use of an honest broker. Data sources within the RUSH DISCOVER Repository are linked to EPIC data found within the EPIC data warehouse (Clarity); linked datasets include subsets of Clarity with pre and post-processing, as well as relevant Cogito data; Pathology reports with National Language Processing derived interpretations; Radiology Reports with NLP derived interpretations; Microbiology and Laboratory Results; Operative Data; Rush Research Portal data; electronic Case Report Forms obtained from the RedCAP data collection system; and biospecimen data generated from instruments. Survey instruments are available on demand to investigators through an on Site implementation of RedCAP, which is maintained by corporate IT. The data model for the research data has been standardized and is a superset of the national Patient-Centered Outcomes Research Network (PCORnet) data model, of which Rush is a participant. Users access data from the RUSH DISCOVER Repository via several options of user interfaces: a self service portal which can be used to generate count data and demographic information for cohorts; third party software which can identify cohorts on demand through custom tools; and a SQL user interface which can access the research data set through ad hoc queries, views, and stored procedures.



Data standards

Data standards in use at RUMC include use of ICD-9/10; CPT coding; SNOMEDCT for clinical concepts;RxNorm for medications; and LOINC coding for clinical laboratory tests.

LOYOLA UNIVERSITY

Computing Infrastructure

Loyola University Chicago HSD and Stritch School Medicine (SSOM) computing resources include a state-of-the-art 2,200 sq. ft. research computing facility supported by a 500KW uninterruptable power supply (UPS), a 1MW external diesel generator and redundant 100T cold water chilling units. The facility has 33 42U racks each fed by redundant and diverse conditioned electrical subsystems. The facility operates more than 140 physical and 40 virtual servers that provide more than 1.5 petabytes of storage. The Loyola University Chicago (LUC) Health Sciences campus has both wired and wireless networks. Campus connectivity to the Internet is accomplished via a primary 250Mbs AT&T Ethernet circuit and a second diverse 250Mbs Ethernet circuit provided by XO Communications. Over 1,200 end-user devices (e.g., desktop computers) are provided on the health sciences campus. Principal investigators are provided secured, centralized file server storage to support approved research projects. Disaster recovery and business continuity services are provided through a second diverse backup computing facility that is located across main campus.

Computing Infrastructure Components

- High-Performance Computing Cluster (HPCC): This Linux-based ROCKS (http://www.rocksclusters.org) cluster featuring 72 Dell server compute nodes with 525 Intel processing cores and 550TBS of shared GPFS clustered file system storage.
- High-Performance Molecular Visualization Cluster: This Linux-based ROCKS cluster featuring seven Dell server compute nodes with 448 Intel processing cores and 40TBs of file system storage dedicated to molecular structure and movement visualizations.
- Production (CRDB) Hadoop Cluster: A Linux-based Hadoop (Cloudera) cluster with 15 data nodes providing 265TBs of Hadoop distributed file system (HDFS) storage. The cluster provides Hive, python and java frameworks for "big-data" processing related to advanced clinical analytics.
- Development (CRDB) Hadoop Cluster: A Linux-based Hadoop (Cloudera) cluster with 12 data nodes providing 15TBs of Hadoop distributed file system (HDFS) storage. Cluster provides Hive, python and java frameworks for "big-data" processing related to advanced clinical analytics.
- General Scientific Hadoop Cluster: A Linux-based Hadoop (Cloudera) cluster with 13 data nodes providing 21TBs of Hadoop distributed file system (HDFS) storage. Cluster provides Hive, python and java frameworks for "big-data" processing relating to general scientific processes.
- Symmetric multiprocessing (SMP) servers: Three symmetric multiprocessing (SMP) servers each with 24 processing cores and 512GBS of random access memory are provided for virtual server support and for analyses that require large physical memory spaces. These SMP servers have access to the GPFS file systems that are attached to HPCC resources.
- Infrastructure servers include more than 20 web/file/print/video servers that are load balanced by F5 Network and A10 hardware load balancers. The majority of systems operate on Linux (Centos 6.3).

Bioinformatics Core/Computing Resources

The clinical research database (CRDB) is comprised of a limited dataset of patients from Loyola University Health System's Epic electronic medical record (EMR). The CRDB consist of a Hadoop-based clinical data repository and a supporting end-user, self-service web application. The CRDB is accessed via the institution's intranet portal and is available to all active users. Users can perform "preparatory-to-research" patient cohort queries on a self-serve basis and request access to underlying data through an online institutional review board (IRB) process. To date, the CRDB has been utilized by 1,302 users to perform 1,527 patient cohort queries.

The Relationship of Clinical Knowledge to Events Tool (ROCKET) is an innovative "big data" research and education tool that supports clinical analysis, data visualization and knowledge linking to allow users to explore large, temporally analyzed clinical datasets. Clinical events (e.g., chronic and non-chronic disease, medications, etc.) are defined and longitudinally analyzed on the institution's Hadoop cluster with resultant temporal data passed to ROCKET. The institution's Hadoop-based clinical research database (CRDB) with 2M patients and nine years of clinical data is longitudinally analyzed with ROCKET clinical events that currently include 26 chronic diseases, 32 non-chronic diseases and 12 classes of medications. Users also can perform ad-hoc multi-event visualizations by selecting an "alignment" event (e.g., acute myocardial infraction) and a desired number of temporal events. Events are Medical Subject Heading (MeSH) coded to support linking to online knowledge content.

Clinical Informatics and Systems Development Resources

The Office of Informatics and Systems Development (OISD) houses a number of clinical data analysts, programmer/analyst and advanced systems developers. OISD was first established in 1987 as the Department of Medicine's Division of Medical Informatics and has developed a total of more than 750 clinical research and medical education applications. The division developed the medical center's first electronic medical record (EMR) in 1990 and currently provides advanced analytics support for the institution's EPIC-based EMR. A specific division focus is the use of "big data" technologies such as Hadoop, Hive, "R" and python to accomplish

advanced large-scale clinical analytics. Beyond "preparatory-to-research" activities, OISD annually supports analytics on average for 130 IRB-approved clinical research projects and 50 quality/clinical improvement projects. OISD staff members serve as informatics members representing the institution on the current PCORI-funded CAPriCORN clinical data research network project.

Computing Infrastructure Components

- High-Performance Computing Cluster (HPCC): This Linux-based ROCKS (http://www.rocksclusters.org) cluster featuring 72 Dell server compute nodes with 525 Intel processing cores and 550TBS of shared GPFS clustered file system storage.
- High-Performance Molecular Visualization Cluster: This Linux-based ROCKS cluster featuring seven Dell server compute nodes with 448 Intel processing cores and 40TBs of file system storage dedicated to molecular structure and movement visualizations.
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COMMUNITY AND COLLABORATION

UNIVERSITY OF CHICAGO

Center for Community Health and Vitality (CCHV)

The Center for Community Health and Vitality (CCHV) uses a systematic approach for addressing personal and community health within the neighborhood setting via three main program elements:

- Academic partnerships
- Community connections
- Community grand rounds

The CCHV and its partners recognize that good health is not merely the absence of disease, it also fosters vitality -- the capacity to live and develop. The CCHV works individually and collectively with the community to develop programs and activities that address issues determined by the community as concerns. The center engages the community to provide a place where community residents and organizations, along with university physicians, professors and staff, can work together to determine ways to improve health and vitality within South Side communities. The CCHV puts this approach into practice via:

- Educational innovation
- Workforce development and career training

- Violence prevention
- Capacity building for community-based organizations
- Wellness programs
- Employment and economic development opportunities

CCHV was originally conceived by first lady Michelle Obama during her tenure as vice president of community affairs at the University of Chicago Medicine. The CCHV, along with the Urban Health Initiative, aims to promote positive relationships between the University of Chicago and South Side communities and improve health services and support to residents. The CCHV also provides a means by which the university and South Side communities can create sustaining collaborative relationships and partnerships that address both medical and social issues that threaten the health and vitality of community.

Through positive engagement with communities served by the medical center, these initiatives were developed to build positive relationships that will initiate a new spirit of collaboration and cooperation. CCHV and its partners seek to achieve this goal by finding new ways to understand more fully the perspectives of our communities' members, organizations and institutions.

South Side Health & Vitality Studies (SSHVS)

The South Side Health & Vitality Studies (SSHVS) are a component of the University of Chicago Medical Center's Urban Health Initiative. SSHVS are a family of research studies that join community members with faculty, staff, doctors and nurses from the University. Together, they help generate knowledge about health and the impact of interventions in order to create and maintain good health on the South Side of Chicago. Through this collaboration, SSHVS seeks to design and conduct studies that result in meaningful benefits to researchers and communities.

Researchers with the Studies gather information that contributes to a holistic understanding of the factors that influence the health and wellness of residents on Chicago's South Side. SSHVS seeks to both strengthen existing relationships and foster new partnerships. SSHVS researchers are also committed to making data accessible to community residents and organizations. By working with the communities, the SSHVS learn innovative ways to make the research meaningful and useful to local residents and organizations. Lastly, the Studies inform UHI planning and programming and the Center for Community Health and Vitality (CCHV).

A flagship project of SSHVS is MAPSCorps. MAPSCorps pairs high school youth with science-oriented University students. Working in teams, MAPSCorps participants walk every block of our communities, observing, collecting, cataloguing, and analyzing data about all public-facing businesses and organizations. Through hands-on, real-world experiences youth learn to practice integrity in interpersonal relationships, in the workplace, and in science. Community organizations, students, and urban planners are using the MAPSCorps database as a tool for planning programs and identifying assets and needs in the 24 SSHVS communities. This project has been carried out to advance knowledge about communities on the South Side of Chicago, providing information to individuals looking for services, researchers studying how community resources relate to health and vitality of communities, and community-based organizations seeking to identify areas of need.

Office of Community Engagement and Cancer Disparities

Office of Community Engagement and Cancer Disparities (OCECD) is part of the UCCCC. The OCECD, under the direction of Dr. Kim (Director), has formed strategic alliances with other University of Chicago entities, such as ITM, UHI, and other healthcare organizations, as well as community, ethnic, and faith-based groups to create innovative programs that will increase access to care, reduce risk factors for cancer, increase participation in cancer research, and improve the quality of life for cancer patients and survivors. Specific OCECD activities have focus on African American communities on Chicago South Side, Asian American communities throughout Chicago, and Hispanic and Native American communities in the Chicago Area. Community outreach and engagement are essential to addressing the unequal burden of cancer carried by many racial and ethnic groups,

particularly in a major metropolitan city with a diverse population such as Chicago. To reach the different ethnic groups, the program partners with over 50 community and faith-based organizations. Through such collaborations, OCECD is able to not only tailor outreach efforts to each community, but also to teach community leaders to become health advocate. In 2015, OCECD conducted 36 cancer outreach events in six languages (English, Spanish, Cantonese, Mandarin, Korean and Vietnamese), and reach 7000+ community members. The OCECD will provide a mechanism to integrate with the National Cancer Institute's National Outreach Network, enhance dissemination and access to other minority communities and provide bilingual community health educators for the program. The community educator supplement is directed by Dr. Kim and is funded through 2018. Two CHE's are supported through the CHE program. Lisa Hinton, MPH has focused on engaging member of the African American community, while Helen lam, RN, PhD works with the Asian American community. Together, the CHEs have developed, implemented and evaluated community based programs to increase cancer screening and prevention.

Midwest Clinicians Network

The MWCN is a well-established not-for-profit professional development organization comprising 120 community Health Centers (HCs) throughout 10 Midwestern states, serving very diverse, medically underserved patient populations in both urban and rural settings. Most HCs encompass multiple practice sites; MWCN represents over 300 primary care practices serving approximately 2 million patients overall, of whom approximately 25% are African American and 22% are Latino (HRSA Bureau of Primary Health Care data).

Overall, MWCN HCs average approximately 3 primary care practice sites per HC, and the 120 member HCs represent over 300 primary care practice sites throughout the Midwest. Nearly all Midwestern HCs (> 92%) have implemented Electronic Health Records and are learning to use them to improve screening, patient tracking and care, including care for obesity.

For nearly 20 years, MWCN has had a productive collaborative Research Committee that includes HC members along with health services researchers and QI leaders from the University of Chicago. The Research Committee utilizes the principles of CBPR and community-engaged research to improve care and outcomes of HC patients. Most research topics emanate from the priorities of MWCN membership as assessed through surveys and in-person meetings. The Research Committee is chaired by Loretta Heuer, RN, PhD, and Cynthia Schaefer, RN, CS. Amanda Campbell, Executive Director of the MWCN, provides direct support and connection to the regional network. Additional infrastructural support for the MWCN Research Committee is funded with a subcontract from the NIDDK P30 Chicago Center for Diabetes Translation Research (PI: M. Chin). Supported by AHRQ, the MWCN-University of Chicago collaboration performed the comprehensive evaluation of HRSA's Health Disparities Collaboratives. Other projects have examined health literacy, care of Latino patients with diabetes, group diabetes visits, care coordination in HCs, and the COACH pilot study to improve weight management programs in HCs. The Research Committee disseminates study results throughout the HC, academic, and policy communities. In addition to the extensive networking of HCs within its network, MWCN has the support of each of the 10 state Primary Care Associations (PCAs) in the region. PCAs are funded by HRSA's Bureau of Primary Health Care to provide resources and assistance to HCs to increase access and meet the needs of underserved populations, with special emphasis on behavioral health interventions. PCAs assist with dissemination of information from MWCN to HCs in their states at their annual meetings and through their clinical networks.

Health Outcomes Research Group

The Section of General Internal Medicine, led by Dr. Deborah Burnet, has an active program in health services research and QI directed by Dr. Marshall Chin. Research and teaching in health services and QI are significant, with a strong record of publication, external funding, and an AHRQ-funded National Research Service T32 Award in Health Services Research. For more than 10 years the Health Outcomes Research Group hosted the Robert Wood Johnson Clinical Scholars Program. The development and growth of the Public Health

Sciences Department (Dr. Gao) in direct proximity to the Section adds resources in epidemiology, biostatistics, health services research and QI. The close proximity of premier social science departments and long history of interdisciplinary collaboration provide an unusually rich environment for health services research and QI at UC.

Chicago Center for Diabetes Translation Research

Marshall Chin, MD, MPH, directs this NIDDK P30 center with mission to improve lives of people with diabetes or at risk for diabetes through innovative, high-impact research and programs. The Center seeks to prevent diabetes, improve the quality and value of diabetes care, and empower patients and communities. The Center collaborates with researchers, policymakers, healthcare providers and community partners; shares findings to improve practices and policies; improves the health of vulnerable populations and reduces racial, ethnic and socioeconomic disparities in health and health care. The Center has cores in Outcomes Improvement (led by Dr. Burnet), Quantitative Analysis, and Health Disparities and Community-Based Participatory Research.

Project ECHO

Extension for Community Healthcare Outcomes (ECHO) expands access to specialized care in vulnerable, underserved communities. Funded by the UHI, ECHO uses advanced videoconference technology to bring together academic medical center experts and local primary care providers, allowing patients to receive state-of-the-art, evidence-based care for complex chronic conditions at their medical homes. Specialty care experts use case-based, iterative learning to train primary care providers (PCPs) during regularly scheduled videoconferences. Technology is also used to track patient progress and provider participation in order to support detailed evaluation and identify areas needing additional improvement or support with greater efficiency and effectiveness. Pioneered for a rural population by the University of New Mexico, ECHO offers a robust, efficient, cost-effective solution to one of the most vexing healthcare issues - access to subspecialty care for complex chronic disease in underserved communities. UC has partnered with the SSHC to bring ECHO to Chicago, marking the first effort to implement ECHO to serve an inner-city population, and representing the first project involving a largely African American population.

Center for Asian Health Equity

Directed by Dr. Kim (PI), CAHE is a community academic partnership formed to develop and enhance capacity for Asian health research, training, community engagement and public policy and is the only center focused on Asian health in the Midwest. With 9 full time public health staff and funding from the CDC, SAMHSA, NCI and foundations, CAHE's goals are to

- Develop and conduct research to understand, address, and reduce health disparities in Asian American communities and expand to include comparative research for other minority groups;
- Build new and strengthen existing private and public partnerships in order to increase outreach, advocacy, and research capacity to address Asian American health disparities and social inequalities;
- Use research to inform policy and advance forward, public health issues impacting Asian Americans in Midwest.
- Establish a model health delivery system for Asian Americans

CAHE's mission aligns with the CTSA and will provide resources for research, training and administrative support.

Urban Health Initiative

Urban Health Initiative (UHI) is the University of Chicago Medical Center's long-term commitment to improving health and access to quality care for the South Side of Chicago through patient care, community-based research and medical education. UHI is working to establish strong, lasting relationships with civic leaders, community organizations, health care providers and residents to develop a comprehensive health care system

that is rooted in collaboration. The UHI is designed to encourage wellness and connect patients to the care they need. The collaboration with UHI will create a synergistic interaction between UHI and OCCED, both offices aim to improve community health care access and quality, to build health literacy and trust throughout the community and to enhance a translational research program informed by and responsive to the needs of the community, and so to reduce health disparities. The infrastructure that built under this proposal and lessons generated will enhance UHI's dissemination efforts for the South Side population.

RUSH UNIVERSITY

Offsite Clinical Research Space for Community-Based Epidemiologic Studies

Clinical evaluations for the Religious Orders Study Core of the Rush ADCC and Memory and Aging Project are performed at more than 80 convents, monasteries, continuous care retirement centers, retirement homes, and subsidized housing venues, in addition to community centers, churches, and participant's homes across northeastern Illinois and the United States. Participating facilities provide the clinical evaluation team (study coordinators, nurses, neuropsychological test technicians, research assistants, clinical assistants, phlebotomists, and physicians) with a waiting room, rooms with outlets for examination, testing, and interviewing. Many other clinical evaluations are performed as individual home visits. Clinical evaluations for the Clinical and Latino Cores of the Rush ADCC, the Minority Aging Research Study, the Center of Excellence on Disparities in HIV and Aging, and the many other community-based research projects are performed at participants' single-dwelling homes and subsidized housing venues, in addition to community centers and churches across the metropolitan Chicago-land area. All clinical evaluations are performed as individual home visits. Study participants are also offered the opportunity to be tested at the Rush Alzheimer's Disease Center.

Offsite Space for Community-Based Education and Recruitment Activities

Community-based education and recruitment activities are performed in sites including, but not limited to, community centers, churches, City of Chicago Department of Aging Senior Centers, and library conference rooms across the metropolitan Chicago area. The locations vary widely allowing the Rush Alzheimer's Disease Center recruitment staff to reach a large number of racial and ethnic minorities. One-on-one education efforts on research participation may be done at community sites in addition to participants' single-dwelling homes and subsidized housing venues. For an activity requiring a centralized location for community members throughout the Chicago metropolitan area to attend, Medical Center conference rooms with electronic media equipment for small, medium, and large groups are accessible by staff in addition to Medical Center catering services.

TRANSLATIONAL ENDEAVORS

WORKFORCE DEVELOPMENT

University of Chicago Pipeline Programs

The University of Chicago administers several successful pipeline programs to prepare and inspire talented high school and college students to pursue careers in medicine and health-related research. The unique experience of working side-by-side with scientists and physicians allows the students, who are often from disadvantaged backgrounds, to gain firsthand knowledge from members of the scientific community about the exciting efforts underway to unravel cancer's mysteries. These pipeline programs illuminate the field for the next generation of brilliant cancer scholars.

Continuing Umbrella of Research Experience (CURE)

The Comprehensive Cancer Center launched this program in the spring of 2014 to introduce talented minority high school and undergraduate students to cancer research. Funded by a Continuing Umbrella of Research

Experience (CURE) grant from the National Cancer Institute and the University of Chicago Cancer Research Foundation Women's Board, the program provides a hands-on summer research experience for students under the mentorship of Comprehensive Cancer Center faculty.

Spreading Teen Research Inspired Videos to Engage Schoolmates (STRIVES)

As our nation's population becomes increasingly diverse, it is important that all aspects of our health care workforce represent that diversity. A diverse health care work force is an important part of expanding health care access for the underserved, enriching the pool of leaders and policymakers to meet the needs of a diverse population, and fostering biomedical and clinical research to address diseases that affect these populations. Unfortunately, data suggests that few high achieving minority youth would consider a career in research, thereby limiting the success of early outreach programs in identifying potentially successful future researchers.

One promising way to increase interest in clinical research careers among youth is through the spreading of video messages crafted and created by teens for their classmates through social media. Through STRIVES, TEACH Research students research, create, and launch a viral social media campaign that encourages their peers to consider a career in clinical research. Expert staff and faculty guide students as they conduct focus groups, shoot video, edit footage, and launch a successful campaign. The aim of this study is to assess the impact and reach of these student-led social media campaigns.

Hexacago Health Academy

Hexacago Health Academy (HHA) is a game-based science and health program. HHA engages high school students in learning about and addressing major health issues through game play, interaction with STEM and health professionals, and mentoring. HHA is supported in part by R25OD020243, a Science Education Partnership Award (SEPA) in which the ITM is a collaborating partner.

<u>The Hexacago Board</u>

In 2013, the Game Changer Chicago Design Lab created a game board that could be used to design a variety of games related to health and STEM issues. The board, Hexacago, symbolizes the city of Chicago and the different city regions overlaid with a grid of hexagons. Each game played on the board brings a systems-level perspective to health and wellness and helps players understand how personal, social, community, and policy factors affect help.

<u>Hexacago Game Design Program</u>

A three-week summer program for youth that provides in-depth exposure to public health and science careers while fostering game development using the Hexacago board. Topics have included sexual and reproductive, alcohol and drugs.

<u>Ci3 and GCC</u>

The Center for Interdisciplinary Inquiry and Innovation in Sexual and Reproductive Health (Ci3) was founded in 2012 by Melissa Gilliam, MD, MPH, and is led by executive director Brandon Hill, PhD. Ci3's Game Changer Chicago (GCC) is co-led by Patrick Jagoda, PhD (English and New Media Studies) and Dr. Gilliam. Located at the University of Chicago, Ci3 focuses on the health and well being of youth and takes a broad view of sexual and reproductive health, considering how biological, social, and systems-level factors influence individual health and behaviors. A critical part of Ci3's success is rooted in The Game Changer Design Lab. The GCC lab designs serious games, interactive learning experiences and digital media arts projects with youth and for youth. Youth participate in game play and design to gain new literacies, health knowledge, scientific awareness, technological skills, and positive interactions with adults that can lead to empowerment and long-term well-being.

Health and Science Professionals

A critical part of HHA is youth interacting with STEM science and health professionals. The main objectives for these workshops are to increase youth's interest in science and health careers, as well as provide opportunities for students to learn about particular science or health topics, thus helping youth build positive futures and improve sexual and reproductive health outcomes. Partnering with science and health professionals provides rich information on health topics and offers opportunities for students to ask questions about careers and make steps toward college readiness.

STEM, health, and science workshops expose students to traditional and non-traditional careers. Faculty and professionals from the University of Chicago and the community are incorporated into these programs including: doctors, nurses, lawyers, epidemiologist, anthropologists, and basic scientists. Workshops help students learn about disciplines a wide-range of disciplines from sociology to health policy. Students then take what they learn in each workshop to design games.

Youth Initiated Mentoring (YIM)

To address the need for a lack of mentors for many youth, HHA incorporates natural mentoring relationships through an approach called as Youth Initiated Mentoring (YIM). Through YIM, youth are trained to seek and build relationships with non-parental adults from their community (e.g., teachers, extended family). In one study, YIM has been shown to create mentoring relationships that last longer than formal mentoring relationships among youth who have dropped out of school. YIM has been developed by researchers at the University of Massachusetts, Boston.

Teacher Professional Development

Professional development sessions are held for teachers in Chicago on game-based learning and the Hexacago Game Design Program. These sessions serve as a learning opportunity for both high school teachers and the team of HHA.

researcHStart

The researcHStart program is an 8-week cancer-focused research and career development experience for the most promising high school students from the Chicago and Champaign-Urbana areas. The research experience is the core of the program, which provides hands-on, full-time immersion into a cancer research environment under the supervision of an established, funded investigator. Depending on the specific project and mentor, students will develop an understanding of cancer epidemiology, treatment of cancer, imaging, molecular and biochemical underpinnings of cancer, immunology, pharmacogenomics of anticancer agents, engineering, biomarker development, development of anticancer agents, experimental cancer therapeutics, and/or cancer disparities.

Young Scientists Training Program (YSTP)

The Young Scientists Training Program (YSTP) is an 8-week summer program sponsored by the Pritzker School of Medicine for up to 10 outstanding minority high school students to gain experience in research, medicine, and the biological sciences. Students work in the laboratories of University of Chicago faculty where they learn skills in basic science and clinical research.

Chicago Academic Medicine Program (CAMP)

The Chicago Academic Medicine Program (CAMP) is a 6-week summer program for undergraduate students who have completed freshman or sophomore year, or high school seniors who have been accepted into college. The Pritzker School of Medicine Office of Multicultural Affairs developed CAMP to help multicultural and disadvantaged students prepare for success in a premedical program.

Pritzker School of Medicine Experience in Research (PSOMER)
The Pritzker School of Medicine Experience in Research (PSOMER) program is an 8-week research, education, and mentoring experience with University of Chicago faculty. PSOMER is open to college students who are rising juniors and seniors graduating after January 1. The program seeks high-achieving students from disadvantaged backgrounds to gain experience with basic and clinical research.

Training Early Achievers for Careers in Health (TEACH)
Training Early Achievers for Careers in Health (TEACH) Research provides opportunities for talented Chicago Public Schools high school students to gain exposure in health-related research through a summer experience at the University of Chicago. This program, sponsored by the Pritzker School of Medicine, is designed to prepare the students for academic success at the best colleges and universities.

The Leadership Alliance
The Leadership Alliance is a national consortium of more than 33 leading research and teaching colleges, universities and private industry, of which the University of Chicago is a member, that aims to train, mentor and inspire a diverse group of students into competitive graduate training programs and professional research-based careers. The Leadership Alliance Summer Research – Early Identification Program (SR-EIP) is a rigorous research experience providing undergraduates with training and mentoring in the principles underlying the conduct of research and prepares them to pursue competitive applications to graduate schools.

Post-Baccalaureate Research Education Program (PREP)
The University of Chicago Post-Baccalaureate Research Education Program (PREP) is a training program aimed at members of groups underrepresented in the biomedical or behavioral sciences who want to pursue graduate school but need additional preparation. The program provides students holding a bachelor's degree in science with the opportunity to work in a laboratory as a technician for one year as well as participate in educational activities to help them prepare for successful application to a PhD program.

Rush University

Rush University/Malcolm X Community College Partnership
Rush University Medical Center provides resources, from equipment donations to clinical rotations and guest lecturers to nearby Malcolm X College, helping to train people for jobs in the health sciences that are available now but remain unfilled due to a skills gap. The agreement allows MXC students to gain valuable experience at Rush through clinical rotations, career ladder programs and other initiatives that had already been in place.

Chicago Public Schools Career and Technical Education Program
In the Chicago Public Schools (CPS) Career and Technical Education (CTE) Program, Rush and other local health care institutions partner with six CPS high schools in the community to encourage the pursuit of careers in health care via lectures, internships and mentorships with Rush faculty.

RESEARCH METHODS

BERD

University of Chicago

Department of Public Health Sciences
The Department of Public Health Sciences at the University of Chicago is an interdisciplinary department that includes Epidemiology, Biostatistics, and Health Services Research, as well as the Biostatistics Laboratory. The Department provides strong institutional support for research, including outstanding IT and administrative

support. This Biostatistics facility is located in the Billings Hospital under the direction of Dr. Ted Karrison and provides statistics expertise for both animal and human studies. The Biostatistics Laboratory provides University researchers with biostatistical, epidemiological, and health services research expertise in a collaborative setting. Investigators may request assistance with study design, protocol development, sample-size determination, preparation of grant proposals, randomization, data analysis and interpretation, and manuscript preparation. Investigators are encouraged to inquire about collaboration at the earliest feasible time, generally during the planning stage of a study or proposal.

Computer: All faculty and staff of the Department of Public Health Sciences, in which the statisticians reside, are provided with desktop and laptop computers (Dell and Apple) for data management, statistical analysis, and word processing. Statistical software maintained on the desktop machines includes SAS, Stata, and R. Development languages include C++, C, Java, etc. High quality, color laser printers and copying machines are also extensively utilized.

Department of Public Health Sciences members also have access to various systems working in unison to provide a comprehensive information system:

1. The clustered fileserver (comprised of two virtual machines each with a quad-core processor running at 2.60GHz; 6GB memory and connected to Dell MD3260i RAID disk array with 57TB of storage), stores members data directories. The fileserver is also running Volume Shadow Copy; this provides point-in-time copies of data. Minimally, file system backups of members data is performed on a weekly interval and archives are stored at an offsite location called Iron Mountain. The fileserver is located in a physically secure, environmentally controlled room with a back-up power supply.

2. The Application Server is a Dell R920 (quad-processor quad core running at 2.99GHz, equaling 48 cores; 768GB memory) running Windows Server 2012 R2 Enterprise x64. This server runs Microsoft Hyper-V which hosts the Application Service virtual machine, which has 46 cores running at 2.99GHz, and 719GB memory along with 1.45TB for starch data storage. The Application Service provides statistical software packages including: SAS, STATA, MPLUS, and R to all members of the Department of Public Health Sciences. The Application Server is physically housed in a secure, environmentally controlled room with a back-up power supply.

Office: The Department of Public Health Sciences has 18,629 square feet of office space. Three private or shared offices, totaling 400 square feet, are available for this project.

Rush University

Biostatistics Core

The Rush Bioinformatics/Biostatistics Core supports biostatistics and informatics needs for RUMC, including data extracts from the electronic record, development of data collection instruments, and clinical database development; bioinformatics pipelines and analysis; statistical design, and analysis; and innovative application development. The Core provides access to data for researchers from the electronic record and can also incorporate external data sets for linkage and/or analysis.

Loyola University

Biostatistics Support Office

The biostatistics core provides consultative and collaborative statistical support to faculty, staff and students pursuing clinical research. The CRO Biostatistics Core is headed by a senior PhD biostatistician and the team consists of two MS level biostatisticians who are seeking PhD in biostatistics. Expertise and services are provided in areas such as study design, power calculations, statistical analyses, database development and management using REDCap, grant and manuscript preparation and educational training. Education is provided via private consultation and lectures. Requests for statistical support come through the CRO portal and are re-

viewed on a weekly basis. Over 20-25 requests for statistical, study design and data storage come through the research portal each month. The senior biostatistician provides input and percent effort for federal grants. The bio-statistical core also provides support for the Cancer Center and sits on the Cancer Center protocol review and safety committee.

RKSE

University of Chicago

Office of Clinical Research

The Office of Clinical Research (OCR) was created to further the missions of the University of Chicago Biological Sciences Division and the University of Chicago Medical Center by developing and supporting specific infrastructure components related to clinical and translational research. The clinical research portfolio includes 530 Principal Investigators with 2700 IRB approved protocols and 3000 engaged faculty and staff. Of those, over 200 investigators are conducting approximately 1,000 interventional clinical trials. To provide the highest level of support and resources, the Office of Clinical Research (OCR) is divided into two groups- the Institutional Review Board Administrative Staff (IRB) and the Research Operations and Conduct group (ROC). Together, they are tasked with: ensuring that federal, state and local regulations governing clinical research and human subject protection are followed: providing support for conflict-of-interest management: clinicaltrials.gov registration and facilitating results reporting; all research related hospital and professional billing compliance; support for PI held IND/IDE submission and on-going management; and facilitating institution-wide systems implementation as related to clinical research compliance and conduct. The novel organizational structure of having the IRB administrative staff and research training/conduct/oversight staff in one office allows for a greater level of coordination and collaboration early in the protocol review and approval process as well as throughout the life of the study. By providing high level guidance in the process of clinical and translational research conduct, the OCR seeks to enhance the excellence, scope and efficiency of these research efforts by facilitating and integrating activities already in place and by fostering clinical and translational research activities in areas where they are not yet fully developed. The OCR focuses on five key areas of service including:

- Human Subject Protection (IRB)
- Training and Education
- Regulatory and Contract Oversight
- Financial/Billing Compliance
- Institutional Infrastructure

<u>Human Subjects Protection (IRB)</u>

The BSD/UCMC IRBs are charged with the responsibility for review, approval and surveillance of all research involving human subjects carried out in the BSD and the University of Chicago Medical Center. This review and surveillance is conducted to assure the protection of the rights and welfare of all research subjects, including volunteers and patients, as well as ensure compliance with regulations. The BSD/UCM IRB is comprised of three committees with 36 meetings a year where new submissions, annual continuing reviews, amendments and unanticipated problems are reviewed. Each committee has a dedicated vice chair and the IRB committee chairman is part of all three committees. In addition to the meeting preparations and committee review and approval, the IRB chairs and administrative leadership regularly meet with faculty to discuss new research endeavors and offer guidance about how to comply with applicable regulations. Additionally, they are deeply involved in many committees and projects furthering our clinical research missing.

<u>Education and Training (i.e., Conduct)</u>

These initiatives focus on training faculty and research staff on the regulatory requirements and best practices of conducting clinical research. This includes but is not limited to navigating local operations and identifying

resources necessary for compliant and efficient research conduct. Educational programming out of the OCR includes a formal 10-week training program for new research staff; quarterly workshop series; training sessions throughout the year on key topics like the informed consent process and management of clinical research; educational tools, templates, and guidance documents published on the OCR website; a bi-monthly newsletter on research operations and local processes; and frequent informal mentoring/ training sessions to help meet the needs of individual investigators and staff. This group is also the point of contact for our online training options in CITI and establishing annual training requirements to fulfill our training policy. Investigator initiated research and the associated principal investigator-sponsor responsibilities are a key area of focus for this group. They work with investigators and research teams to ensure that all training requirements and documentation are completed as well as monitoring plans and data collection methods. ResearchMatch and assistance with other recruitment efforts are also handled by this team.

Regulatory and Contract Oversight

Their focus is on providing investigators and staff with comprehensive study initiation, conduct, and ongoing regulatory guidance and support. This team provides services to enhance the investigator's ability to achieve excellence in their research while adhering to federal and state regulations as well as institutional policies. The Regulatory and Contract Oversight team ensures harmonization of key documents and identifies applicable regulations at the initiation of a study in order to support the investigator in adhering to all of the applicable requirements of their project. This group is also responsible for supporting investigator IND/IDE submissions to the FDA as well as ensuring compliance with clincaltrials.gov registration and results reporting regulations. Master clinical trial agreements and challenging contract terms are also coordinated between this team and the University officials who sign contracts.

Financial and Billing Compliance

Financial Management services are designed to facilitate compliant research billing based upon coverage determinations and identification of research billed services at study initiation. The Financial Management team works closely with budget managers and research staff to ensure services rendered for research purposes only are appropriately charged to the research account thereby ensuring compliance with Centers for Medicare and Medicaid Services (CMS) requirements. Special attention is paid to protocols involving investigational devices and the associated special clinical billing requirements. Additionally, this group is responsible for financial reporting and helping implement divisional standards regarding earnings tracking and account management.

Institutional Infrastructure

The OCR plays a key role in coordinating and collaborating with the clinical departments and medical center leadership to ensure that intuitional infrastructure is in place to support investigators in conducting clinical research in an efficient, timely, and compliant manner. Infrastructure support also includes acting as the business owner of institutional electronic systems for clinical research administrative and financial management. In the current year this work is related to implementation of a new clinical billing system. In prior years it was new electronic IRB systems and grants/contract management systems. The OCR works closely with both Departmental research support offices such as the Cancer Clinical Trials Office, the Medicine Clinical Research Support Office, and the Pediatrics Clinical Trials Office as well as divisional and hospital research support offices such as the Human Imaging Research office and the Investigational Drug Service.

MacLean Center for Clinical Medical Ethics

Founded in 1984 with generous support from Dorothy MacLean and her family, the MacLean Center was the nation's first program devoted to clinical medical ethics, directed by GIM Professor and world renowned ethicist Dr. Mark Siegler. The MacLean Center is the leading program in the country devoted to the study and teaching of clinical ethics (ranked #1 by US News and World Report). Dr. Chin organized last year's MacLean series on

Health Care Reform, bringing national policy leaders to teach UC faculty and trainees the implications of the Affordable Care Act for patients and populations.

Bucksbaum Institute for Clinical Excellence
The Bucksbaum Institute for Clinical Excellence was created in 2011 with a focus on improving the doctor-patient relationship through patient care, teaching and research, with a $42 million endowment. Studies document that better doctor-patient communication leads to improved outcomes in a variety of common Primary Care conditions, including diabetes, hypertension, chronic headaches and depression. Consequently, the Bucksbaum Institute specifically promotes research into improving the relationship patients have with their physicians

The Bucksbaum Institute supports the career development and activities of physicians at three career stages – as medical students, junior faculty, and senior clinicians. These physicians devote themselves to improving doctor-patient communication and clinical decision-making. The goal of the Institute is to enhance the skills of physicians as advisers, counselors, and navigators to help patients make informed decisions when facing complex treatment choices.

Medical students and physicians trained at the Bucksbaum Institute serve as role models in communication and shared decision-making. About 30 percent of physicians educated at the University of Chicago go on to careers at academic medical centers. Bucksbaum Scholars will bring, to academic medical centers, the sharp focus on doctor-patient communication. Each year, the institute appoints three to five medical students as Bucksbaum Scholars, up to four Junior Faculty Scholars in two-year appointments and a senior physician-teacher as a Bucksbaum Master Clinician.

The Cancer Clinical Trials Office (CCTO)
The Cancer Clinical Trials Office (CCTO) provides oversight and quality control for cancer clinical trials at The University of Chicago Medicine through centralized regulatory management, reporting, staff supervision and training, auditing, and event tracking. The overall objective of the CCTO is to provide the infrastructure to support successful clinical research across departments. The CCTO interacts with the Biostatistics Core Facility, the Protocol Review and Monitoring System (PRMS), and the UCCCC Informatics Group.

<u>Services</u>

- Regulatory Affairs - Provide centralized regulatory management for the conduct of all adult cancer clinical trials at UChicago regardless of sponsor, department, or type of study:
    - Complete required forms and submissions to the Clinical Trials Review Committee (CTRC), the Institutional Review Board (IRB), and other required committees (e.g., Institutional Biosafety Committee)
    - Submit Letters of Intent (LOIs) and coordinate NCI review and approval of NCI-sponsored Phase I and Phase II studies
    - Prepare IRB forms, PI-initiated IND applications, FDA annual reports, amendments, and communications
    - Report and track serious adverse events and IND safety reports; coordinate review of external safety reports
- Affiliate Institution Coordination and Oversight - Provide infrastructure for the participation of affiliate institutions enrolling patients on trials at the UCCCC:
    - Serve as the primary regulatory point of contact between the UCCCC investigators and outside institutions or cooperative groups
    - Manage affiliate or cooperative group communications document distribution and response to queries

    - Collect and track affiliate site initial and continuing IRB approvals and all other regulatory documents
    - Generate reports for DSM conferences and file required reports to the NCI or cooperative groups
    - Coordinate Site Initiation Visits
- Protocol Tracking, Management
    - Enter protocol-specific data into a centralized database (Velos eResearch, REDCap)
    - Provide web-based direct access (e.g., in clinics) to current protocol documents (e.g., consent forms)
    - Generate serious adverse events, and other status reports
- Quality Control
    - Provide required training to nurses, data managers, faculty, fellows and regulatory managers across departments
    - Support continuing education
    - Oversee designated data and safety monitoring activities [e.g., tracking unanticipated problems (UPs)]
    - Coordinate the audit program
- Develop and implement associated Standard Operating Procedures (SOPs) (e.g., Serious Adverse Event reporting, audits)

Pediatrics Clinical Trials Office

The Pediatric Clinical Trials Office (CTO) facilitates clinical research in the Department. Staffed by eight clinical research associates, it provides support for institutional, multi-institutional and pharma studies.

The CTO role includes all administrative aspects of clinical research: recruiting patients, writing consent forms, obtaining patient consent, submitting research to the IRB, and collecting and entering data in databases that are complaint with privacy laws. It is particularly expert in the unique regulatory nuances of pediatric clinical research. Services can be tailored to the needs of the individual investigator.

The Pediatric CTO is currently running 140 pediatrics studies from sections such as neurology, rheumatology, hematology/oncology, and gastroenterology.

Clinical Research Support Office (CRSO)

The mission of the Clinical Research Support Office (CRSO) is to promote and facilitate the conduct of clinical research in the Department of Medicine. The Department of Medicine has a long tradition of conducting original and rigorous biomedical and clinical research that has dramatically affected the way in which diseases are treated. The CRSO was created to assist in the expansion of this remarkable research record by providing centralized support services for our faculty. These services include:

- Protocol development consultation
- Study execution planning
- Regulatory Support
    - IRB submission and ongoing management
    - FDA submission and ongoing management
    - CRC submission and ongoing management
    - FDA audit support
- Research staff planning
- Research nurse and coordinator training
- Short-term research nursing and coordinator support

Institutional Biosafety Committee
The IBC is charged with the responsibility for review, approval and surveillance of all research protocols at the University of Chicago involving the use of biohazardous materials including recombinant DNA, agents infectious to humans, animals or plants, and other genetically altered organisms and agents.

The IBC works closely with other research-related compliance offices to ensure that all ongoing research on the Hyde Park campus and the Howard Taylor Ricketts Laboratory at Argonne National Labs is conducted in a manner that minimizes risk to both laboratory personnel and the surrounding environment. The IBC also collaborates with UC Departments of Occupational Medicine and Infectious Diseases to appropriately manage laboratory exposures to potentially infectious agents or materials and to monitor laboratory staff for symptoms indicative of potentially-acquired laboratory infections.

Services and Responsibilities

- Conducts reviews and risk assessments of all Institutional Biosafety Committee (IBC) protocols upon submission
- Advises laboratory personnel on biosafety matters
- Conducts annual laboratory inspections for BSL2 and BSL3
- Provides guidance on rDNA guidelines and associated regulations as well as other aspects of genetic engineering, including Dual Use Research of Concern.
- Performs initial biosafety inspections of laboratories using rDNA and/or pathogenic agents to ensure that labs are equipped and the investigators are prepared for research as described in their IBC protocols.
- Provides appropriate biohazard signage for posting in laboratories using biological agents
- Provides guidance on the design of biocontainment laboratories and the purchase of containment equipment such as Biological Safety Cabinets (BSCs).
- Recommends methods of handling, transporting, decontaminating and disposing of biohazardous materials
- Manages the UChicago Select Agent Program.
- Through laboratory inspections, provides assistance with lab-specific research safety risk assessment, recommends safe laboratory procedures, advises regarding containment devices and equipment, and confirms regulatory compliance.
- Prepares and provides basic biosafety training via classroom and web-based formats.
- Collaborates with UC Departments of Occupational Medicine and Infectious Diseases to appropriately manage laboratory exposures to potentially infectious agents or materials and to monitor laboratory staff for symptoms indicative of potential laboratory acquired infections.

Radiation Safety Committee
The Radiation Safety Committee, based in the Office of Research Safety, aims at reducing human exposure to radiation through the proper management and disposal of all radioactive materials utilized in teaching and research activities. The committee is responsible for the review and approval of all routine clinical and research laboratory aspects of ionizing radiation use.

Under the direction of the Radiation Safety Committee, the Radiation Safety Program works diligently to reduce human exposure to radiation through the proper management and disposal of all radioactive materials utilized in clinical, teaching and research activities at the University of Chicago. It also oversees UChicago's X-ray radiation program and laser safety program.

Services and Responsibilities

- Assists with Principal Investigator protocol for radioactive material (RAM) consultation and review
- Initial and annual radiation safety training

- Implementation of the radiation safety program and establishing policies and procedures
- Assists in RAM procurement
- Tracks all RAM on campus
- Prepares all RAM shipments from the University
- Personnel exposure monitoring (external and internal)
- Survey instrument calibrations and initiates instrument repair
- Inspects labs for proper radiation safety equipment and practices
- Oversees RAM security
- Emergency response (e.g. radioactive spill, irradiator alarm, code orange)
- Radioactive waste management (e.g. issuance of waste management containers, radioactive waste pickup, prepares radioactive waste for waste broker pickup, manages decay-in-storage of short-lived waste)
- Patient clinical procedures (e.g. room setup, room devon, patient and room surveys, patient instruction and education, outpatient therapy procedures, release calculations)
- Manages the University Research X-ray radiation safety program (e.g. registration and annual inspection)
- Manages the laser safety program (e.g. laser equipment registration, laser inventory, laser safety training, signage, lab inspections)

Rush University

Office of Research Compliance

The Office of Research Compliance (ORC) promotes a culture of compliance, research integrity, and high quality research within the Rush community. Oversight of the regulatory (federal, state and local), ethical and compliance aspects of research conducted at RUMC is a complex multidimensional undertaking, and the ORC divides the responsibility for managing these dimensions across operational areas. Although collaboration and consultation among the areas is a frequent occurrence, each operational area has primary responsibility for a specific regulatory or compliance area within the institution. The areas targeted for evaluation of compliance with conducting research include but are not limited to:

- Human Research Protection Regulations
- Effort Reporting
- Financial Conflicts of Interest in Research
- Clinical Trial Billing
- Scientific Misconduct
- Intellectual Property
- Sponsored Research/Grants/Contracts

<u>Compliance Oversight Mechanisms.</u>

ORC oversight of compliance is accomplished through policy review, education and training, directed audits, and periodic compliance reviews. Directed audits are conducted in response to identified concerns to assess the Investigator's compliance with federal, state, and local laws, as well as Rush University and RUMC IRB policies. This process identifies areas for improvement, and makes recommendations based on existing policies and procedures and best practices. Periodic compliance reviews are conducted using a systematic method to review IRB-approved research and IRB records/activities on a regular basis. Results of all directed audits and periodic compliance reviews are reported to the Associate Vice President for Corporate Compliance, the Chief Compliance Officer, the Associate Provost for Research, and the Director of Human Subject Protections and in certain instances, the Audit Committee of the Board of Trustees.

Research Conflict of Interests (COI).
The Office of Research Compliance is responsible for the administrative collection, review and management of interests that have the potential to impact an individual's professional or research responsibilities at RUMC. The goal of this program is to develop and maintain processes for identifying and managing external interests in conjunction with the Conflict of Individual and Institutional Interest in Research (COIIIR) Committee that have the potential to impact an individual's professional or research responsibilities.

Scientific Misconduct.
The Director of Research Compliance serves as the Research Integrity Officer (RIO) for RUMC and is responsible for reporting annually to DHHS's Office of Research Integrity about allegations and investigations of scientific misconduct. Scientific misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Reporting suspected research misconduct is a shared and serious responsibility of all members of the academic community. Any person who suspects research misconduct has an obligation to report the allegation to the RIO. Allegations are handled under procedures described in RUMC's policy titled Research Misconduct: Policy For Review and Reporting Allegations. All reports are treated confidentially to the extent possible, and no adverse action will be taken, either directly or indirectly, against a person who makes such an allegation in good faith.

Human Subjects Research Protection Program
Under its Director of Human Subjects' Protection, the Division of Human Subjects' Protection supports two equally constituted Institutional Review Boards (IRBs) at RUMC. RUMC is registered with the Federal Government under Federal Wide Assurance (FWA) number 00000482 that is valid until 9/26/2016; and the IORG number 00000298 which is valid. All human subject research must be submitted to the IRB for approval. Documents are submitted and reviewed in an electronic workspace, the Rush Research Portal (RRP). Once the protocol is approved, this information is forwarded to the PHS.

Rush is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). All research at Rush involving human subjects adheres to the federal regulations 45 CFR 46 and 21 CFR 50, 56, as appropriate. The Rush IRBs evaluate the research conducted with vulnerable subjects, such as the inclusion of children as participants in research involving human subjects, pregnant women, fetuses and prisoners; assuring that additional safeguards for vulnerable populations are addressed as required. The IRBs monitor the required education of the research community on human subject research, and assure that the Informed Consent process and the Informed Consent Form include all required information about risks and benefits for the subject to be able to make an educated, informed decision about participating in a study.

Biological Safety Program
Since 1997, Rush University Medical Center has operated an Institutional Biosafety Committee (IBC) to review all research activities involving recombinant or synthetic nucleic acids as required by the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (rev. 2013)* and by university policy RA-IBC-001. This 11-member committee chaired by Amarjit Virdi, PhD has cross-representation from the Institutional Animal Care and Use Committee (IACUC) and from the division of Environmental Health and Safety (EHS). Committee members include faculty from the departments of Immunology and Microbiology, Anatomy and Physiology, and the Divisions of Gastroenterology and Infectious Diseases, and representatives of hospital Infection Control and the Office of Research Compliance. IBC business is conducted in standing monthly convened meetings. The Biological Safety Officer (BSO) pre-reviews applications to assist the investigator prior to official review by the full committee, reviews literature relevant to applications in service to the IBC, and schedules the agenda of the IBC. The IBC maintains a database of approved programs as well as an informative web site, and submits annual reports to the NIH Office of Biotechnology Activities. Investigators or their designees are trained in the shipping of dangerous materials by EHS. A mandatory web-based Biosafety Training Program for both investigators and their laboratory personnel has been established. Approved programs

are subject to annual continuing review and a formal amendment process for all substantive changes. All laboratories of IBC-approved programs are inspected initially and periodically by the BSO. In addition, the BSO will work with investigators to assess and ameliorate potential hazards of new classes of agents such as nanoparticles.

Radiation Safety Program

Rush University Medical Center has a Radiation Safety Program under the direction of Radiation Safety Officer (RSO). A broad-based Radiation Safety Committee (RSC), as required by the State of Illinois, also exists. All routine clinical and research laboratory aspects of ionizing radiation use, such as dose monitoring, radiation protection, nuclear medicine hygiene, and radioactive waste disposal, are managed by the RSO under oversight by the RSC. A Subcommittee of the RSC advises the Institutional Review Board on the Informed Consent language for clinical studies in which the radiation dose to prospective research subjects will be changed by participation in a study.

Laser Safety Program

Rush University Medical Center has a Laser Safety Program under the direction of Clinical Engineering Services. The purpose of the program is provide clinical staff, researchers, students, patients, and visitors with a safe laser use environment by managing the selection, use, and maintenance of lasers and laser-containing systems at Rush RUMG and Rush University Medical Group. This program implements guidelines to ensure that no laser radiation in excess of the maximum permissible exposure (MPE) limit reaches the eye or skin of clinical staff, students, patients, and visitors. Additional guidelines ensure adequate protection against non-beam hazards that can be associated with the use of lasers: risk of electrical shock, explosions, fire, and exposure to harmful chemicals or biological hazards. The program also conducts relevant educational programs, performs work place inspections including those used for clinical procedures, and inspects and repairs laser equipment, documenting maintenance histories to satisfy applicable regulations. Program responsibilities are drawn from guidelines established by the American National Standards Institute (ANSI) standard Z136.1-2007, ANSI standards for the Safe Use of Lasers and standard Z-136.5-2009, ANSI standard for Safe Use of Lasers in Educational Institutions, and FDA CFR 1040.10. The Program complies with the Illinois Emergency Management Agency (IEMA) regulations for acquisition, registration, use, transfer, and disposal of class 3b and 4 lasers. A Laser Safety Committee, (LSC), as required by ANSI and IEMA, exists. Its purpose is to advise on laser activity and enforcement of operational policies and procedures at RUMC.

Loyola University

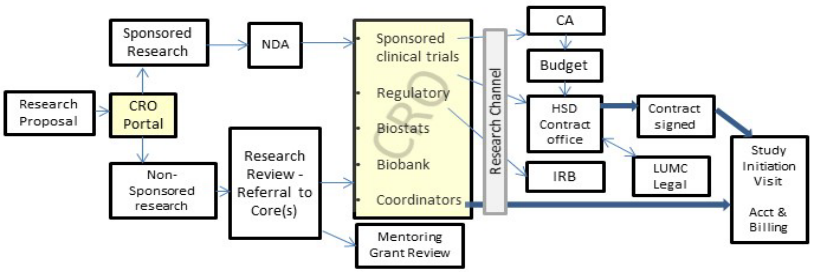
Research Channel

While different research services at LUCHSD may be coordinated by specific/appropriate Institutional offices, all are centralized and made accessible to researchers and administrators via a web-based intranet portal referred to as Research Channel. It is through Research Channel that services are requested, protocols are submitted, contracts are submitted, and services are billed if relevant.

Clinical Research Office

The CRO is an umbrella organization for a diverse group of services essential for the support and conduct of clinical research. The CRO was established in 2013 with support from both LUHS and LUCHSD to provide clinical research infrastructure to parallel the opening of the CTRE. The CRO provides clinical research support across the LUHS and LUCHSD including the Stritch School of Medicine and the Marcella Niehoff School of Nursing. The CRO is headed by a senior clinical research scientist who oversees the various CRO core services which include: Biostatistics; Biobanking; Regulatory; Sponsored Clinical Research (non-cancer related); study and nurse coordinator support; and Junior Faculty Mentoring and Grant review. The CRO provides support for both sponsored (Industry and Federal) and non-sponsored clinical research as described in more detail below.

All clinical research studies requiring CRO support services are submitted via a web based CRO portal within the Research Channel as depicted in the diagram below. Studies are separated into sponsored (industry and federal) or non-sponsored clinical research.



Sponsored Clinical Research - Following a signed non-disclosure agreement(NDA), sponsored clinical research trials are uploaded into research channel where investigators and research personnel can monitor the progress of contracting, coverage analysis (CA) and budget preparation, as well as IRB submission/approval. Each week progress is updated in the research channel. For non-cancer center projects the CRO regulatory office works with the investigative team to prepare IRB applications at the same time as the contract undergoes legal and cost analysis (CA). The HSD contracting legal office works closely with the LUHS legal office. Once sponsored clinical research contracts are signed by both LUHS and LUC, appropriate nurse and research coordinator and budgetary support is developed and the study is initiated.

Non-Sponsored Clinical Research - CRO support requests through the research portal for non-sponsored clinical research are reviewed weekly by the CRO staff and CRO director and the appropriate core service support is determined. Investigators are notified within a week regarding the type of support that would be provided. For non-sponsored clinical research, appropriate budgets are determined based on core utilization including nurse and coordinator support.

Sponsored Clinical Trials Support

For non-cancer center clinical trials, the CRO provides a senior Nurse Manager, Jessica Shore RN, PhD who shepherds studies through all stages. Start-up activities include assistance with contracting and budgeting (via interactions with the contracting office in HSD), IRB submission and consent preparation, sponsor regulatory approval, assignment of study coordinators, and management of pre-site and investigator meetings. This is then followed by assistance with all aspects of study conduct and maintenance of regulatory documents.

Regulatory Office

The regulatory office works with investigators to ensure clinical research is conducted with the highest quality standards, as well as serves as a resource for investigators and study teams regarding regulatory issues and research conduct. Services include: drafting/editing consent forms, preparation of IRB submissions, help with continuing review, safety reports, IND and FDA applications and supports investigators for completing and maintaining applications for Clinical Trials.gov. This core also provides computer based learning opportunities for investigators. The regulatory office supports sponsored as well as non-sponsored clinical research projects and works closely with all the CRO core to assure that the appropriate federal guidelines are met across all clinical research projects handled throughout the CRO.

NorthShore University Health System

Research Administration Office
NorthShore's Research Administration Office is the primary point of contact for all clinical trial research. All non-disclosure agreements are reviewed and negotiated, protocols are submitted, IRB applications are submitted and contracts and budgets are submitted for review approval and negotiation. Billing for specific services is also processed through this office. The Research Administration Office also conducts pre study reviews to confirm that all components of a study are accurate and that the requirements of the study are understood by all parties. A subsequent review takes place after the enrollment of the first participant to confirm that there are no items that need renegotiation with the sponsor.

Compliance and Education Office
The compliance officer works with investigators to ensure clinical research is conducted in accordance with all regulatory standards, as well as serves as a resource for investigators and study teams regarding regulatory issues and research conduct. Services include: drafting/editing consent forms, assisting with the preparation of IRB submissions, help with continuing review, safety reports, IND and FDA applications and supports investigators in completing and maintaining applications for Clinical Trials.gov<http://trials.gov>. The office provides services including coverage analysis, budgeting and insuring that all billing is processed according to study requirements. This office also provides learning opportunities for investigators and coordinators. The office supports sponsored as well as non-sponsored clinical research projects.

HUB RESEARCH CAPACITY

PARTICIPANT AND CLINICAL INTERACTIONS

University of Chicago

Clinical Research Center
The Clinical Research Center (CRC) at the University of Chicago, is directed by Arlene Chapman, MD, and funded by the National Center for Research Resources of the National Institutes of Health (CTSA). The mission of the combined adult and pediatric Clinical Research Center is to provide the resources and environment to the faculty of the University to conduct human subject research of the highest scientific merit. The facility is located on the fifth floor, W corridor, of the Gilman-Smith wing of the University of Chicago Hospitals. The unit, which encompasses a total of approximately 4,160 square feet, includes six private and 1 semiprivate inpatient rooms, for a total of 8 beds (when not occupied by inpatients, these rooms are frequently used for outpatient testing); one suite of adjoining spaces for outpatient use, with 4 beds for procedures plus 2 phlebotomy chairs; a centrally located nursing station with Hospital computer terminal, tube station and other standard amenities; a Core Laboratory plus a sampling room from which blood can be drawn through portholes into the 2 adjoining inpatient rooms; a fully equipped metabolic kitchen; a sleep recording and analysis room with light-blocking shades, video monitoring and taping capability; and a conference room with seating for about 12 people. Specialized equipment available to conduct research under CRC auspices include Yellow Springs Instruments model 2300 "point-of-care" glucose meters; Accutor automated blood pressure monitors; a digital strain gauge; infusion pumps; stadiometers; and pulse oxymeters.

Large-Scale Sample Collections
Although many individual University of Chicago investigators have initiated sample collections in a wide variety of diseases, there are now several coordinated large-scale sample collection efforts underwritten by departments now being conducted at the University as well. These efforts are designed to build research infrastructure, as it is widely appreciated that the time required to develop sufficient patient sample collections is a key

challenge for fellows and junior faculty members in building their early research portfolios. The sample collection efforts in the Department of Medicine (TRIDOM), the Department of Pediatrics (KIDGENES), and Department of Obstetrics and Gynecology (CLIPP) were coordinated from the beginning with each other and with the Institutional Review Board for the Biological Sciences Division, as well as with the General Clinical Research Center (GCRC) and Department of Pathology. This coordination not only improves the efficiency of the individual sample collection efforts, but also maximizes the ability of the studies to communicate with each other.

For TRIDOM (Department of Medicine), patients are consented during visits to the University of Chicago Deptartment of Medicine outpatient clinics as well as inpatient services and samples are taken at the time blood is being collected for other lab work. These data are collected with patient medical record identifiers to enable linking to medical records and tissue samples to support basic and translational research. Sample processing, including preparation and aliquoting of DNA, plasma and serum, is conducted through the GCRC and samples are stored in the Department of Pathology Human Tissue Research Center. Investigators may access samples and information through a simple (1 page) application procedure; Drs. Cox and Solway are members of the access committee for TRIDOM.

Rush University

Clinical Research Core

The Clinical Research Core promotes excellence in clinical research for human subjects by supporting clinical investigators with regulatory submissions, study coordination and data management. The team partners with clinical research investigators and their research staff to assist with activities throughout the protocol lifecycle. This support includes training and mentoring of research staff, protocol feasibility assessments, and assistance with locating the resources needed to conduct clinical trials. Regulatory Services include management of all regulatory affairs, from protocol submission and processing of protocol-related actions and documents to trial closeout as well as IRB. Study Coordination staff members provide services in all aspects of trial conduct and data management, including but not limited to:

- Trial logistics assessment
- Eligibility verification
- Budget development
- Study coordination
- Data collection
- Record retention
- Data safety and monitoring reporting
- Audit and monitoring preparation
- Adverse event assessment and reporting
- And data summary completion for analysis

Education and Training activities exist for new hires and established staff. Topics range from performance expectations, to protocol interpretation, informed consent process, research ethics and data integrity. These sessions are in addition to mandatory requirements such as CITI and HIPAA training.

A Division of the Cancer Center that has strong relationships with Clinical Research Administration is the Rush University Cancer Clinical Trials Office. It encompasses functions similar to the Clinical Research Core, but on a larger scale and is focused on oncology clinical research only. It consists of a regulatory team, a research nurse team, a research coordinator team, and an ancillary services team. Together, under the direction of the Director, they currently conduct about 200 trials across the Cancer Center. Their focus is on pharmaceutically sponsored trials phase I through IV.

NorthShore University HealthSystem

Clinical Trial Center (CTC)
The CTC provides services for the support and conduct of clinical research at NorthShore. The CTC was established to provide clinical research support across all departments as needed. The CTC is headed by an administrative director who oversees the various CTC services which include: Regulatory support; study and nurse coordinator support; budget and coverage analysis support; and facilities support.The CTC provides support for both sponsored (Industry and Federal) and non sponsored (Department).

All clinical research studies requiring CTC support services are submitted to the administrative director for review and approval.

Illinois Institute of Technology

Clinical Nutrition Research Center
The Clinical Nutrition Research Center, constructed in the IIT Research Tower on IIT's main campus in Chicago and part of the IIT's Institute for Food Safety and Health, is a 5,000 sq. ft. facility designed and dedicated for the purpose of conducting outpatient clinical research studies.

Facility highlights

- On-site subject/patient screening and training
- Metabolic kitchen for test food preparation and distribution
- Two food intake suites for communal dining and or individual dining and larger refrigerators for food storage
- Multiple private examination and consultation rooms, and stations adapted for phlebotomy use or catheter implantation and management
- Dedicated rooms equipped for vitals assessment, flow-mediated dilation assessment (GE-LOGi-Q, ultrasound equipment with a special ultrasound bed), anthropometrics, food intake and appetite evaluation, among others
- Separate laboratory space equipped for specimen processing, storage and fresh sample analysis
- Biological freezers, refrigerators, centrifuges (clinical, superspeed, micro-ultracentrifuge), biological safety hood, platelet function analyzer, portable glucose, hemoglobulin and lipid analyzers
- Randox Daytona fully automated clinical analyzer, capable of running 180 different clinical chemistry tests and 270 tests per hour
- Licensed with specialized computer programs for food intake analysis (ESHA nutrient data base) and statistical analysis

INTEGRATING SPECIAL POPULATIONS

Examples of Clinical Cohorts and Registries to be Federated in the Potential Participant Registry (PPR)

University of Chicago

Preterm Infants Cohort.
This cohort was established to prospectively investigate development of intestinal microbial colonization patterns over time in preterm infants. Included are 173 near-consecutive infants who were born with mean birth weight of 785 gms and 26 weeks gestation between 2008-2012; these patients are now 5-8 years old. Weekly fecal samples were obtained and biobanked, and correlating clinical data include head ultrasound, seizure, anticonvulsant, sepsis, BPD, ROP, NEC, and length of ventilation data for all. Brain MRI data are available for 40 infants. At 2 yrs adjusted age, 54 (31%) had abnormal neurologic exams (cognitive, motor or language), and

93 (54%) had normal neurodevelopment as measured by the Bayley III exam. Ongoing clinical data and fecal samples are being collected from this patient population as part of NICHD R01HD083481 (Erika Claud, PI). Coinvestigator Dr. Bree Andrews is the primary care physician for the majority of these patients and thus has an active ongoing relationship with them. In previous large trials (ELGAN, NOVA 1 and 2) she has had >80% success in retention for follow-up evaluations.

Monogenic Diabetes Registry.
Mutations in any one of a number of genes (more than 20) can cause monogenic diabetes, which may represent as much as 2% of all diabetes patients. Though its identification can have a transformational impact on treatment, the majority of monogenic cases remain unidentified and little is known about their natural history. Led by Drs. Louis Philipson, Siri Greeley, Rochelle Naylor, and Graeme Bell and supported by NIDDK funding, this Registry (www.kovlerdiabetescenter.org/registry/) includes well over 2000 patients with either neonatal diabetes (diagnosed before 1 year of age) or with a phenotype suggestive of maturity-onset diabetes of the young (MODY). Inclusion criteria and consent documents are downloadable and allow secure collection of contact information to facilitate telephone consent and enrollment. Comprehensive medical, family, and historical data are collected longitudinally from a variety of sources. For example, about 100 subjects have rare KCNJ11 mutations causing permanent neonatal diabetes, and about 275 have more the common GCK/MODY 2 mutations. Increasingly, participants are referred by their physicians rather than family members or themselves. Associated private Facebook and email discussion groups have already fostered active participation and psychosocial support.

Airways Disease Research Registry and Biospecimens Repository.
This registry includes asthma and COPD patients who have participated in previous clinical research studies, patients in UChicago clinical practices and healthcare systems, and subjects recruited externally through IRB approved advertisements. Registry participants in the last 5 years:

	Number	Age (mean)	Sex	Race/Ethnicity (self-report)
COPD	247	65	M: 101 (41%) F: 144 (59%)	White: 95 (39%) Black: 127 (52%) Latino: 3 (1%) Other/Unknown: 23 (9%)
Asthma	457	59	M: 137 (30%) F: 312 (70%)	White: 173 (39%) Black: 238 (53%) Latino: 8 (2%) Asian: 7 (2%) Other/Unknown: 33 (7%)
ACOS*	60	64	M: 25 (42%) F: 34 (58%)	White: 22 (39%) Black: 32 (56%) Latino: 2 (3%) Other/Unknown: 3 (5%)

**ACOS = asthma COPD overlap syndrome*

The biospecimen repository includes endobronchial biopsies, bronchoalveolar lavage, and blood/DNA specimens from research subjects with asthma or COPD participating in IRB-approved research bronchoscopy studies, including the *ABRIDGE* (NHLBI Asthma BioRepository for Integrated Genomics Research); *AsthmaNet* (NHLBI clinical trials network); and *AADCRC* (NIAID *Asthma and Allergic Diseases Clinical Research Center*. Biospecimens are linked to relevant clinical data; specimens from 103 asthmatics and 26 control subjects are available.

Interstitial Lung Disease (ILD) Natural History Registry and Biorepository

Interstitial Lung Disease (ILD) Natural History Registry and Biorepository is a longitudinal database of carefully phenotyped patients with ILD evaluated at UChicago since 2006. The registry contains 1,581 patients with 6,514 encounters. 640 patients have blood biobanked through the registry, and 822 patients have blood banked through UChicago TRIDOM (see below). Of the 1,581 patients, 377 have idiopathic pulmonary fibrosis, 256 have connective tissue disease-related ILD, 173 have interstitial pneumonia with autoimmune features, 138 have hypersensitivity pneumonitis, 220 have unclassifiable or miscellaneous ILDs, and 67 have sarcoidosis. Data are stored in REDCap. The vast majority of patients have HRCT scans read by nationally recognized chest radiologists and a sizable minority have surgical lung biopsy specimens reviewed by a dedicated thoracic pathologist. Longitudinal repeated collection of clinical data (including comprehensive autoimmune serologic testing, serial pulmonary function testing, and serial blood specimens) allows for determination of clinical, immunologic and physiologic biomarkers of prognostic value.

Bronchiectasis Registry and Biorepository

This is a database of 225 patients with non-cystic fibrosis bronchiectasis who have undergone systematic and comprehensive evaluation at UChicago since 2009. Patients have been carefully phenotyped for the etiology of their bronichiectasis, which has been determined in a much higher percentage of cases than in previous cohorts. In ~60% of patients, the etiologies involve immune dysregulation from either deficiency, autoimmune disease, or hematologic malignancy which is a newly recognized cause of bronchiectasis. Data are stored in REDCap, and a subset have blood biobanked in TRIDOM. Clinical data include autoimmune serologic testing, serial microbiology culture and microbiome analysis, PFTs and serial HRCT scans which have been read by nationally recognized chest radiologists.

Hospital Medicine Cohort (Hospitalist Project)

Over the past 25 years, hospitalist physicians who specialize in inpatient care have taken over an increasing proportion of the care of hospitalized patients, often displacing traditional internal medicine doctors who cared for patients in clinic and in the hospital. Since 1997, UChicago has have had a hospitalist program led by ITM Assoc Director Dr. David Meltzer; the program has sought to interview all patients on general services at admission and 1 month after discharge, obtaining consent for linkage to medical records, claims data and biospecimens. To date, about 100,000 patients have already been enrolled, and about 7,000 additional patients are enrolled per year. Standard interview questions assess patient reported health and functional status, and outcomes measures and diverse socioeconomic determinants of health. Research coordinators recruiting patients also serve to identify patients for sub-studies of specific conditions, and have supported multiple research project grants and NIH career development awards, as delineated in the Learning Health Care System Core (Chapter 10). This "hospitalist project" infrastructure also contributes substantially to recruitment for UChicago's engagement in CAPriCORN, the Illinois Precision Medicine Consortium, and the YouChicago Biobank.

Comprehensive Care Physician (CCP) Program

The CCP Program seeks to improve quality of care and outcomes, and to lower the cost of care for patients at increased risk hospitalization by giving them the ability to receive care from the same physician in the inpatient and outpatient setting. In 2012, Dr. Meltzer began to study the CCP program at UChicago through a randomized clinical trial funded by the Center for Medicare and Medicaid Innovation that compares CCP care to care by different physicians in the inpatient and outpatient setting. Two thousand patients were recruited and have been followed by quarterly patient interviews that focus on health determinants, health status, and health outcomes, and by using claims data. Results to date suggest substantial improvements in quality of care and patient outcomes, and large reductions in hospital utilization and total cost of care. A minimum of 1 year of follow up for all patients will be completed in July 2017, at which point primary outcomes will be reported. Efforts are underway to continue to follow this cohort to assess the durability of benefits. A two-year, 600-person follow-on

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pilot study funded by the Robert Wood Johnson Foundation to improve the ability of the program to engage the most difficult patients has just begun.

Chicago Multiethnic Prevention and Surveillance Study (COMPASS)

Led by Dr. Habib Ahsan, COMPASS is a prospective, multi-ethnic, multi-disciplinary population-based study among a representative sample of Chicago residents (with oversampling of minority participants). Using a population-based probability-sampling scheme, the project has already recruited 3,000 (eventual goal is 100,000) multiethnic participants (>50% African Americans) with interview, clinical measurements, and biological samples (blood, saliva and urine) with an overall response rate of 25%. Biological samples are processed within a few hours of collection to preserve all fractions including sources of RNA, DNA, serum/plasma and oral microbiome.

YouChicago Biobank

Led by ITM/CTSA co-PI Dr. Susan Cohn, the YouChicago Biobanking Initiative offers UChicago patients the opportunity to allow unused blood specimens collected for clinical indication to be stored for nucleotide and other analyses (with results linked to EMR clinical data), and also invites consent for future recontact based on clinical conditions or on genetic or other results. Just emerging from its pilot implementation phase, it includes 245 subjects consented (200 samples obtained).

TRIDOM

The TRanslational Initiative in the Department of Medicine is a biobanking initiative aimed at understanding the genetic basis of human disease; biospecimens are linked to clinical information from the CRDW. Patients at UChicago outpatient clinics are consented and blood is collected with the next clinically-indicated venipuncture. Over 9900 individuals have enrolled (representing 85% of those invited), and samples have been collected from 6601 individuals (58% white, 33% African American, 6% unknown/not reported, 2% Asian, 1% more than 1 race, <1% American Indian/Alaska Native or Native Hawaiian/Other Pacific Islander). This program is being replaced by the more universal YouChicago Biobanking Initiative described above.

Cancer Patients

The UChicago Comprehensive Cancer Center Cancer Registry provides a full range of oncology data services for this nationally recognized American College of Surgeons (ACoS)-approved clinical cancer program. Since the 1920s, the Registry has collected, maintained, and reported detailed information for patients diagnosed with, and treated for, cancer or benign central nervous system neoplasms. A dedicated team of data management specialists ensures that records are maintained for patients at both UChicago and the newly opened UChicago Cancer Center at Silver Cross Hospital. The Cancer Registry provides important data services to advance basic, translational, and clinical research at the Comprehensive Cancer Center. All data collected by the Registry can be accessed via the CRDW (Chapter 3), and many specimens are stored in the Human Tissue Resource Center. In 2015, 4,327 patients were diagnosed and/or treated at UChicago for a malignancy or benign central nervous system neoplasm. Of these, the majority of patients (3,592, 83%) were newly diagnosed, and the remaining (695, 16%) had recurrent or progressive disease. The most frequently seen cancers were of the digestive system. More than half (2,227, 54%) were diagnosed between the ages of 50 and 69 years; racial/ethnic demographics: white (2,839 patients, 65.6%), African American (1,066 patients, 24.6%), Hispanic (232 patients, 5.4%). These trends are similar to those seen in recent years (in which patients were: 2011 – 3,660, 2012 – 4,062, 2013 – 4,388, 2014 – 4,287). The majority (3,449, 80.5%) seen in 2014 were Illinois residents, with the highest number residing in Cook County (2,107, 49.1%) followed by Will County (493, 11.5%), and Lake County (140, 3.3%).

Familial Hematologic Disorders Biobank

This biobank, led by Drs. Lucy Godley and Jane Churpek, includes >1000 individuals (including children age 7 and older) from >500 families with familial clustering of hematopoietic malignancies. Genetic information is protected by a Certificate of Confidentiality. Samples have been used to describe two new predisposition syn-

dromes, germline ETV6 and DDX41 mutations, and are expected to lead to the discovery of several more. Through the work of Drs. Godley and Churpek, there is increasing recognition of the clinical importance of germline predisposition to hematopoietic malignancies within the field of hematology, as evidenced by inclusion of these syndromes within the updated World Health Organization classification of myeloid malignancies and within the latest NCCN and European LeukemiaNet guidelines.

Multiple Myeloma Epidemiology Study

Led by Dr. Brian Chiu, this registry includes approximately 650 patients with monoclonal gammopathy of undetermined significance (MGUS), smoldering multiple myeloma (SMM), or multiple myeloma (MM) enrolled since October 2010. Blood samples and epidemiology questionnaires have been obtained. These resources have been invaluable in several multi-institutional genomics initiatives including the African American Myeloma GWAS (CA134786), genome-wide DNA methylation, and exosome miRNA sequencing studies (CA186646).

Chicago Multiethnic Breast Cancer Epidemiologic Cohort (CoBEC)

Led by Funmi Olopade, MD and Dezheng Huo, MD, PhD, CoBEC includes approximately 10,000 breast cancer cases and controls as well as individuals evaluated in the Cancer Risk Clinic for inherited susceptibility breast to cancer. Dr. Olopade established a high risk clinic to identify and care for individuals who have an increased risk of cancer due to family history and genetic factors. Through the clinic, breast cancer patients and non-cancer controls were enrolled into a Longitudinal Registry to investigate the impact of *BRCA1/2* mutations, evaluate mutation prediction models, and mutation spectrum of other high penetrance genes in African Americans and Caucasians. Early-onset breast cancer cases with positive family history were oversampled. In 2008, the study was expanded to include all patients with histologically confirmed breast cancer as part of the UChicago Breast Cancer Specialized Program of Research Excellence (SPORE) funded by the NCI between 2006-2010. Controls were patients without breast cancer who visited the hospital. Data from the SPORE case-control study have been used to investigate low penetrance genetic variants for breast cancer, especially for African Americans. Data collected include medical records, imaging, tumor specimens, blood, urine, saliva, questionnaire, and medical records from other institutions. The Institution Review Board required separate consent for each domain so patients could have flexibility in participating in the study. The consent rate was 100% for internal medical records, 98.8% for tumor specimens, 73.7% for blood, 79.3% for urine, 78.6% for saliva, 84.5% for questionnaire interview, and 78.9% for release of medical records from other hospitals.

The Breast Cancer Survivorship Program

Susan Hong, MD, MPH leads this multidisciplinary team of medical oncologists, surgeons, radiation oncologists, radiologists and lymphedema specialists. This program addresses the health problems of woman with breast cancer from the time of diagnosis and continues throughout the survivor's life.

~~***Chicago Multiethnic Breast Cancer Epidemiologic Cohort, CoBEC:*** Led by Funmi Olopade, MD and Dezheng Huo, MD, PhD,, CoBEC includes approximately 10,000 breast cancer cases and controls as well as individuals evaluated in the Cancer Risk Clinic for inherited susceptibility breast o cancer. Dr. Olopade established a high risk clinic to identify and care for individuals who have an increased risk of cancer due to family history and genetic factors. Through the clinic, breast cancer patients and non-cancer controls were enrolled into a Longitudinal Registry to investigate the impact of *BRCA1/2* mutations, evaluate mutation prediction models, and mutation spectrum of other high penetrance genes in African Americans and Caucasians. Early-onset breast cancer cases with positive family history were oversampled. In 2008, the study was expanded to include all patients with histologically confirmed breast cancer as part of the University of Chicago Breast Cancer Specialized Program of Research Excellence (SPORE) funded by the NCI between 2006-2010. Controls were patients without breast cancer who visited the hospital. Data from the SPORE case-control study have been used to investigate low penetrance genetic variants for breast cancer, especially for African Americans. We collect medical records/imaging data, tumor specimens, blood, urine, saliva, questionnaire, and medical records from other institutions. Our Institution Review Board required us to do separate consent for each do-~~

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The Childhood Cancer Survivorship Program

Led by former ITM KL2 Scholar Tara Henderson, MD, MPH, this multidisciplinary program was created to address the health problems of survivors of childhood cancers. A childhood cancer survivor registry and biobank has recently been established and includes data on > 700 individuals. UChicago recently joined the Childhood Cancer Survivorship Study, the largest cohort study of >14,000 childhood cancer survivors diagnosed at 30 medical institutions in North America.

International Neuroblastoma Risk Group (INRG) Data Commons

The development of this data commons has been led by Drs. Susan Cohn (ITM co-Director), Samuel Volchenboum (ITM Informatics Director), and Robert Grossman (former ITM Informatics Director). This ecosystem mirrors the Genomic Data Commons (GDC), which was developed by Dr. Robert Grossman and houses clinical and genomic data generated from projects sponsored by the National Cancer Institute (NCI). The INRG Data Commons contains clinical data on >17,800 neuroblastoma patients and genomic data (tumor copy number, whole genome sequencing, RNAseq and germline genotype) from >1,600 patients. Investigators can either download these genomic data to their own systems or use the Bionimbus Protected Cloud environment to conduct analyses.

Von Hippel-Lindau Disease Clinical Care Center

This center was formed in 2012 in conjunction with the nonprofit VHL Alliance; the UChicago VHL Center of Excellence is the only one in Illinois. This multidisciplinary group of specialists from 13 clinical areas follows over 80 families. Patients are invited to join the Cancer Risk Cancer Clinical Trials program, allowing for quick identification of eligible patients for participation in research.

Digestive Disease Center Integrative Translation Core (ITR) / Genesys Registry

The ITR is one of four core components of the NIH-funded UChicago Digestive Disease Research Core Center; it supports biospecimen acquisition, storage, analysis, and clinical data linkage for prospectively consented. In 2015, a protocol (Genesys) was implemented to recruit all patients across adult gastroenterology, liver, GI surgery, and transitional (age 14-17) inflammatory bowel disease clinics. The Genesys registry currently includes 5545 patients, the celiac registry contains 1053 patients, and 1007 subjects with IBD have been enrolled in the Sinai Helmsley Alliance for Clinical Excellence (SHARE) registry with a total recruitment through the ITR for all GI studies since 2009 of 7366 patients. Since 2014, 2004 new patients have been consented and enrolled in Genesys and 219 to the celiac registry. Of the patients in Genesys, 4535 have a diagnosis of IBD. In the last year, there have been 69 requests for clinical data using this database. ITR also maintains a prospectively collected biospecimen repository that is linked with phenotypic information of subjects in the clinical database. Tissue biospecimens are collected through the Genesys protocol and are available on 876 patients and DNA, serum, and plasma are banked from 823 patients. In total, over 29,000 biospecimens (including aliquots) comprising serum, plasma, DNA, tissue RNA, tissue DNA, frozen whole biopsies, FFPET blocks, mucosal brushings, mucosal aspirates, saliva, and stool samples are available with over half of these samples collected in the last 2 years. In the last 12 months, the ITR has received 76 requests for use of biospecimens.

Autosomal Dominant Polycystic Kidney Disease Center

Over 700 families with 1432 participants form the ADPKD cohort at UChicago. These individuals have undergone genotyping, careful renal phenotyping including iothalamate and inulin clearances and novel biomedical

imaging utilizing T1- and T2-weighted MR based estimates of total kidney volume, total liver volume and quantitative renal blood flow. Biofluids (urine, plasma, serum, DNA and stool) have been collected to allow for biomarker research for measures of disease severity. This patient population provides materials for a number of federally funded programs including the Biomarkers Core for the PKD P30 program at KUMC, the metabolomics HALT Ancillary R01 funded study with University of San Diego and the CRISP U01 consortium now in its 16th consecutive year. Participants are also involved in multicenter Phase II and III clinical trials evaluating the therapeutic efficacy of inhibition of the Vasopressin V1 receptor and the impact of inhibition of the EGF Receptor.

Kidney Stone Program
Active since 1969, it now includes >1500 well-characterized patients with a variety of stone disorders. An NIDDK program project grant funding research is in its 44th consecutive year and is led by Dr. Elaine Worcester (who directs EPOR, Chapter 5). This program investigates the physiologic, urologic, pathologic and proteomic signatures of a variety of stone disorders focusing on calcium-based kidney stones. This center communicates with patients through websites and portals with educational materials and results of clinical trials available for those who visit the site. There are over 50,000 visits a month to this site with plans to include permission to contact for participation in research based studies at UChicago.

Hereditary Hemorrhagic Telangiectasia (Osler-Weber-Rendu) Center
UChicago is now designated as an HHT Center of Excellence by Cure HHT. This is the 22nd center in North America and the only one in Illinois. The HHT center is led by Dr. Issam Awad and multidisciplinary research teams led by Dr. Jessica Kandel, Chief Section of Pediatric Surgery are actively involved.

Tuberous Sclerosis Program
This program is led by a multidisciplinary team of geneticists, dermatologists, neurosurgeons, urologists, and nephrologists. Over 35 families participate in this center, representing >90% of the families in Chicago, and have been systematically included in the TSC patient registry.

Rush

Necrotizing Enterocolitis in NICU Infants
This registry includes data from medical records of infants admitted to the Rush NICU during 2005-2015, and were diagnosed with NEC or intestinal perforation. Clinical data include the daily infant weight, parenteral fluids (clear intravenous fluids and/or hyperalimentation), enteral feeding (human milk and/or premature formula), the disposition of each infant (discharge, death), the day of life that NEC occurred, and the management approach (medical alone or surgical), from birth throughout the hospital stay for all of the infants. Data have also been collected from very low birth weight (VLBW) infants who did not develop NEC to serve as control subjects.

Newborn Screening for Fragile X
Over 5200 infants have been enrolled since this registry was established in 2008. Objective for this project are to learn more about the fragile X syndrome, its presence in the general population, and the effect of early help for infants who have fragile X syndrome. This project will examine the frequency of fragile X mutations in the general population and race/ethnic groups through newborn screening and the extent of clinical involvement in babies identified with the mutation. Data may be used by Illinois to determine whether it will implement mandatory screening.

Fragile X Clinical and Research Consortium (FXCRC) Online registry with Accessible Research Database (FORWARD)
The FXCRC is a collaborative endeavor initiated in 2006 by the National Fragile X Foundation (NFXF) to advance clinical practice and facilitate coordinated, collaborative multi-site research on Fragile X syndrome. The FXCRC currently consists of 27 clinics. This project was created to establish standards of care, facilitate the

conduct of multi-institutional clinical research projects, coordinate and organize research across sites, build a reliable, dynamic patient registry and assist member clinics in data collection and analysis, including effective and relevant outreach and surveillance. The FXCRC works closely with the CDC, the NFXF and other stakeholders to continue to build data resources and expand its capacity to collect and analyze these data. Rush has enrolled almost 500 subjects in this registry.

Orthopaedic Implant Retrieval Registry

This is the principal source of study material for tribological and other analyses of implant performance by investigators at Rush University Medical Center. Several thousand retrieved orthopaedic surgical implant components have been procured and are maintained and cataloged on a continually expanding basis. This implant repository and the Rush laboratory facilities are available to intramural and extramural researchers to examine retrieved components for quality control and product development purposes. Overall, the devices comprise a broad sample of joint replacement designs as well as other implants. Approximately 500 additional surgically retrieved hip and knee replacement components and 30 components retrieved postmortem are received, processed, and cataloged annually.

Rush Orthopedic Hip and Knee Replacement Registry

Established in 1984, this registry stores data for current and future research pertaining to patient and implant related outcomes, including hip and knee replacements performed by all Rush orthopedic surgeons. Current enrollment exceeds 31,000 patients, both living and deceased, with over 46,000 joints. Surgeries represent ~85% primary and ~15% revision arthroplasties. Patient demographic and medical information, patient related outcomes surveys, surgical and implant variables, details related to short and long-term complications, and implant survivorship are included. In 2011, the Rush Orthopedic Hip and Knee Replacement Registry was one of the first joint replacement registries to share its data with the American Joint Replacement Registry, which was incorporated in 2010 to establish a US national registry of hip and knee replacement outcomes.

Rush Aging and Neurodegenerative Disease Registry

Rush has six community-based cohort studies of aging and Alzheimer's disease (AD) involving >15,000 participants (of whom many are African Americans or Latino) followed for up 22 years, and another cohort study of HIV and aging. These assess risk factors for common chronic conditions of aging, including behavioral- and neuro-economics of aging, and well-being. Two, the Religious Orders Study and the Rush Memory and Aging Project, are the only studies in the world of AD risk that are community-based and in which all participants are organ donors (of brain, spinal cord, nerve and muscle). The availability of brain tissue from >1,300 participants to date has allowed the development of a unique rich genomic characterization of the human brain including genome-, epigenome-, transcriptome-, proteome-, metabolome-wide data from the same set of human brains. These data are now used as the front end of an AD drug discovery pipeline supported by four of the six high profile Accelerated Medicines Partnership for AD (AMP-AD) grants that emerged from the 2012 NIH AD Research Summit, as well as several other R01s. The unique data and biospecimens are shared with investigators across the US and around the world.

Rush Dementia Prevention Intervention Registry

Rush is on the ground floor of establishing a community registry of participants for randomized clinical trials in the prevention of brain neurodegeneration. November 2016 marks the initiation of screening of some 12,000 community residents of Chicago and Boston for the first multicenter trial of the MIND diet to prevent Alzheimer’s disease. The initial trial will include 600 participants aged 65-84 years in a 3-year diet intervention. Subsequent trials are planned to add other lifestyle preventions such as physical activity. The data registry of this unprecedented study funded by the National Institute on Aging will eventually include a rich characterization of the changes in biochemical markers of inflammation and oxidation, MRI-derived brain macro- and micro structure, clinical neurodegenerative and cardiovascular conditions and gut microbiota. A whole host of risk factors for common chronic conditions of aging will also be assessed including behavioral changes with aging

and well-being. This is the first study world-wide that will test the effects of diet on dementia prevention. Many ancillary studies are planned to maximize the impact of this landmark diet intervention study including PET imaging of amyloid and tau accumulation in the brain, organ donation of brain, spinal cord, nerve and muscle; metabolomics, genetics, proteomics; assessment of sleep quality, depression, and physical decline; and additional interventions such as exercise.

Rush Biospecimen Repository

Housed in the Section of Gastroenterology, Rush has had a sample repository since 1999 that is directed by Dr. Ali Keshavarzian (ITM KL2 site leader at Rush). The repository currently has thirteen -80°C freezers on alarms and back-up systems. Samples are logged using the Freezerworks Unlimited Inventory system. The current repository has over 300,000 samples from 30,964 patients: (1) alcoholic patients, (2) patients with non-alcoholic liver disease, (3) patients with inflammatory bowel disease, (4) patients with irritable bowel syndrome, (5) patients with Parkinson's disease, (6) Alzheimer's disease patients, (7) Multiple sclerosis patients, (8) HIV patients, (9) healthy obese patients, (10) metabolic syndrome patients, (11) food allergy patients, (12) epilepsy patients, (13) shift workers and nurses for circadian studies, (14) breast cancer patients, and (15) lung cancer patients. In addition, there are over 100,000 samples from more than 5000 rodents from ongoing studies including NIH funded research. A new effort to accrue biospecimens (tumor tissue, serum, plasma) from cancer patients was also begun in 2015.

Digestive Disease Patients

Dr. Keshavarzian also supervises recruitment for more than 25 ongoing clinical studies and has weekly meetings with clinical coordinators to ensure that recruitment goals are met and all activities are conducted in accordance with approved IRB protocols. All participation is voluntary and specimens are only obtained after full informed signed consent. Consent is only obtained from patients 18 years old or older and no surrogate consent is obtained. All HIPAA regulations for protecting patient information are strictly adhered to. Inventory data is password protected and is behind the RUMC firewall. Quality control occurs on a regular basis by generating and monitoring multiple types of reports including by sample-, aliquot-, and user-specific reports. All repository donors are administered a standardized questionnaire regarding medical surgical history, current complaint, smoking and alcohol history, sleep habits, dietary history, food timing, and family history of disease.

Zimmerman Program for the Molecular and Clinical Biology of von Willebrand Disease

This study, which began in 2008, has enrolled 92 subjects. The goals are to identify mutations in the VWF gene associated with type 1 or type 3 VWD and correlate with a clinical bleeding assessment; to identify mutations in the VWF gene associated with type 2 VWD and correlate these with a clinical bleeding assessment; and to determine the frequency low plasma VWF being caused by increased VWF clearance. The hypothesis is that most VWD is caused by a mutation in the VWF gene that causes reduced or abnormal VWF to be produced and these results in clinical bleeding and the diagnosis of VWD. Families are included where there is either a current evaluation or previous diagnosis of VWD and then determine the segregation of bleeding symptoms, VWF protein abnormalities, and linkage with molecular defects in the VWF gene or other genes affecting VWF levels or bleeding symptoms. It is recognized that there may be VWF-level modifying genes (such as ABO blood type) and potential other genes such as glycosylation enzymes that in the murine system can cause the type 1 VWD phenotype by altering rates of VWF clearance.

CDC Public Health Surveillance for Bleeding and Clotting Disorders

This project collects surveillance data from the US network from Hemophilia Treatment Centers (HTCs) to describe the epidemiologic characteristics of people with bleeding disorders and the complications of these disorders. The target populations for the Registry for Bleeding Disorders Surveillance are people of all ages with bleeding disorders, primarily those due to congenital factor deficiencies such as hemophilia, VWD, and other rare clotting factor deficiencies. The primary objectives of this project are to characterize populations with bleeding disorders receiving treatment at HTCs by collecting routine clinical information in order to monitor

health indicators of importance to the bleeding disorders population. These data will be used to measure rates of complications of bleeding disorders (including those related to blood and treatment product safety) and monitor trends over time; identify high risk populations for prevention programs; and identify issues that require further study. This project builds on information and experience gained through data collection for the UDC over the previous 12 years. In order to monitor complications and trends over a longer period of time, information from UDC will be linked to current surveillance information where appropriate if the participant provides authorization. Rush has enrolled 19 subjects in this study to date.

American Thrombosis and Hemostasis Network (ATHN)
The ATHN is a non-profit corporation founded in July 2006 by the network of federally funded Hemophilia Treatment Centers. The registry seeks to provide stewardship of a secure national web-based information and data collection infrastructure, offers support services to ensure the successful implementation by HTCs, and compiles non-identifiable patient data to create the ATHN dataset. Rush has enrolled 151 subjects in the Network.

Intracranial Hemorrhage in Children with Hemophilia A or B (ICH Study)
This study began in 2013, with 7 children enrolled at Rush to date. The goal is to improve the quality of care for children with hemophilia by investigating the mortality and morbidity caused by intracranial hemorrhage, and determining whether those aspects can be improved by adjusting the treatment regimen. The following hypotheses are explored: 1) children on prophylactic treatment rarely develop intracranial hemorrhage compared to children with on-demand therapy; 2) intracranial hemorrhage in children on prophylaxis is caused by a combination of trauma and low factor VIII/IX concentrations; 3) After intracranial hemorrhage, sequelae are less common in children on prophylaxis than in those without prophylaxis.

Rush Center for Veterans and Their Families (RCVF) Data Repository
The Rush Center for Veterans and Their Families has implemented a system for improving practice management and care by monitoring both veteran and family member outcomes data. The primary purpose of this data collection, established in 2014, is care management, quality improvement, and assurance. These data will be used to ensure that clinic practices meet the needs of a veteran population primarily with PTSD and Traumatic Brain Injury and their adult family members. Data are being collected from patients who are adult (aged 18 or greater) veterans and/or their adult family members receiving services (psychopharmacology, individual and group psychotherapy, and evaluative services) at the Rush Center for Veterans and their families for the purpose of characterizing our population in order to formally examine care outcomes. There are 181 subjects enrolled to date in this repository.

NorthShore

Preterm Infants Cohort
This cohort was established to investigate normal microbial colonization patterns as well as determine alterations in microbial patterns leading to NEC in preterm infants. *It was funded as a joint collaboration between Drs. Michael Caplan (NorthShore) and Erika Claud (UChicago) through an ITM/CTSA pilot grant*. All premature infants cared for in the infant special care unit at NorthShore weighing <1500 gm at birth were eligible for the study. Those infants with severe congenital anomalies, including major congenital heart disease or major kidney, lung or brain malformation were excluded, as were those infants with a genetic syndrome. 156 patients were enrolled in this cohort from 2009-2012. Weekly fecal samples were obtained and biobanked, and correlating clinical data were retained. Ongoing clinical data and fecal samples are also being collected at NSUHS from patients <1500 gm as part of a study to investigate the role of oral colostrum swabs on microbial community structure development and clinical outcomes. Likelihood of cohort rerecruitment: The majority of the patients in this cohort receive primary care through pediatric groups affiliated with NorthShore, and we expect to

be able to contact these patients both through their primary care physician as well as directly. Dr. Matthew Pellerite has trained with Bree Andrews, MD, MPH of UChicago and was recruited by NorthShore specifically to invest in follow-up care of these patients along with newly recruited patients; we expect high levels of recontact and re-recruitment.

DodoNA Project: DNA Predictions to Improve Neurological Health

This large biobank is led by Dr. Demetrius Maraganore, Chief of Neurology at NorthShore. “DodoNA” is a metaphor – just as the oracle at Dodona, would predict the “future,” DNA variations promise similar potential. Structured clinical documentation and decision support tools in the Epic EMR capture standardized data during routine office visits that measure the progression and outcomes of patients with 11 well-defined neurological disorders: brain health (primary prevention of Alzheimer's in at risk subjects), brain tumors, epilepsy, migraine, mild cognitive impairment, mild traumatic brain injury, multiple sclerosis, neuropathy, Parkinson's disease, restless legs syndrome, and stroke. DodoNA is a clinical practice initiative (note writing and workflow efficiencies), a quality initiative (best practices), and a research initiative in which up to 1,000 subjects for each of the 11 disorders (11,000 subjects total) will be invited to provide informed consent for blood sample for DNA extraction and storage, and permission to associate information in their blood with information in their medical records (for the purposes of developing molecular prognostics and therapeutics). 3,500 of the targeted 11,000 DNA samples are already collected, and are being genotyped for 1M SNPs. These patients will be followed at least annually for a median of 10 years.

Neurology Practice Based Research Network (NPBRN)

NorthShore leads an 11-institution NPBRN that includes Dartmouth, Univ of Pennsylvania, Wake Forest Univ, Medical Univ of South Carolina, Ochsner Health System, Univ of Nebraska, Univ of Arkansas, Univ of Cincinnati, St. Luke's Health System, and Univ of Florida, in addition to NorthShore. They are sharing structured clinical documentation and clinical decision support tools for 11 common neurological disorders (brain health, brain tumors, epilepsy, migraine, mild cognitive impairment, mild traumatic brain injury, multiple sclerosis, neuropathy, Parkinson's disease, restless legs syndrome, and stroke) with Neurology Departments at the other institutions (all use Epic EMR) and are planning pragmatic trials for these disorders using the EMR, subgroup based adaptive assignment of treatments (as described in Chapter 6), electronic consenting, and outcomes data capture at the point of care using the EMR. There are already 16,000 encounters captured (up to 1,000 fields of data per encounter) in the NorthShore-hosted patient registry.

Genomic Health Initiative (GHI)

The Genomic Health Initiative at NorthShore began in 2014, aiming to investigate how an individual’s genetic makeup impacts health, wellness, and the effectiveness of treatment options. Participants are adult NorthShore patients who grant research access to their electronic medical record and donate a conveniently collected blood sample after providing informed consent. Over 13,500 individuals have enrolled, and samples have been collected from over 10,700 individuals and sent to the NorthShore BioBank for DNA isolation. The GHI participants reflect the NorthShore catchment area, and are thus predominantly European, but also with some Asians, African Americans, and Hispanics.

Clinical Centers of Excellence with Special Patient Populations at ITM Institutions

University of Chicago

UChicago Comprehensive Cancer Center

The UCCCC (Michelle Le Beau, PhD-Director) is one of the two NCI-designated Comprehensive Cancer Centers in Illinois, and is a major referral center for patients with cancer from the Chicago metropolitan area, the Midwest, and the nation. Specially, the UCCCC is located on the South Side of Chicago, defined as a 5 square mile region including 34 of Chicago’s 77 community areas. Seven of the 8 poorest communities in Chicago are found on the South Side. The mission of the UCCCC is to elucidate the determinants of cancer, to develop

cures for cancer, and to prevent cancer. An extremely important component of this mission is to ensure quality cancer care for our diverse surrounding communities. UCCCC has extensive experience and expertise in the design, implementation, and evaluation of innovative multifactorial interventions to improve community capacity for cancer prevention, early detection and treatment. The UCCCC has approximately 215 members from over 20 departments. Members belong to one of six scientific programs (Molecular Mechanisms of Cancer; Hematopoiesis and Hematological Malignancies; Immunology and Cancer; Pharmacogenomics and Experimental Therapeutics; Advanced Imaging; and Cancer Prevention and Control.

The Biostatistics Core Facility provides collaborative statistical support to investigators for the design, conduct, and analysis of clinical trials, observational and population-based studies, and basic science research projects. The Cancer Clinical Trials Office (CCTO) provides oversight and quality control for University of Chicago Cancer Research Center's (UCCRC) clinical trials activity by centralizing regulatory and reporting functions. The overall objective of the CCTO is to provide the infrastructure to support successful clinical research across departments.

Cancer Resource Center

Center is staffed by a specially-trained social workers and an administrator-counselor, who help patients and their families: Access comprehensive cancer information, including facts about specific types of cancer, treatment information and pain management; learn about innovative cancer research trials and how to participate in them; connect with community resources that supply housekeeping, home healthcare, child care, medical equipment, and other support services; and join support groups designed to serve their emotional and information needs. The Center also makes computers available to provide information access for staff, patients, families, health care professionals and other interested individuals. An open area provides an extensive array of informational materials. The Cancer Resource staff is available to help people find the resources they need either online or in the Center's library. In addition, the Center has a closed conference area in which patients and their families can consult in private with Cancer Resource Center staff, who are experienced, well-trained advocates for cancer patients and their families. They assess the needs of individuals and help them obtain the services they require in dealing with cancer's uncertainties.

Ataxia Center

The University of Chicago Ataxia Center was modeled after the University of Minnesota Ataxia Clinic established by Dr. Christopher Gomez in 1991 as a specialty clinic devoted to the diagnosis, treatment and management of ataxias. Dr. Gomez has over 20 years of expertise in the evaluation and treatment of patients with diverse forms of degenerative ataxia. This experience coincides with the era of an enormous explosion of genetic discovery, paving the way for understanding disease pathogenesis, the necessary prerequisite for developing rational therapies. In January 2006 Dr. Gomez assumed the Chair of the Department of Neurology at the University of Chicago and later that year assembled a team of specialists needed to establish the new University of Chicago Ataxia Center.

The founding principle of the University of Chicago Ataxia Center is that patients with the many types of rare ataxic gait and balance disorders can benefit from the enlarging experience of multidisciplinary specialists devoted their care. The center specializes in the diagnosis and treatment, as well as prevention and management of complications affecting this group of patients. All patients presenting with progressive problems of gait and balance, falling, or vertigo are seen at the University of Chicago Ataxia Center. The Ataxia Center receives referrals predominantly from internists and neurologists in the Chicago area. However, patients are regularly referred from adjoining Midwest states and from throughout the US and continent. Occasional referrals to the Ataxia Center team have come from the Middle East, Asia and South America.

In the past twenty years there has been an explosion of genetic discovery that has revolutionized our understanding and approach to diagnosis of ataxia. A total of 28 distinct forms of autosomal dominant ataxia, at least

10 forms of recessive ataxia and several x linked forms have been discovered. Patients are provided with the most current genetic testing available.

Brain Tumor Center
Led by Drs. Steven J. Chmura, Rimas V. Lukas and Bakhtiar Yamini, the University of Chicago Brain Tumor Center provides sophisticated care for primary and metastatic tumors of the central nervous system (CNS), including brain and spinal cord tumors, using a multidisciplinary team of neuro-oncologists, neurosurgeons, radiation oncologists and hematologist/oncologists in the integrated planning and delivery of individualized patient care, including:

- Definitive diagnostic assessments using the latest technology and minimally invasive techniques to pinpoint even the most difficult-to-detect tumors
- A range of comprehensive treatment options for benign and malignant CNS tumors
- Multidisciplinary management of metastatic cancer by experts in the University of Chicago CNS Metastases Center
- Specialized expertise in hemangioblastomas of the brain and spine associated with von Hippel-Lindau disease

Research within the Brain Tumor Center includes a both basic science program, investigating underlying mechanisms involved in the development, survival, and dissemination of tumors in the nervous system and a team of clinical trialists involved in Phase I-III research including NIH, industry and investigator sponsors. The Center is Chicago's only National Cancer Institute (NCI) sponsored Lead Academic Participating Site (LAPS), and one of only 30 sites nationwide.

Burn and Complex Wound Center
The University of Chicago Burn and Complex Wound Center is a specialized care program where patients who have sustained burn injuries and other severe wounds are treated by a unique, multidisciplinary team of experts. Located within the University of Chicago medical center, the Burn Center is accredited by the American College of Surgeons and the American Burn Association. The center features an eight-bed intensive care unit (ICU) dedicated to adult and pediatric burn patients and provides cross-disciplinary care and research that includes specialists from:

- Surgery
- Anesthesiology & Critical Care
- Pediatrics
- Nursing
- Dietary Services
- Physical Therapy
- Occupational Therapy
- Social Services
- Psychology
- Child Life

The Burn Center addresses all aspects of thermal injuries--from transport to acute care to post-burn rehabilitation. It provides state-of-the-art care for burns and complex wounds as well as treatment for burn scars and deformities.

Research at the Burn Center focuses on:

- Biology of scar formation and control
- Molecular and cellular aspects of electrical injury
- Impact of nutritional supplements to wound healing
- Anesthetic pain management

- Pediatric pain control
- Aspects of pediatric post-traumatic stress disorder (in conjunction with a psychologist at La Rabida Children's Hospital)

Craniofacial Anomalies Multidisciplinary Program (CAMP)
The Craniofacial Anomalies Multidisciplinary Program (CAMP) at the University of Chicago provides a thorough, team approach for the evaluation, diagnosis and treatment of children with craniosynostosis and other craniofacial disorders, such as frontonasal dysplasia, cleidocranial dysplasia, encephaloceles, and rare craniofacial clefts. CAMP is one of the largest craniofacial programs in the region, and is staffed by the largest pediatric neurosurgery group in Chicago, as well as premier pediatric plastic and reconstructive surgeons and renowned experts in genetics and neuroradiology.

Comprehensive Care for Adults with Congenital Anomalies of the Nervous System (CANS)
The neurosurgery program at the University of Chicago Medicine is one of the few programs in the country dedicated to providing comprehensive care for adults with congenital anomalies of the nervous system. The center neurosurgeons see adult patients who have grown up with congenital anomalies, as well as adult patients who have recently started experiencing complications. Conditions treated include:

- Syringomyelia
- Hydrocephalus
- Chiari Malformation Type 1
- Spina Bifida and Tethered Cord Syndrome
- Craniosynostosis

Multiple Sclerosis Clinic
Neurologists at the University of Chicago Medicine Multiple Sclerosis Clinic are dedicated to improving the quality of life for people with multiple sclerosis (MS), providing definitive diagnoses and comprehensive treatments to help patients manage their symptoms and limit flare-ups. The clinic has consistently been at the forefront of advancements in autoimmune diseases, including the development and testing of interferon, the first FDA-approved treatment for multiple sclerosis.

Neurofibromatosis Program
The Neurofibromatosis Program at the University of Chicago provides care for patients with neurofibromatosis type 1 (NF-1) and neurofibromatosis type 2 (NF-2) as well as scwhannomatosis. The program is one of the few programs in the country that treats both adults and children and thus has a unique specialty in NF related conditions, NF-2 and schwannomatosis, which are both primarily adult diseases.

Parkinson's Disease and Movement Disorders Research Center
The UChicago Parkinson's Disease and Movement Disorders Clinic is designated a Center for Advanced Research by the American Parkinson Disease Association. Center physicians are investigating movement disorders at the molecular level to identify precise causes of these diseases. They conduct clinical trials, regularly publish findings, and serve as editors and on editorial boards of respected medical journals. Sharing knowledge with institutions throughout the world, center physician-scientists work with grant-funded studies, including support from the National Institutes of Health, Michael J. Fox Foundation, and Parkinson's Disease Foundation, among other organizations.

Center for Peripheral Neuropathy
The Center for Peripheral Neuropathy was established at the University of Chicago in May 2001. It is committed to educating the public and healthcare providers about this disease, providing state-of-the-art care to patients affected by peripheral neuropathy, and contributing to basic and clinical research in an effort to identify the causes and potential cures for these disorders. Through the use of the Internet, newsletters, public outreach programs and other resources, the Center aims to provide neuropathy patients, and their families, with

detailed, accurate and comprehensible information concerning the various types of peripheral neuropathies, including approaches toward their diagnosis and treatment.

Sleep Disorders Center
The University of Chicago is a leading institution in the study of sleep medicine. UChicago physicians and scientists are credited with significant breakthroughs in sleep research, including the discovery of rapid-eye-movement (REM) sleep in 1953. Current research focuses on leading-edge investigations to better understand how sleep patterns affect metabolism, the immune system, and other aspects of health, including:

- Sleep apnea
- Narcolepsy
- Idiopathic hypersomnia
- Restless legs syndrome
- Periodic limb movement disorder
- Circadian rhythm disorders (including delayed and advanced sleep phase syndromes, irregular sleep-wake patterns, shift work sleep disorder, and jet lag)
- Chronic insomnia
- Snoring
- Parasomnias (including confusion arousals, leg cramps, nightmares, acting out dreams, periodic and rhythmic movement disorders, sleep starts, sleep talking, sleep terrors, sleepwalking, and REM sleep behavior disorder)

Comprehensive Stroke Center
The University of Chicago Medicine is a Joint Commission-Certified Comprehensive Stroke Center, nationally recognized for its expertise in providing the highest level of care for stroke patients. UCM is the first academic medical center in the Chicago region to receive this recognition. This collaborative effort allows a multidisciplinary team of neurologists, neurointensive care specialists, neurosurgeons, neuroradiologists, advanced practice nurses, therapists, and other experts to provide comprehensive diagnostic and therapeutic care for people with the following disorders:

- Ischemic stroke
- Transient ischemic attack (TIA or "mini-stroke")
- Critical narrowing or blockages of brain blood vessels
- Intracerebral hemorrhage
- Aneurysms, subarachnoid hemorrhage
- Vascular malformations of the brain
- Vascular tumors of the brain and head/neck region
- Venous occlusions such as dural sinus thrombosis and cortical vein thrombosis

Von Hippel-Lindau Disease (VHL) Clinical Care Center
In 2012, the nonprofit VHL Alliance (VHLA) designated the University of Chicago Medicine as a comprehensive VHL Clinical Care Center for children and adults -- the only such center in Illinois. The VHL center harnesses the combined expertise of specialists from 13 clinical areas, including neuro-oncology, endocrine surgery, genetics, medical oncology, urology, gastroenterology and more. Care is tailored to each patient's needs, and appointments are coordinated across specialties to reduce visits to the medical center. The VHL Center provides the full range of genetic services, screening and medical and surgical treatment options for VHL, offering genetic counseling and genetic testing for individuals and families at risk. For those already diagnosed with VHL, the center develops a detailed plan of care and provides resources to help patients learn about and adjust to their diagnosis. A comprehensive surveillance plan is initiated to screen for early signs of VHL complications, and specialists are consulted as needed.

Digestive Diseases Center
The Digestive Diseases Center at The University of Chicago Medicine is a collaborative, multidisciplinary network of physicians, researchers, and allied health professionals who share a legacy of innovation and a common purpose: to improve the lives of patients who suffer from digestive diseases. Sub-specialties of this center include:

The Celiac Disease Center
The University of Chicago has one of two research teams in the world that is working to understand the nature of the immune system in the gut and the earliest response of the intestine to the presence of gluten.

Center for Esophageal Diseases
The Center for Esophageal Diseases at the University of Chicago Medicine is one of the few centers in the United States solely dedicated to diagnosing and treating disorders of the esophagus. Center physicians have the focused expertise and depth of experience to offer patients options, resources and a level of experience and innovation that are available at only a handful of leading medical centers in the world. The center's approach to care is both personalized and multidisciplinary. A team of gastroenterologists and surgeons work hand-in-hand to coordinate all aspects of care from diagnosis to offering the most innovative and state-of-the art treatment for even the most complex disorders.

Inflammatory Bowel Disease Center
The University of Chicago Medicine Inflammatory Bowel Disease Center provides the highest caliber of care to patients who suffer from inflammatory bowel diseases. Center faculty conduct medical research that advances the science and understanding of these conditions and offer unique and highly relevant educational programs for patients and professionals.

The center provides nutritional counseling to help patients decrease the effects of Crohn's disease or ulcerative colitis and offers minimally invasive approaches for complex surgeries to reduce pain, scarring and recovery times. Unique, comprehensive programs include the Transitional IBD Clinic for Teenagers and Young Adults as well as a multidisciplinary Fertility, Pregnancy and Sexual Function Program to address the challenges facing women with IBD.

The IBD Center includes a dedicated inpatient wing – the only one of its kind in the region – that is located in the Center for Care and Discovery, the University of Chicago Medicine's new, state-of-the art hospital.

Food Allergy Research and Clinical Trials
The University of Chicago Digestive Diseases Center focuses on developing new methods for the prevention and treatment of food allergy, with particular focus on better understanding how and prebiotics influence food allergy, and the use these observations to develop new therapies. As a Food Allergy Research & Education (FARE) Center of Excellence, the University of Chicago Medicine offers a variety of clinical trials and is helping to develop a national food allergy patient registry.

Center for Endoscopic Research and Therapeutics (CERT)
At the University of Chicago Center for Endoscopic Research and Therapeutics, physician scientists perform more than 2,000 specialized ultrasound and interventional endoscopy procedures annually, ranking among the nation's leaders in progressive techniques. The interventional endoscopy program attracts patients from around the country due in part to the center's expertise, innovation, patient focus, and strong partnerships. The CERT also partners with the Comprehensive Cancer Center to treat pancreatic diseases (cancer and benign diseases), bile duct cancer, and other gastrointestinal cancers, such as esophageal, gastric and colon cancers.

Center for the Surgical Treatment of Obesity
The University of Chicago Medicine is nationally recognized for its surgical weight loss program, which offers state-of-the-art approaches to obesity through surgical means. The center's multidisciplinary team is the most experienced in the Chicago area, with board-certified surgeons specializing in advanced minimally invasive (laparoscopic) surgical techniques as well as bariatric surgery. The center is one of a few programs in the country -- and the only program in the Midwest -- that offers all four major surgical options for the treatment of severe obesity using minimally invasive techniques:

- Vertical Sleeve Gastrectomy (VSG)
- Roux-en Y gastric bypass (RYGB)
- Biliopancreatic diversion with duodenal switch (DS)
- Adjustable gastric banding (Lap-Band®)

The center is also a regional and national referral center for complex and revisional bariatric surgery.

University of Chicago Center for Aortic Diseases (UCCAD)
The University of Chicago Medicine's Center for Aortic Diseases is led by a team of experts who specialize in the rapid and coordinated treatment of complex aortic aneurysmal disease, including:

- Aortic aneurysms
- Thoracic aneurysms
- Abdominal aortic aneurysms
- Aortic dissections

In addition to working in a multidisciplinary fashion with cardiologists, imaging experts and radiologists, center surgeons perform these highly complex procedures in state-of-the-art facilities that enable them to perform surgery using endovascular and hybrid approaches.

Center for Adults with Congenital Heart Disease
This Center's multidisciplinary staff of adult and pediatric cardiologists, cardiac surgeons, electrophysiologists, and other specialists provide personalized care for adults 18 years and older with any type of congenital heart problem. This multidisciplinary approach affords the ability to treat patients with repaired or unrepaired defects who also may have co-existing heart and medical diseases. Center heart specialists are internationally recognized for their expertise in treating congenital heart disease

Center for Arrhythmia Care
At the University of Chicago Medicine Center for Arrhythmia Care manages complex cases with a team of cardiovascular intensivists, cardiac surgeons and heart failure specialists. The center includes robotic heart surgery options to perform hybrid procedures, combining the best of surgical and interventional cardiology. Additionally, electrophysiologists and heart failure experts are able to provide advanced ventricular care to patients with congestive heart failure and ventricular dysfunction. With access to the latest technological advancements, the arrhythmia care team can deliver personalized treatment designed to improve success and safety. The Center for Arrhythmia Care also has a strong commitment to basic, clinical and translational research with the goal of discovering new methods for preventing arrhythmias and improving patient care, developing new technologies to better understand atrial fibrillation, and creating novel treatments for better outcomes and quality of life.

Comprehensive Hypertension Center
The UChicago Comprehensive Hypertension Center specializes in the treatment of high blood pressure that is difficult to manage. The center is accredited by the American Society of Hypertension (ASH) -- the first center

in Chicago to earn this designation. The center offers individualized care through inpatient and outpatient consultation to patients who have hypertension in addition to other complex health conditions, including:

- Early kidney disease
- Diabetes
- High risk for heart attack or stroke
- Previous occurrence of heart attack or stroke

Physicians in primary care, obstetrics, cardiology, nephrology, endocrinology, and other specialties refer patients to the Comprehensive Hypertension Center for a second or third opinion on treatment and causes of high blood pressure.

Kidney Stone Management Program

The University of Chicago has one of the nation's most recognized programs for the treatment, prevention and management of kidney stones. UChicago nephrologists have led the field in scientific research has had a profound impact on how doctors around the world evaluate, treat and prevent kidney stones. The program not only treats problematic stones, but also invests significant time discovering why a patient's stones occurred in the first place – involving a thorough evaluation of medical history and crucial aspects of day-to-day life, including job, diet, habits (such as daily water intake) and other lifestyle choices. The program runs its own specialized stone analysis laboratory. In collaboration with the University of Chicago Medicine urologists the program provides the full spectrum of medical and surgical treatment options, including minimally invasive and non-invasive procedures, extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy and ureteroscopy. The vast number of people treated in this program – more than 7,000 to date – has created unparalleled research opportunities, including the opportunity to monitor individual patients for years or even decades.

Center for Advanced Lung Diseases

The Center for Advanced Lung Diseases offers a comprehensive approach to diagnosing and treating complex, chronic and rare lung diseases. The center includes nationally recognized experts in pulmonary and critical care medicine, thoracic surgery, pulmonary rehabilitation, cancer care, sleep medicine, transplant medicine, genetics, radiology, pathology, respiratory therapy, nursing and more. Together these specialists provide focused care for the full spectrum of diseases of the respiratory system, including asthma, lung cancer, interstitial lung diseases, cystic fibrosis, sleep apnea, Alpha-1 antitrypsin deficiency, chronic obstructive pulmonary disease (COPD), sarcoidosis and lung failure. Center physicians are also conducting leading-edge research, from diagnosing lung diseases using innovative minimally invasive 3-D navigational technology, to investigating better anti-rejection drug regimens for lung transplant recipients.

Center for Pelvic Health

At the University of Chicago Center for Pelvic Health, women and men of all ages benefit from the combined expertise of a team of subspecialists, whose depth of expertise is unique in the region. The center is dedicated to helping patients overcome the physical, emotional and social issues surrounding pelvic floor disorders. The center includes specialists in urogynecology, urology, gastroenterology, colorectal surgery, plastic and reconstructive surgery, radiology, physical therapy and nursing. Disorders treated at the center include urinary incontinence, overactive bladder, fecal incontinence, pelvic floor dysfunction and pelvic organ prolapse.

Asthma and COPD Center

The University of Chicago Asthma & COPD Center is dedicated to the promotion of excellence in the care of asthma & COPD, including research and education, both within the institution and in the larger community. Center respiratory disease specialists provide a full range of services to help understand and manage asthma and chronic obstructive pulmonary disease (COPD). The center offers the latest advancements in diagnostic testing, including spirometry, lung volumes, methacholine challenge and other pulmonary function testing

methods. Center physician-scientists conduct clinical trials and other types of studies to investigate improved therapies and procedures for the treatment of asthma and COPD.

Polish-American Transplant Center

The University of Chicago Medicine Polish-American Transplant Center serves Polish-speaking patients and their families. The center is run by a Polish-speaking team of experts who coordinate all aspects of care for patients before, during and after transplant. Services are provided for all types of transplants, including the following:

- Kidney transplant
- Pancreas transplant
- Liver transplant
- Lung transplant
- Heart transplant
- Islet cell transplant
- Stem cell transplant (bone marrow transplant)
- Multiple organ transplant

Kovler Diabetes Center and the Diabetes Research and Training Center

The Kovler Diabetes Center, Directed by Dr. Philipson, in the Section of Endocrinology, Diabetes and Metabolism at the University of Chicago is one of the top programs in the United States. The outpatient clinic handles over 10,000 visits per year. The laboratory space is approximately 20,000 sq. ft. primarily in the Knapp Center for Biomedical Discovery (KCBD) as well as Billings Hospital and the Peck Pavilion. The laboratories involved in this project have all the necessary space and resources to carry out the proposed studies. There is also sufficient office space for all investigators and administrative support. The University of Chicago has an outstanding environment for diabetes- and genetics-related research. The University of Chicago is also the site of a of the NIH funded Diabetes Research Center, The University of Chicago Diabetes Research and Training Center (DRTC), of which Dr. Graeme Bell is PI and Director. The DRTC is an interdepartmental and cooperative endeavor involving investigators from many University departments with differing scientific backgrounds, yet sharing a common interest in diabetes and related research. It fosters collaborative, multidisciplinary diabetes and research program designed to enhance the clinical and basic research capabilities of diabetes investigators and to speed the transfer of advances in basic biomedical and genetic research to the clinical arena where they may be applied to the diagnosis and treatment of persons with diabetes. The investigators of this application will utilize the DRTC Core facilities (Islet Cell Biology, Molecular Biology and Genetics and Animal Models and Physiology) as well as a Pilot & Feasibility and Enrichment Programs.

Chicago Center for Diabetes Translation Research

Elbert Huang and Rochelle Naylor have offices and computation resources within the same set of connected buildings as Drs. Bell and Philipson. Dr. Huang is Co-Director of the NIH-funded Chicago Center for Diabetes Translation Research and Director of the Quantitative Analysis Core (CCDTR; PI – Marshall Chin). Dr. Marshall Chin leads the CCDTR; Dr. Huang is director of quantitative methods and enrichment programs. The CCDTR aims to expand its role as one of the pioneering national leaders in investigating the translation of diabetes research findings into real-world practice, with a particular emphasis on improving the quality of care and outcomes for vulnerable populations and reducing racial and ethnic disparities in health care. The Center builds upon the University of Chicago Diabetes Research and Training Center Prevention and Control Core's strengths in disparities, community based participatory research (CBPR), cost-effectiveness analysis, health services research, quality improvement, behavioral change, and geriatric diabetes within the context of a University with world-class strengths in both the basic and social sciences. The Center serves as both a provider of core services and expertise, and equally importantly, as a true working community of collaborators who help each other on projects. The Chicago CDTR facilitates innovative interdisciplinary diabetes translation research

that integrates health care system and community. The Center frequently applies new methods and approaches from areas such as economics, organizational theory, and other disciplines of the social sciences. This innovative work bridges the gap between the research arena and real-world practitioners, administrators, and policymakers seeking to improve diabetes care. The Specific Aims of the Chicago Center for Diabetes Translation Research are: 1) To create an environment that encourages and supports innovative diabetes research to translate scientific findings into real-world practice, with a special focus on improving the care and outcomes of vulnerable populations and reducing racial and socioeconomic disparities. 2) To serve as a local, regional, and national resource to improve diabetes translation research in community health centers and other safety net settings by forming partnerships with the Chicago Department of Public Health, ACCESS Community Health Network, MidWest Clinicians' Network, Association of Asian Pacific Islander Community Health Organizations, and National Association of Community Health Centers.

Center for Translational and Policy Research of Chronic Diseases

The Center for Translational and Policy Research of Chronic Diseases is a self-sustaining center of excellence in chronic diseases at the University of Chicago. It seeks to tackle the most fundamental research questions facing developed countries with growing populations who suffer from chronic diseases. The Center has a unique range of research that includes the development of innovations for clinical practice, evaluations of the economic and policy implications of those innovations, and linkages of these findings to the study of broader health care policies. The Center has a twofold purpose: to directly improve the care and health of individual patients that seen in clinic through care innovations and to influence the policies that affect the financing and organization of care that ultimately determines whether innovations can be adopted.

Core Areas of Expertise

- Content in health care policies addressing needs of the poor and vulnerable
- Primary care services – FQHCs
- Prescription drugs – 340B
- Hospital care – Community benefit
- Chronic disease management – Diabetes
- Methods related to medical decision making and policy analysis
- Decision analysis
- Cost-effectiveness analysis
- Quality of life
- Decision aids/decision support
- Medicaid support

Rush University

Alzheimer's Disease Center

The Rush Alzheimer's Disease Core Center (Rush ADCC) is housed in the Rush Alzheimer's Disease Center, a free-standing multi-disciplinary clinical and research center within Rush Medical College of Rush University Medical Center (RUMC). The Center Director reports directly to the Dean of Rush Medical College. The Center administers the contracts of 21 faculty, who also have an appointment in one or more of six departments across the Medical College, including Neurological Sciences, Behavioral Sciences, Pathology (Neuropathology), Internal Medicine, Family Practice, and Diagnostic Radiology. The Center also has a wide range of strategic partners, including visiting or adjunct professors at the Brigham and Woman's Hospital and Broad Institute (Rush Department of Neurological Sciences), the University of Sao Paulo Medical School (Rush Department of Pathology, Neuropathology), and the University of Illinois at Chicago (Rush College of Nursing). The Center has about 125 salaried staff. It has 15,634 ft2 of dedicated administrative and community-based research office space, wet laboratory space, biospecimen storage space, and clinic space.

Administrative and Community-Based Research Office Space

The Rush Alzheimer's Disease Center has 5,210 ft^2 of modern office space on the 10th floor and 2,530 ft^2 on the 7th floor of the Armour Academic Facilities Building. These spaces are equipped with faculty offices, and also house administrative staff, data management staff, statistical programming staff, and personnel involved in community-based education and research. All offices are equipped with modern desktop or laptop personal computers along with telephones with voicemail and conference call options. They either have printers or are connected to network printers. The space includes four black and white and one color network printers, two high speed color copiers, and a high-throughput fax machine. The Department Manager has a separate fax machine and desktop scanner. The two neuropathologists each has an office with a dual head light microscope, one with an Olympus BX-41 with an attached Olympus DP72 digital color camera, and one with a Leica DM2500. One 200 ft^2 storage room has a high density file storage system along with space for storing supplies for community-based education and research including a portable projector for electronic media presentations. There is a 300 ft^2 break room with a long work table for assembling education materials, a refrigerator for storing light refreshments for education activities, and a special waste container for documents with personal health information that is shredded by Citadel weekly. There is also a 135 ft^2 conference room for faculty and staff planning purposes.

Wet-Laboratory Space

The Rush Alzheimer's Disease Center has a fully equipped 4,624 ft2 Research Laboratory on the 4th floor of the Cohn Research Building, across from the Armour Academic Facilities Building. The space includes sixteen standard wet laboratory benches for histochemistry, immunocytochemistry, whole blood processing and separation, DNA extraction and quantification, microscopy, stereology, and image analysis. An annex for storage of fixed tissue is also in the laboratory. The laboratory includes a separate tissue culture room and a separate gross dissection room. The space includes two black and white and one color network printers.

Ante- and post-mortem biological specimens are currently stored in refrigerators and freezers located in 1,829 ft^2 of a bio-specimen storage facility dedicated to the Rush Alzheimer's Disease Center on the 9th floor of the Jelke building. The lab also has access to a 1,830 ft^2 centralized biospecimen storage facility for Rush University Medical Center, also located on the 9th floor of Jelke. Additional space is available on the 4th floor adjacent to the laboratory and on the 2nd floor of Cohn (additional 159 ft^2). The Jelke Building is located across the street. All units are connected to an alarm system and backup power; all –80°C and –120°C units have dedicated CO2 and LN2 backup, respectively. The alarm systems and backups are maintained by Rush Alzheimer's Disease Center staff. In addition, the Rush Alzheimer's Disease Center has a small 121 ft^2 wet-laboratory space for dissections. Autopsies are performed in the Rush University Medical Center Department of Pathology morgue located in the basement of the Jelke Building across the street from the laboratory by Rush Alzheimer's Disease Center personnel on call 24/7.

Clinical and Patient-Oriented Research Space

The Rush Alzheimer's Disease Center has a fully equipped 1,282 ft^2 clinical space on the 1st floor of the Armour Academic Facilities Building below the office space and across the street from the Cohn Building. The space is entered from the outside at street level, and has easy access for older study participants and patients. The space includes three family conference rooms, and three examination rooms one of which serves as a clinical laboratory. An in-suite washroom is available for collection of urine specimens. Family conference rooms have bulletin boards and desks for display of educational and recruitment materials along with flatscreens with built-in DVD players. Examination rooms have supplies for conducting physical and neurological examinations including fundoscopy and for collecting vital signs. Laboratory space includes dry ice storage, a phlebotomy chair with appropriate supplies to collect blood samples, sharps containers, medical waste containers, a centrifuge, a temperature monitored refrigerator to store study drugs that cannot be maintained at room temperature, and an electrocardiogram machine. Dataports for connecting laptop computers to complete clinical work and collect research data are present in every room. Cubicle space also is available to house

study monitors, as needed. Fax machines, telephones with voice mail and conference calling, printers, and copier machines are available to facilitate communication. A 24/7 answering service is maintained with American MediConnect, Inc. They have both English and Spanish speaking operators. On-site patient records are stored in locked file cabinets and a temperature monitored locked medical cabinet is available to store study drugs. The Rush Alzheimer's Disease Center contracts with Iron Mountain for off-site long-term storage of patient records which can be retrieved in approximately 24 hours. A special waste container for documents with personal health information is collected for shredding by Citadel every two weeks.

Computing Infrastructure

The Rush Alzheimer's Disease Center has a computing infrastructure to support the needs of complex data acquisitions, management, and reporting activities as well as statistical processing. This computing structure is dedicated to the needs of the Center and is integrated into the powerful computational environment of Rush University Medical Center.

The Rush Alzheimer's Disease Center utilizes two Hewlett Packard ProLiant DL380 G7 servers with dual 3.46 GHz 6-core Xeon Intel processors. The servers are described in more detail under MAJOR EQUIPMENT below. One server is used for primary database storage and for web-server activities and connects to the University's storage area network (SAN) where an additional 11.7 terabytes of storage is available. We employ IBM's Informix Dynamic Server 11.70 enterprise level database as our primary data store for all data collected, which as of September 2015 contains over 7,900 database tables for 11 independent databases. Appropriate isolation level utilization in Informix allows concurrent reading of data by multiple users. All database activity is performed under the appropriate transactions with log files saved to separate drives for efficiency and protection from unlikelihood of multiple drive failures. The Informix tools 4GL 7.50 FC4 and DB-Access 11.70 FC4GE (SQL) are used primarily for error checking, recording nightly database change audits, complex report writing and ad-hoc database querying. An Apache Tomcat server is used to provide secure web-based access to forms and tools for project coordination.

Statistical processing is performed on a dedicated Hewlett Packard ProLiant DL380 G7. server configured with SAS, S-Plus and R for mathematical programming, statistical analysis and graphics, PLINK for genome wide association studies, and PASS for sample size calculations; SAS, S-Plus and Stata are also licensed for the PC.

Both servers are stored in the main Rush University Data Center, a physically secure computer environment with power, cooling and other infrastructure redundancies that is monitored 24 hours a day. Backups are run across the university's enterprise backup system with a daily backup snapshot transferred to a secure offsite facility to protect from an unexpected disaster.

Confidentiality is protected by two levels of control, at the computer operating system and at the Informix database system. At the operating system level, entry onto the system is protected by passwords, and all sensitive data are encrypted via the secure sockets layer, SSL/HTTPS. Files and database tables on the system are designated as to the individuals that may have access to them. The Informix database system adds another level of protection that allows a user access to only particular records in the database or only specific data elements within a record according to that user's specific privileges.

The Rush University Medical Center local area network, including our Hewlett Packard Linux Servers and desktop data acquisition computers, is protected from Internet users behind a firewall. Outside access to the Rush network via the Internet can only be obtained by authenticating to a Cisco VPN with a remote access account assigned by the Rush University Information Services Department. In addition to providing a correct username and password, users on computers first connecting to the VPN must also respond correctly to a series of predefined personal questions. Upon successful authentication, all data transmitted between the computer and the Rush network is fully encrypted.

Genomic, Epigenomic, and Proteomic Data Analyses

The Rush Alzheimer's Disease Center has six HP workstations dedicated to processing of genomic, epigenomic, transcriptomic, proteomic, and metabolomic data. Each workstation runs a 64-bit Linux operating system and is configured with an Intel Core i7-2600 3.4 GHz 4-core processor, 16 or 32 gigabytes of RAM, 2 terabytes of hard drive storage and connected to the local gigabit Ethernet network. A shared configuration for each workstation includes common software packages, accounts and shared encryption keys which allows distributed processing of very large datasets to be divided into components (by chromosome for example) and then initiated remotely. Analytic output is directed back to a central location where the data are further processed, aggregated or summarized.

MRI Data Handling and Analyses

The Rush Alzheimer's Disease Center has two Apple Mac Pro workstations and a one Linux workstation dedicated to the processing of functional and structural MRIs. Each Mac workstation has two 3.0 GHz 4-core Intel Xeon processors, 16 gigabytes RAM and 2 terabytes of hard disk space. The Linux workstation has an Intel Core-i7 2600k 3.4 GHz 4-core processor with 8 gigabytes of RAM and 2 terabytes of hard drive space. All three imaging workstations connect to the main data server over a gigabit Ethernet network that allows for high-speed transfer of large data sets. A variety of open source and licensed software is used for data processing including FreeSurfer and Mathworks MATLAB. An Apple MacBook Pro laptop with a 2.4 GHz Intel 2-Core processor, 4 gigabytes RAM and 250 gigabytes hard disk is used for data acquisition and storage at offsite MRI facilities. MRI data is synchronized between the Mac Pro desktop, MacBook Pro laptop and the Rush Alzheimer's Disease Center's main Linux server over a high-speed gigabit Ethernet network in the Armour Academic Facilities Building.

Rush Center of Excellence on Disparities in HIV and Aging (CEDHA)

The goal of the Rush Center of Excellence on Disparities in HIV and Aging (Rush CEDHA) is to provide an infrastructure to support collaborative, multidisciplinary epidemiologic research focused on understanding and eliminating racial disparities in the aging-related consequences of HIV. The Research Core will collect annual cognitive and motor function data, psychosocial risk factors, co-morbidities, and biospecimens in older adults (>50 years) with and without HIV infection, and compare them to existing data from HIV-uninfected persons age 65-90 matched on race, gender, and socioeconomic status. Project 1 will collect MRI data and serum inflammatory markers on subjects to test hypotheses concerning the relationships among age, race, and inflammation in HIV. Project 2 will measure immune perturbations and markers of immune senescence in lymphocytes to estimate the age-associated acceleration in aging due to HIV and test the hypothesis that racial differences in immune perturbations lead to early immune senescence in African Americans with HIV.

Rush Center for Urban Health Equity

The Rush Center for Urban Health Equity is based upon the principle that continued documentation of avoidable deaths and disabilities from these disparities in observational studies is insufficient Instead; the Center is dedicated to preventing them through the conduct of rigorous behavioral clinical trials, in partnership with communities. The Center's mission is to integrate the management of stress and trauma into multi-level interventions that will reduce health disparities in cardio metabolic risk and cardiopulmonary disease. The long-term objectives for the Center are to 1) Develop and integrate rigorous clinical trial methodology into disparities-focused behavioral clinical trials; 2) Test innovative multi-level interventions across the lifespan from children to the elderly; 3) Empower inner-city communities to become active participants in the design and conduct of interventions to improve their health; and 4) Provide training opportunities for promising individuals from underrepresented and underserved communities to pursue careers in transdisciplinary research on health disparities.

Chicago Center for the Study of Women's Health Across the Nation (SWAN)

The Study of Women's Health Across the Nation (SWAN), a 7-site longitudinal cohort study initiated in 1994 in response to RFA AG-94-002. SWAN was mandated "to characterize the chronology of the biological and psychosocial antecedents and sequelae of the menopausal transition (MT) and the effect of this transition on subsequent health and risk factors for age- related disease", and to extend this information from White women to "...the range of peri-menopausal experiences in women of other racial/ethnic background(s)." A total of 3302 Black, Chinese, Japanese, Hispanic and White women were enrolled, with 78% completing up to 13 visits spanning the premenopause to early post-menopause (PM). During SWAN V, the plan is to extend observations through the late PM, a necessary step to assess the impact of the MT on age-related diseases. Specific aims are to: 1) complete the characterization of the natural history of reproductive aging through the late PM; 2) evaluate the impact of reproductive aging through the late PM on health outcomes clinically relevant to women in their 60s and 70s, including: cognitive and physical function, psychological well-being, sleep, bone and cardiometabolic health, urogenital symptoms, sexual function and vaginal health; and 3) identify potential underlying mechanisms linking reproductive aging and health by assessing the relation of inflammation, hemostasis and adipokines to the occurrence and progression of biological, functional and clinical outcomes and delineating the interrelationships of body size and composition, race/ethnicity and socioeconomic status with these outcomes. SWAN is uniquely positioned to fill important scientific gaps in understanding of the impact of the MT on women's health in their 60s and 70s and to facilitate the application of new knowledge to clinical practice. SWAN V can disaggregate the contributions of aging and the MT to women's health, address difficult and critical questions about the temporal nature of MT-disease associations, assess differences by race/ethnicity, and provide insights into modifiable factors relevant to the design of innovative prevention and treatment programs for aging women.

Fragile X Clinic and Research Cooperative Consortium

Fragile X syndrome (FXS) is the most common inherited cause of intellectual disability and autism spectrum disorder with an estimated frequency of about 1:4000-5000, affecting all racial and ethnic groups worldwide. A number of these agents have shown signal for benefit in open-label and early phase trials, but it has been challenging to meet primary behavioral outcomes in larger phase 2b and 3 trials, due to multiple complex issues including dosing age of subjects, length of treatment, placebo effects, and primary outcome off target for drug effect. A significant problem has been poor availability of biomarkers and well-validated cognitive and other objective outcome measures that do not rely on parent report. The Rush Fragile X Clinic collaborates with the other Component C FXS clinics to enhance cohort sizes and collect a comprehensive core battery of outcome measures yearly to begin to define the longitudinal trajectory of all aspects of the FXS phenotype The Rush Center also collects pilot data longitudinally for outcome measures that address two areas of need in the field: objective direct measures of CNS function (auditory event-related potentials), and sensitive direct measures of communication function in very young and non-verbal individuals with FXS (Communication Complexity Scale).

NETWORK CAPACITY

ILLINOIS INSTITUTE OF TECHNOLOGY

PI, Sato and Co-PI Basapur will be working on the research project at their offices and facility at the Institute of Design. TRIO Solution Studio Session will be held both at Rush University Medical Center facility and facilities at the Institute of Design.

Institute of Design

Institute of Design (ID) is one of seven colleges of IIT, a graduate design school with a history of innovation and strong research program. It pioneered the development and dissemination of modern design from our founding in 1937 as the New Bauhaus in Chicago. In the 1960s, ID became a center of the first design methodology research and developed systematic and methodical approaches to design. We were among the first to

apply computers to design. In the early 1990s, we helped pioneer the human-centered approach to design that has become a standard of design practice. We have been integrating ethnography and other social/human science research methods together with systematic approaches as part of the design process. In the early 2000s, it helped launch the design thinking movement, linking design more closely to business innovation. Research at ID covers diverse areas including interactive systems, communication, strategic design, service systems, and human system Integration with application projects in areas such as healthcare, medical systems, urban planning, business innovation, and transportation systems.

ID also supports IIT's general education program through its involvement in the planning, design, and teaching of the university's distinctive undergraduate Interprofessional Projects (IPRO) Program. Using ID's innovation methods, all IIT undergraduate students spend an entire semester identifying an opportunity space, defining a problem, conducting research and analysis, and developing concepts that are then prototyped and shared with real stakeholders.

The Institute of Design is located at IIT downtown building in Chicago downtown area with IIT Chicago-Kent College of Law and IIT Stuart School of Business. It is supported by the University Information Technology service as its secure information and computing infrastructure. Its own facility includes a model shop for research and educational use with its quick and precision prototyping capability by 3D printers and machine tools.

RADIOMICS

UNIVERSITY OF CHICAGO

Radiology Imaging Research Institute

The Radiology Imaging Research Institute located in the Department of Radiology at the University of Chicago will be the facility for the proposed research. The laboratories for x-ray imaging have over 30 faculty and staff members with 14,000 square-feet of recently renovated laboratory space. The facility includes two shared computer rooms, eight laboratories (one psychophysics with two rooms dedicated for observer performance studies, one scientific computing and visualization, three digital image processing), three x-ray rooms (containing x-ray generators and x-ray tubes, including a Faxitron DX20), one darkroom, and three conference rooms.

Radiology Department

The Radiology Department has 47 attending radiologists, 7 fellows, and 24 residents. There are 5 full-time radiologists and three fellows performing breast imaging. Over 15,000 mammographic examinations are performed each year in the department. The department has six dedicated mammographic imaging units (a GE Senographe D2000 full-field digital mammography (FFDM) system and a GE Essential FFDM system, and three GE analog mammography units), one Fischer digital stereotactic breast needle biopsy unit.

The Department of Radiology at the University of Chicago operates two GE 1.5 Tesla GE SIGNA MR Scanners, four Philips 1.5 Tesla Achieva MR, and two Philips 3T MR. Although these scanners are primarily used for clinical service, a generous amount of time is available for research.

The Imaging Reading Area has multiple iSite–PACS (Philips Healthcare, formally Stentor) terminals with monitors suitable for display of digital mammograms. Several workstations with advanced viewing capabilities including GE, CADStream and DynaCAD.

Computer: Computer workstations include over 60 PC workstations running Linux. Each computer has 200 Gbytes of disk space on average with data backup done centrally. All workstations are connected via 100 Mbps ethernet. Each investigator has a Macintosh/PC in their office. Also available is a high performance 256-

CPU computer cluster through a funded Shared Instrumentation Grant from the NIH. It has 512 GB of memory and 20 TB of disk and tape storage. In addition, the University's acquisition via a high-end NIH shared instrument grant makes available Beagle, a 150 teraflops, 18,000-core Cray XE6 supercomputer (https://ibi.uchicago.edu/projects/beagle/) of which the proposed research is a selected project for compute support.

Human Imaging Research Office

The Human Imaging Research Office, or HIRO, was created in early 2009 by the Biological Science Division's Imaging Research Institute. It is intended to be the facilitator, or "go-between," for clinical trials and research protocols that require radiology and imaging exams for their subjects. In this regard, the HIRO's goal is to make this process more efficient and accurate and to provide investigators with a wide selection of human research imaging services.

The HIRO currently has three primary responsibilities (or "arms"): (1) coordinating the acquisition of imaging data for clinical trials in a manner consistent with trial protocol, (2) providing assessment and measurement of disease response for clinical trials in a consistent and coherent manner, and (3) managing and distributing clinical image data for research studies in an IRB- and HIPAA-compliant manner.

- The Image Acquisition Arm is responsible for coordinating any issues related to the planning and execution of research-related human imaging. This includes protocol preparation and review with the principal investigator and his/her team, imaging protocol coordination with clinical and research radiology staff, scan scheduling and billing coordination, resource and data management, and quality assurance.
- The Image Measurement and Analysis Arm is responsible for providing investigators with tumor and lesion measurement data in a consistent and efficient manner. This includes ensuring that measurements are made in accordance with the study protocol's specific requirements (e.g., RECIST), providing consistent measurements for follow-up scans, and ensuring that required measurement data is completed and delivered in a timely fashion.
- The Image Collection and Database Arm is responsible for providing researchers with "de-identified" (or "anonymized") consented patient information and medical images for use in biomedical research. The image collection arm also interacts with the acquisition arm to provide support and data delivery services for prospective clinical trials, and it is involved with several data mining projects with the Radiology Informatics team.

The HIRO's patient image and information request service was developed to provide researchers and clinicians with "anonymized" patient information and medical images for use in biomedical research and/or clinical practice. For this purpose, an "honest broker" paradigm was instituted under the Department of Radiology to serve as a disinterested intermediary between researchers and the individuals whose data are being studied. Although the honest broker is an actual person, this system was instituted in order to disallow direct contact between the broker and researcher, thus providing complete anonymity to patient information. This system also provides a more efficient means of handling a greater number of anonymized image requests while increasing the speed in which researchers will obtain their requested data.

Image Computing, Analysis, and Repository (ICAR) Facility

The Image Computing, Analysis, and Repository (ICAR) Facility allows researchers to take maximum advantage of available imaging modalities by supplying expertise in image analysis from simple consultation to shared development of new analysis software to analysis and delivery of results. The ICAR complements the Integrated Small Animal Imaging Research Resource (iSAIRR), which provides initial consultation to identify the appropriate imaging studies, and to ensure that animal preparation and imaging procedures are accomplished correctly and consistently, leading to maximum data quality. ICAR provides researchers with free access to computers and storage and fee-based analysis services, supporting image acquisition, construction of

databases, reconstruction techniques, image analysis (including computer-aided diagnosis), and technology assessment. The facility supports basic research involving modeling and simulations, applied research involving the development of new image-analysis methods, and the development of grid-based technologies.

Services

- Access to a high-performance computing system and scientific software packages (Mathematica, MATLAB, IDL, etc.)
- Access to parallel and grid computing applications and services
- Multi-terabyte online storage and archiving for computing involving large datasets and for storage and retrieval of animal imaging data
- Design of image analysis protocols suited to a specific preclinical imaging research application
- Development of image analysis software solutions (incorporating existing and/or newly developed applications)
- Turnkey image analysis

ILLINOIS INSTITUTE OF TECHNOLOGY

Dr. Suzuki and investigators will use office and laboratory space in Medical Imaging Research Center (MIRC) in the Pritzker Institute of Biomedical Science & Engineering and Department of Electrical and Computer Engineering at Illinois Institute of Technology (IIT) to conduct the proposed research projects in radiomics and precision medicine in Radiomics and Learning Health System Cores in Network Capacity Cluster.

The Medical Imaging Research Center (MIRC)

MIRC in the Pritzker Institute of Biomedical Science & Engineering at IIT is a 10,000 square foot research facility on the main campus of IIT in Chicago. The MIRC has dedicated office and laboratory space, including 6 offices for 6 core faculty members, 12 other offices for 48 postdocs, visiting professors, and graduate students, a reading room for observer performance studies, two x-ray shielded work rooms designed specifically for phase contrast x-ray imaging studies, a conference room, a machine shop, and a computer sever room. The 6 core faculty members are distinguished researchers in machine learning in medical imaging, computer vision and artificial intelligence in medical imaging, computer-aided detection and diagnosis, medical image processing and analysis, image reconstruction, magnetic resonance imaging, biological imaging, and x-ray imaging. The MIRC is designed to facilitate integrated research and to encourage collaborations and knowledge exchanges across laboratories. Investigators have close access to such leading knowledge and expertise that will tremendously benefit the proposed research projects.

Equipment

Dr. Suzuki (Co-PI) and investigators have access to MIRC's computing facilities, which reside in a commercial-grade data center down the hall from the MIRC. The data center has MIRC's Linux computer cluster with 256 CPU cores, including 12 compute nodes with 12-core dual-processor 2.6 GHz Interlagos CPU with 64 GB RAM, 9 compute nodes with dual-core dual-processor 2.2GHz Opteron CPU with 8 GB memory, and 2 GPU compute nodes (Quad-Core dual-processor Xeon Westmere 2.4 GHz CPU, each with 96 GB memory, plus 4 x NVIDIA Tesla C1060 GPU; Quad-Core dual-processor Xeon Westmere 2.4 GHz CPU, each with 96 GB memory, plus 2 x NVIDIA Tesla C1060 GPU and 2 x NVIDIA "Fermi" Tesla C2050 GPU). The data center houses two RAID storage systems (Promise VR1840i Raid 6, 25TB, and Linux box Raid 6, 6TB), which are incrementally backed-up daily. In addition, Dr. Suzuki' research lab in the MIRC houses 6 Linux computers with 24 CPU cores (Intel Core i5 at 3.5 GHz), 6 GPU computing units (NVIDIA Quadro), 48 GB of RAM, and 12 TB storage, with dual booting with Windows Pro operating system, 7 computing servers with 40 CPU cores (Intel Core i7 at 4.5 GHz), 3 high-end GPU computing units (NVIDIA GeForce GTX), 112 GB of RAM, and 17.5 TB storage. Such massive computational power will facilitate the training and testing of the proposed image-based machine-learning in CT dose reduction. Each computer running Ubuntu Linux has a C++ compiler and

Matlab software that are sufficient for developing and evaluating our proposed technology. These computers are connected to a high-speed network (Gigabit Ethernet).

Computer

Dr. Suzuki (Co-PI) and investigators have access to MIRC's computing facilities, which reside in a commercial-grade data center down the hall from the MIRC. The data center has MIRC's Linux computer cluster with 256 CPU cores, including 12 compute nodes with 12-core dual-processor 2.6 GHz Interlagos CPU with 64 GB RAM, 9 compute nodes with dual-core dual-processor 2.2GHz Opteron CPU with 8 GB memory, and 2 GPU compute nodes (Quad-Core dual-processor Xeon Westmere 2.4 GHz CPU, each with 96 GB memory, plus 4 x NVIDIA Tesla C1060 GPU; Quad-Core dual-processor Xeon Westmere 2.4 GHz CPU, each with 96 GB memory, plus 2 x NVIDIA Tesla C1060 GPU and 2 x NVIDIA "Fermi" Tesla C2050 GPU). The data center houses two RAID storage systems (Promise VR1840i Raid 6, 25TB, and Linux box Raid 6, 6TB), which are incrementally backed-up daily. In addition, Dr. Suzuki' research lab in the MIRC houses 6 Linux computers with 24 CPU cores (Intel Core i5 at 3.5 GHz), 6 GPU computing units (NVIDIA Quadro), 48 GB of RAM, and 12 TB storage, with dual booting with Windows Pro operating system, 7 computing servers with 40 CPU cores (Intel Core i7 at 4.5 GHz), 3 high-end GPU computing units (NVIDIA GeForce GTX), 112 GB of RAM, and 17.5 TB storage. Such massive computational power will facilitate the training and testing of the proposed image-based machine-learning in CT dose reduction. Each computer running Ubuntu Linux has a C++ compiler and Matlab software that are sufficient for developing and evaluating our proposed technology. These computers are connected to a high-speed network (Gigabit Ethernet).

Office

Dr. Suzuki (Co-PI) and investigators will use offices located in the MIRC in the Pritzker Institute of Biomedical Science & Engineering and Department of Electrical and Computer Engineering on the main campus of IIT. All investigators have adequate office space with networked personal computers, which are in close proximity to each other and to the associated laboratories with superb secretarial assistance. The Siegel Hall building on the main campus of IIT houses 34 faculty members' offices and laboratories in Department of Electric and Computer Engineering. Investigators have access to leading knowledge in signal & image processing, computer systems, communications & networking, electronics & electromagnetics, and power & control system.

Department of Electrical and Computer Engineering

The Electrical and Computer Engineering (ECE) department at Illinois Institute of Technology (IIT) is a high-tech center for excellence in education and research at both undergraduate and graduate levels. The department has a tradition of innovation dating back to 1906, when IIT faculty member Lee DeForest invented the first vacuum tube capable of amplifying an electrical signal. Another exemplary technical leader was Martin Cooper (EE '50, M.S. '57), who invented the cellular phone and continues to be a pioneer in the development of wireless communication. ECE faculty, students, and alumni continue to change the world by developing technologies from alternative energy resources and communications advancements, to improving medical imaging and computer hardware and software capabilities.

The ECE department accounts for the largest number of students in IIT's Armour College of Engineering. ECE department faculty members conduct research and teach courses within three areas of expertise: Communications and Signal Processing, Computers and Microelectronics, and Power and Control. The current research strengths of the department include: power electronics and energy systems, medical imaging and big data machine learning, embedded systems and VLSI technology, and multimedia communication networks. We have established world-renowned research centers in the areas of power systems (Galvin Center) and medical imaging (Medical Imaging Research Center). These research activities enable ample opportunities for undergraduate and graduate research experience.

CAREER DEVELOPMENT

UNIVERSITY OF CHICAGO

The Booth School of Business

Chicago Booth is the second-oldest business school in the U.S., the first such school to offer an Executive MBA program, and the first to initiate a Ph.D. program in business. The school belongs to the M7 group of elite MBA programs which recognize each other as peers, consisting of Harvard, Wharton, Stanford, Columbia, Chicago Booth, Kellogg and MIT Sloan. In addition to conducting graduate business programs, the school conducts research in the fields of finance, economics, quantitative marketing research, and accounting. Chicago Booth's MBA program is currently ranked first globally by the Economist.

The Booth MBA program allows students to structure their own course of study subject to the constraint of a broad set of requirements, unlike some other top-tier business schools, which impose a cohort or learning team system that includes coursework to be completed in a pre-determined order. This gives students the flexibility to construct a program of study that is tailored to their needs, and can be as broad or deep as they choose. The only required course for full-time and part-time program students is LEAD (Leadership Effectiveness and Development), which students take in their first quarter for full-time students and within the first four quarters for part-time students. This course focuses on the fundamental skills of leadership: motivating people, building relationships, and influencing outcomes. Students in the full-time program may earn an International MBA, or IMBA, by studying abroad on exchange with another business school, taking certain electives, and by demonstrating oral proficiency in a second, non-native language.

The school's Executive MBA program is unique in that students may elect to spend the required residential periods on all three of the school's campuses worldwide (London, Chicago, Singapore, Hong Kong), while also employing the cohort system. In Business Week Executive MBA Ranking 2011 the school ranked 1st.

The Polsky Center for Entrepreneurship and Innovation

The Polsky Center for Entrepreneurship and Innovation advances the knowledge and practice of entrepreneurship and innovation through a broad range of activities, including academics, research, conferences, competitions, and global and community outreach. The Polsky Center is the foremost resource for University of Chicago students and alumni as they pursue entrepreneurial endeavors and private equity careers. The Center is run by a team of professionals committed to promoting and supporting the entrepreneurial spirit, as well as an entrepreneurial advisory board, made up of some of the country's leading entrepreneurs, venture capitalists, and private equity investors.

MATTER

An outgrowth program of the University of Chicago's BSD and Booth School, MATTER is a community of healthcare innovators, and entrepreneurs working together to solve real and complex healthcare problems and improve patient health and wellness. The MATTER program provides:

- A curriculum purpose-built for healthcare innovators
- Mentors-in-residence who've built healthcare businesses and have deep expertise in healthcare, technology, and entrepreneurship
- State-of-the-art facilities including the Shop, the Stage, and the AMA Interaction Studio
- A culture of innovation, experimentation, and collaboration so crucial in today's changing healthcare landscape
- Inspirational keynotes, fireside chats, and panels
- A community of like-minded individuals who are passionate about solving healthcare challenges

- Access to innovators from across the healthcare ecosystem including pharmaceutical, medical device, diagnostics, and health IT companies; venture capitalists; health systems and hospitals; payers; scientists; and physicians
- Innovative programs, built with our partners, designed to enhance collaboration between stakeholders

Chicago Innovation Exchange

The Chicago Innovation Exchange (CIE) is the University of Chicago's hub for multidisciplinary collaborations and support for business start-up activities by University faculty, students and area entrepreneurs. The CIE brings together the University's distinctive strengths in research and resources from a network of world-class entrepreneurship programs to drive innovation in a range of areas, applying scientific discoveries to generate scalable solutions to difficult societal problems. The CIE occupies 17,000 square feet on the second floor of the Harper Theater complex; 6,000 square feet on the second floor of an adjacent office building; and 13,500 square feet of shared conference center space on the 11th floor of the Harper Court office tower. The CIE facility provides workspace, gathering places, and meeting rooms that can accommodate a wide-range of users and visitors, including:

- Flexible coworking space for up to 150 students, faculty, and community members with passions for entrepreneurship and innovation
- Dedicated office space for the CIE management team, Argonne National Laboratory, and the Institute for Molecular Engineering
- Meeting spaces supporting formal and informal collaboration for groups
- Adjustable immersive-technology classroom
- A variety of informal lounge and café

The CIE brings together people and resources from disciplines like energy, life sciences, engineering, social science, medicine, business development, and others, and includes the involvement of three major research laboratories—including national labs Argonne and Fermilab, and the Marine Biological Laboratory. These affiliations open up vast potential for discovery and innovation in energy, the environment, and security. Additionally, the CIE is an important element in the commercialization strategy for the Joint Center for Energy Storage Research, the US Department of Energy's $120 million energy innovation hub announced in November 2012.

RUSH UNIVERSITY

Rush Research Mentoring Program

The Research Mentoring Program was established July 26, 2006 in order to provide advanced mentoring by funded NIH investigators to an ever-growing population of young faculty. The goal of the program is to prepare junior faculty members at Rush University Medical Center and Cook County Health and Hospital Systems to lead funded programs of translational research. To help junior faculty members become independent researchers, the program relies on two primary mechanisms: good mentoring and resource infrastructure. Mentees are paired with at least one externally funded, experienced, and committed lead mentor who works very closely with the mentee on her/his research project; many mentees also have interdisciplinary mentoring teams. The program's resources include: statistical analysis, data management, professional grant writing and manuscript editing, graphics consultation, communication skills workshops, monthly "in-house study section" meetings, weekly mentee writing groups, monthly workshops and seminars on a variety of research-related and grant-writing topics, a lending library, and an annual symposium. Mentees are nominated to the program by their section heads/chiefs with the commitment of least 20% protected research time. In addition, mentees are expected to dedicate an additional 20% of their personal time for research. The program has two translational research tracks – clinical and laboratory-based. Each track meets monthly where mentees discuss their research in progress. The program has enjoyed university-wide popularity and success. In the past nine years combined, mentees (either as principal investigators or as co-investigators/collaborators) have secured or were

instrumental in securing close to $65 million in awards, 40% of which are from the NIH. Also, over 1100 manuscripts have been published by mentees to date, since their joining the program. The program has more than 80 active mentors.

LOYOLA UNIVERSITY

Researcher Mentoring

Working with the LUCHSD faculty and research offices at the neighboring Hines VA, the Clinical Research Office (CRO) has established a formal mentoring process to support the development of Physician scientists. The program is headed by Thomas Layden MD, the current Director of the CRO. In addition to regular mentoring meetings with the CRO Medical Director and other relevant faculty members, a committee has been assembled to review research grant proposals before submission to the NIH, VA and other sponsored research programs. Additionally, the SSOM Dean has sponsored a Deans Office Clinical Scholars (DOCS) program that supports salary of junior physician scientists for 3 or 4 years (pending progress) as a means to enhance research development. New applicants and progress of current recipients are reviewed annually. To date two of the DOCS scholars have gone on to successfully compete for NIH K23 awards. Research funding is also available as New Investigator awards through the Deans office and these are competitive one year awards (non-salaried). In the last 3 years 6 clinician investigators have successfully competed for these awards.

TRAINING

UNIVERSITY OF CHICAGO

Center for Health and the Social Sciences

CHeSS supports interdisciplinary research in health and the social sciences at the University and is designed to be an attractive home for interdisciplinary projects that span multiple units of the University. Participating researchers come from the BSD, Social Sciences Division, Physical Sciences Division, Business School, School of Public Policy, Law School, Social Services Administration, and National Opinion Research Center. CHESS provides substantive content area and methodological support to investigators performing research that aims to translate knowledge into real-world settings to improve health outcomes. Population translational research draws upon clinical, social science, and quantitative disciplines, and utilizes multiple methodologies. Specific disciplinary and methodological expertise is supplied for health services research, behavioral science, organizational theory, survey research, qualitative techniques, large administrative database research, cost analyses, and related data management and analysis. Additional expertise is quality care processes, neighborhood effects on health and health care, effects of insurance on utilization), cost-effectiveness analysis, health economics and policy. CHeSS provides affiliated researchers with 1) space for interdisciplinary research and training, 2) computing infrastructure, including Unix-based mainframe computing, 3) access to a stable pool of skilled research professionals, including research assistants, statisticians, and specialized programmers (e.g., with experience with Medicare and other health data), 4) focused and efficient grants support, and 5) administrative support to promote collaboration in research and training, including support of training programs.