

## FACILITIES

**Environment:** Loyola University Chicago (LUC), currently enrolls over 17,000 students on its three campuses in the Chicago area: Lake Shore, Water Tower, and the Health Sciences Campus (HSC). In addition, Loyola has a global presence with the John Felice Rome Center (JFRC) in Italy, Beijing Center in China, and the Vietnam Center in Ho Chi Minh City along with more than 100 other study abroad options in 60 countries. The latter offers students the chance to engage with the global community and economy. Loyola's 11 schools and colleges offer more than 80 undergraduate majors and more than 140 graduate, professional, and graduate-level certificate programs. Our Health Sciences Campus, located in suburban Maywood is home to Loyola's Stritch School of Medicine (under which are the Graduate School's biomedical programs), Marcella Niehoff School of Nursing, and the Parkinsons School of Health Sciences & Public Health. Medical students benefit from the University's clinical partnership with the Loyola University Health System and Trinity Health. Loyola is among the eight percent of all American colleges and universities to have a Phi Beta Kappa honor society chapter. Loyola is also among a select group of colleges and universities recognized for community service and engagement by prestigious national organizations like the Carnegie Foundation and the Corporation for National and Community Service. U.S. News & World Report has ranked Loyola University Chicago consistently among the "top national universities" in its annual publications. The total 2022 enrollment is 17,484 students, 1,302 of whom are graduate students. The student body comes from 50 states and 82 foreign countries, with 32 percent represented by students of color.

**Stritch School of Medicine:** The Stritch School of Medicine (SSOM) provides outstanding clinical education to its students with the opportunity to participate in research, global health, and service. SSOM's cutting edge facilities are also used to educate multidisciplinary, collaborative health care teams in quality and safety. Programs offered through SSOM include the MD program (and the MD/PhD program), the Bioethics and Health Policy programs (MA, DBE and Certificate programs), and the Biomedical Science MS and PhD programs (Biochemistry and Molecular Biology, Cell and Molecular Physiology, Integrative Cell Biology, Microbiology and Immunology, Infectious Diseases and Immunology (MS only), Cellular and Molecular Oncology (MS only), Molecular Pharmacology and Therapeutics, and Neuroscience). Stritch students enjoy an opportunity to personalize their own education experience in order to meet their individual professional goals. Students often personalize their education with a focus on research, public or global health and/or bioethics, which collectively prepare our graduates for a well-rounded approach to their professional careers.

**Parkinson School of Health Sciences and Public Health:** The Parkinson School of Health Sciences and Public Health is the newest school within the Health Sciences Campus of Loyola University Chicago. It was launched in 2019 with an eye to creating new opportunities for transdisciplinary collaboration. The Parkinson School of Health Sciences and Public Health offers programs for undergraduate (BS programs in Exercise Science, Healthcare Administration, and Public Health) and graduate students (MS programs in Clinical Research Methods, Dietetics, Exercise Science, Health Informatics, Medical Laboratory Science, and Public Health (MPH)). The Parkinson School also collaborates with other schools to confer dual degrees that include MPH/MD, Masters in Social Work (MSW)/MPH, BS (in Healthcare Administration)/MPH, and a BS in Environmental Sustainability/MPH). These degree programs offer innovation and accessibility to adult learners along with traditional undergraduates, afforded by online instruction and hybrid learning programs residing on Loyola's Health Sciences Campus and Lakeshore campuses.

**Marcella Niehoff School of Nursing:** The Marcella Niehoff School of Nursing (MNSON) provides a transformative education in the Jesuit Catholic tradition, preparing leaders in the health professions to enhance the health of persons, communities, and the larger global environment through the discovery, application, and dissemination of knowledge; and service with others. The SON offers undergraduate (BSN), master's (MSN), and doctoral programs (DNP and PhD) for the education of professional nurses. Over 85 percent of SON's full-time faculty have doctoral degrees. Many are certified in their areas of clinical expertise and serve in leadership positions for regional and national nursing organizations. Graduates of the School of Nursing are highly sought for positions in health-care organizations. On average, graduates who seek positions as professional nurses are hired within two months of graduation.

The work proposed will be carried out in the **Center for Translational Research and Education (CTRE)**, which opened in 2016 on the university's Health Sciences Campus in Maywood. This five-story, 227,000-square-foot, gold LEED (Leadership in Energy and Environmental Design) building is a collaboration among Loyola University Chicago, Loyola University Health System, and Trinity Health. The center accommodates principal investigators, postdoctoral trainees, physicians, nurses, fellows, graduate students, and students from Loyola University Chicago's Stritch School of Medicine, the Marcella Niehoff School of Nursing and the Parkinson School of Health Sciences and Public Health. The CTRE includes laboratory and support space for 72 principal investigators spanning the fields of basic, translational & clinical biomedical research, public health, health services, nursing, bioinformatics, and epidemiology. A 250-seat auditorium provides a link with the local community, serving as a showcase for research and health-related programming.

**Cardinal Bernardin Cancer Center:** The Cardinal Bernardin Cancer Center brings together all aspects of cancer care to one site. Beautifully designed for the comfort and convenience of our patients, the center also promotes optimal collaboration between healthcare providers. Loyola Medicine is nationally recognized for its expert team of specially trained cancer doctors who come from a wide variety of clinical specialties. These multidisciplinary specialists provide the expertise, translational research experience and compassionate care needed to diagnose and treat cancer. They work together, taking a collaborative approach to cancer care. Named in honor of the late Archbishop of Chicago Joseph Cardinal Bernardin, the center contains clinic areas, a day hospital and an Image Renewal Center as well as extensive research laboratories, offices and educational space.

**PI's Laboratory:** *To be entered by PI*

**Computational Resources:** Loyola University Chicago Health Sciences Campus (LUC-HSC) Office of Informatics and Systems Development (OISD) is responsible for the creation and operation of educational and research computing resources for the Stritch School of Medicine (SSOM), Marcella Niehoff School of Nursing (MNSON) and Parkinson School of Health Sciences and Public Health (PARKS).

**Computing Facilities:** The primary physical computing facility is a 2,200 sq. ft. computing center supported by a 500KW uninterruptible power supply (UPS), a 1MW external diesel generator and redundant 100T cold-water chilling units. The facility has 33 42U racks (expandable to 40 racks), each fed by redundant and diverse conditioned electrical subsystems. Currently, the facility operates more than 180 physical and 60 virtual servers that provide more than 2.5 petabytes of on-site storage. The Health Sciences Campus has both wired and wireless networks. Campus connectivity to the Internet is accomplished via a primary gigabyte ethernet circuit and a redundant backup circuit. More than 1,400 end-user devices (e.g., desktop computers) are provided on the LUC-HSC. Principal investigators are provided secured, centralized file server storage to support approved research projects. A backup disaster recovery and business continuity (DR/BC) facility is provided in a second diverse computing center located in the LUC Center for Translational Research and Education (CTRE) building. This facility has 12 42U equipment racks that house backup servers and storage units. This facility is supported by diverse environmental systems including UPS, generator and dedicated chillers.

**Computational Environments:** High-Performance Computing Cluster (HPCC): This Linux-based ROCKS (<http://www.rocksclusters.org>) cluster features 65 Dell server compute nodes with 528 Intel processing cores and 1PB of storage configured with redundant data volumes shared as GPFS clustered file systems. This general-purpose computing cluster provides a wide range of open source software (e.g., Galaxy, BLAST, GROMACS, etc.) utilized in genomics and basic science research.

- High-Performance Molecular Visualization Cluster: This Linux-based ROCKS cluster features nine server compute nodes with 560 AMD Opteron processing cores and 40TBs of file system storage dedicated to molecular structure and movement visualizations.
- Production (CRDB) Hadoop Cluster: A Linux-based Hadoop cluster with 16 data nodes provides 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 cluster with 12 data nodes provides 15TBs of HDFS. The cluster provides Hive, python and java frameworks for “big-data” processing related to advanced clinical analytics.
- **Production (ARIA) Hadoop Cluster:** A Linux-based Hadoop cluster with 16 data nodes provides 800TBs of HDFS. The cluster provides Hive, python and java frameworks for clinical “data laking” and distributed processing related to advanced clinical analytics. Focus of this cluster is to support large-scale natural language processing (NLP) and radiomics. ARIA cluster includes three symmetric multiprocessing (SMP) servers each with 24 processing cores and 512GBs of random-access memory to support analysis that requires large physical memory spaces. These SMP servers have access to the HDFS file systems maintained by the ARIA cluster.
- **General Scientific Hadoop Cluster:** A Linux-based Hadoop cluster with 13 data nodes providing 21TBs of HDFS. 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.
- **REDCap services:** General purpose REDCap (<https://projectredcap.org/>) environment for use by clinical researchers. Environment has been operational for four years and currently has 1,329 user accounts with 390 product projects.
- **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 6.10).

**Bioinformatics 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 consists 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 2,380 users to perform more than 4,000 patient cohort queries. Identified cohorts are utilized to support preparatory-to-research studies and research protocols that can be addressed with limited clinical datasets. The Relationship of Clinical Knowledge to Events Tool (ROCKET) is an innovative “big data” research and education tool that supports longitudinal 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 2.7M patients and 12 years of clinical data is longitudinally analyzed with ROCKET clinical events that currently include 26 chronic diseases, 36 non-chronic diseases and 16 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 LUC-HSD Office of Informatics and Systems Development (OISD) was originally established in 1987 as the Department of Medicine’s Division of Medical Informatics and has developed more than 750 clinical research and medical education applications. The division’s staff include senior-level clinical research analysts, software developers, data architects and system designers. These staff resources support the institution’s clinical and basic science researchers as well as the Offices of Biostatistics, Bioinformatics and the Center for Health Outcomes and Informatics Research (CHOIR). A current division focus is the use of “big data” technologies such as Hadoop, Hive, “R,” python and goLang to accomplish advanced large-scale clinical analytics. Beyond preparatory-to-research activities, OISD annually supports analytics for more than 150 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 grant and the Institute of Translational Medicine (ITM-CTSA) award with the University of Chicago.

**Office:** *To be entered by PI*

**Institute of Translational Medicine (ITM-CTSA):** Loyola University Chicago (Loyola) is also a member of the Institute of Translational Medicine (ITM-CTSA) Program award. The ITM is a partnership between the University of Chicago and Rush University in collaboration with Advocate Health Care, the Illinois Institute of Technology (Illinois Tech), Loyola University Chicago, and NorthShore University Health System.

The ITM receives funding from the Clinical and Translational Science Award (CTSA) initiative of the National Institutes of Health (NIH) and substantial support from the involved institutions. It is a collaborative organization which aims to transform existing clinical and translational research and training efforts into a shared research enterprise. The Vision of the ITM is to accelerate and catalyze the translation of innovative science into improved health and patient care. To achieve this vision, the Mission of the ITM is to:

- Catalyze and enhance scientific discovery, innovation, dissemination and translation across the lifespan
- Educate and sustain a resilient, innovative and diverse translational science workforce
- Promote and ensure an efficient, safe, collaborative and integrated research environment
- Engage stakeholders and communities across the entire translational spectrum

Loyola's contribution to the ITM is founded in its experience and scientific environment in both dissemination and implementation science and the development and translation of health informatics solutions across research networks.

- **Dissemination and Implementation Science.** Loyola houses the ITM's new Implementation Science Cluster as well as the Evaluation Core for the ITM. Loyola researchers have been involved in the dissemination of the Accrual to Clinical Trials (ACT) Network and the I-Corps@NCATS training program across the CTSA Consortium

The ACT Network was established to support the translation of a clinical informatics tool using i2b2 and SHRINE technology that allows CTSA-affiliated clinical investigators to conduct cohort discovery at their desktop using electronic health record data.

Loyola researchers are founding collaborators for the I-Corps@NCATS training program supporting implementation and commercialization of translational innovation, and is currently participating in its national expansion to over 20 CTSA programs. I-Corps@NCATS education is housed within the Parkinson School of Health Sciences and Public Health and its new endowed Center for Health Innovation and Entrepreneurism. The Parkinson School is also the academic home for Loyola's Masters in Implementation Science program.

- **Center for Health Outcomes & Informatics Research (CHOIR):** The Center for Health Outcomes and Informatics Research is a Health Sciences Center-wide center focused on providing research expertise in biomedical informatics to improve health outcomes and reduce health inequities, and on the development of a health informatics-trained workforce. The center provides expertise in machine learning, deep learning, natural language processing and associated computing resources, electronic health record integration, mobile health, and applications to management of chronic conditions, cancer prevention, predictive modeling of cardiac myopathies and events, Parkinson's disease, adverse drug reactions, and drug misuse. CHOIR also hosts 14 faculty members from the Parkinson School of Health Sciences and Public Health, the Stritch School of Medicine, and the Niehoff School of Nursing.
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**CORE FACILITIES:** The LUC Health Science Division makes available to all faculty, the following Core research facilities (for more details for your specific proposal, go to: [http://hsd.luc.edu/research\\_services/facilitiescores/aboutfacilitiescores](http://hsd.luc.edu/research_services/facilitiescores/aboutfacilitiescores)).

### **FLUORESCENCE ACTIVATED CELL SORTER CORE LABORATORY**

The Fluorescence-Activated Cell Sorter (FACS) Core Laboratory (FCL) is a designated core research facility that provides flow cytometric and cell sorting services. The FCL provides cytometric and consultative services to investigators in the basic science departments at Loyola University Stritch School of Medicine of the Health Science Division, clinical departments at Loyola hospital as well as investigators from other institutions in the Chicagoland area. The FACS Core Lab occupies a 1000 square foot laboratory in the Cancer Center. The FCL is equipped with FACS Aria, a FACS LSR Fortessa, a FACS Canto II, and an Amnis ImageStreamX. The FACS Aria is equipped with 5 lasers (488, 633, 405, 561 nm) and near UV and is capable of detecting 15 simultaneous fluorochromes and of high speed sorting and depositing capabilities. LSR Fortessa flow cytometer is equipped with 4 lasers (488, 633, 405 and 561) and is 15 color capable. The FACS Canto II flow cytometer is equipped with 3 lasers (488, 633 and 405) and is 8 color capable. The core also has the Amnis ImageStreamX; this instrument combines the speed, sensitivity, and phenotyping abilities of flow cytometry with the detailed imagery and functional parameters of microscopy. It is equipped with 3 lasers (405, 488 and 633) and is 6 color capable.

### **IMAGING FACILITY**

The Imaging Core Facility provides state-of-the-art imaging equipment and training for students, postdocs, and technicians to support research efforts at Loyola University Chicago. The Imaging Facility includes a Philips CM120 transmission electron microscope equipped with an AMT BioSprint 16 megapixel digital camera with an ActiveVu lens. The facility possesses all the equipment required for specimen preparation, including a Leica EM UC7 ultramicrotome for preparing semi- and ultra-thin sections. The Imaging Facility also houses two confocal microscope systems: (1) A Zeiss LSM 510 inverted confocal microscope equipped with a motorized scanning stage, live cell CO<sub>2</sub> incubation chamber with heated stage, and fluorescent resonance energy transfer (FRET) capabilities; and (2) a Leica SP5 multi-photon microscope equipped with high spatial resolution and resonant fast scanning laser scanning, up to 7 visible lines, a 4-W Coherent IR tunable femto-second infrared laser, and a pulsed 405 ultraviolet laser. The facility includes all ancillary equipment needed to process samples and a workstation equipped with Bitplane Imaris (version 9.5) and EspINA image processing software for semi-automated, high-throughput image (Imaris for fluorescent images, EspINA for stacks of electron micrographs) analysis, 3D rendering, and data analysis.

### **LOYOLA GENOMICS FACILITY (LGF) LABORATORY AND COMPUTATIONAL RESOURCES**

The genomics facility is located within Offices of Research Services, on the first floor of the CTRE. Expertise in the laboratory is focused on a wide range of library prep techniques, genomics project counseling, and collaborations with external genomics cores for sequencing on higher throughput machines. Collaborators offer a range of services from single cell genomics, PacBio, Millipore, regional genomics and transcriptomics. Equipment available at LGF include the Eppendorf EpMotion liquid handling robot, CFX384 qPCR, Agilent Bioanalyzer, and two Illumina MiSeq Sequencers. All equipment is connected via smb and ssh protocols to a central server located at LGF allowing for seamless automation. The LGF has two desks and each is equipped with a 27-inch desktop Macintosh and MacBook Air laptop, with licenses for Microsoft Office and Endnote

### **CENTER FOR HEALTH OUTCOMES & INFORMATICS RESEARCH (CHOIR)**

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### **BIOINFORMATICS CORE**

The Center for Biomedical Informatics (CBMI) collaborates with biomedical scientists to develop computational solutions for their research projects. CBMI members become an integral part of each collaborative project, actively engaging in experimental design, data analysis, publication, and grant proposal writing. With the access to the high-performance computing infrastructure at the Loyola University Chicago Medical School, CBMI is able to perform a wide range of bioinformatics and statistical data analysis tasks in the areas of genomics, metagenomics, transcriptomics, proteomics, epidemiological studies and electronic health record data mining. CBMI also specializes in developing web-based databases to help researchers with data management.

### **HISTOLOGY CORE**

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

### **SMALL ANIMAL SURGERY AND IMAGING FACILITY:**

The Small Animal Surgery and Imaging Facility provides a central resource for creating and studying cardiovascular physiology and pathophysiology in animal models. The Core will customize model development to meet the individual needs of the researcher at a fraction of the cost of an initial equipment investment and maintenance. We assist researchers in writing internal IACUC and IRB protocols. Core staff will instruct graduate students and staff in surgical techniques and echocardiography. Equipment that facilitates these studies includes: Visualsonic Vevo 2100 with 4 probes for performing echocardiography in small animals ranging from mice to rabbits, Zeiss ophthalmic surgical/operative microscope OPMI 6-SDFC, Omano dissecting microscope with light source, Ventilators for both rats and mice, Transonic PV Catheters for rats, mice and rabbits, Stereotaxic apparatuses for brain cannulation/drug delivery, Intubation kits for small animals, Isoflurane anesthesia delivery systems, Drug infusion pumps, STARR Pulse Ox, Accuscan Treadmills, DSI Acquisition System & Implantable probes for Arterial Pressure or ECG monitoring in mice or rats, and an iWorx ECG monitoring system.

### **MACHINE SHOP FACILITY:**

The Machine Shop is staffed by highly skilled technicians experienced in the design, manufacturing and repair of precision instruments. The Machine Shop Core Facility is here to collaborate with faculty, researchers, staff, and students alike to create specialized instruments that will bring about new approaches to their science. Technicians can also work with you to simplify an instrument or make a procedure more manageable. The Shop is fully equipped with 3D design and manufacturing capabilities, allowing you to visually see your project before it is manufactured to ensure that your requirements will be exactly what you have in mind. Services include: CAD Design, 3D Printing, Computer-aided milling, Custom milling/drilling to exact specifications, Instrument and equipment repair.

### **COMPARATIVE MEDICINE FACILITY (CMF) FOR ANIMAL STUDIES**

Loyola University Chicago, Health Sciences Campus, Comparative Medicine Facility has a PHS assurance with OLAW and is a USDA registered research facility. AAALAC International has accredited the animal care program since 1969. All facilities at Loyola University Chicago Health Sciences Campus (LUHSC) are managed by the Section of Comparative Medicine and oversight is the responsibility of the LUHSC Institutional Animal Care and Use Committee (IACUC).

Two full time veterinarians, the Attending Veterinarian and Director of Comparative Medicine and the Clinical Veterinarian support the animal care and use program.

The CMF is approximately 36,000 sq. ft. of animal housing and procedural space in two sites. There are facilities designed to accommodate both large and small animal species. Barrier mice are housed in positively pressurized individually ventilated cage racks and changed in biological safety cabinets. Caging and bedding are autoclaved prior to use and cages are provided with irradiated food. There are specialized areas for research involving imaging, surgery, behavior and biohazardous agents (ABSL 2).

Animal facilities are staffed seven days per week. The Assistant Director and Lead Laboratory Animal Care Technician are on-call for husbandry and the Director and Clinical Veterinarian are on-call for veterinary every weekend and Holiday. Emergency contact information is posted in each facility.

## **HEALTH SCIENCE LIBRARY (HSL)**

The Loyola University of Chicago Health Sciences Library facilitates biomedical discovery by connecting the Health Sciences campus with the best knowledge available. We acquire, organize, and disseminate needed information, provide educational outreach, and design and deliver innovative programming for user-focused support of education, research, and patient care.

**Space:** The library is located on the first floor of the Marcella Neihoff School of Nursing and provides 24/7 access to four group study rooms, the Quiet Study room, Macs, PC's, charging stations, wireless printing, and self-service print, scan and copy. The library is staffed Monday – Thursday from 9:00 AM – 7:00 PM, and Fridays from 9:00 AM – 5:00 PM. After hours building access is available with swipe access at the Stritch School of Medicine.

**Resources:** HSL collections support the teaching/learning, biomedical research and patient care information needs of the health sciences campus. Access to the thousands of electronic journals and hundreds of electronic books, as well as article and index databases, point-of-care clinical-decision support tools, citation management software, protocols and lab methods and scholarly publishing resources requires authentication with UVID/password due to licensing agreements. Connect directly to the library resources from the [HSL web site](#) with your UVID from any device, anywhere. Searching [PubMed@Loyola](#) will link through to the library's licensed content when available. [Discover](#), the library's faculty publications database facilitates collaboration and helps promote health sciences campus scholarly publications to the global scholarly community. The HSL electronics collection contains laptops, Mac notebooks, iPads, Wacom tablet and peripherals, which can be borrowed for up to three hours. A small, print leisure reading collection of notable non-fiction and fiction paperbacks is available in the library. Print titles requested by the biomedical graduate program are permanently available at CTRE on the fourth floor south bookcases in the office area.

**Librarian Support Services:** Librarians provide a wide array of biomedical reference and research support needed for scholarly publishing, course work, lifelong learning, research and patient care. HSL librarians are familiar with copyright law and health sciences library license agreements and can also answer questions about predatory publishing and manuscript submission to the NIH Manuscript Submission System. Liaisons can design and deliver information skills training and orientations for individuals or for your department or course. [Contact us](#) to arrange training for how to identify predatory publishers, effectively and efficiently search a variety of information resources and citation management software and library updates. Individual consultations are also available to assist with complex searching of article and index databases and resources relevant to your topic or research question. Need an article not available from the library? HSL's [interlibrary loan service](#) delivers fast service at no cost to you with a one-time registration. Articles received electronically are delivered to your device within one business day.

**Programs and Events:** Be inspired and join your colleagues at the [Humanities Forum](#) where distinguished speakers explore how the humanities impact and transform health care. Make new connections from across the campus at our monthly [faculty and staff book](#) group. We offer great discussions, hummus and wonderful colleagues. Need a break and a little TLC? Consult with [Miso](#), our dog in residence on Thursdays from noon – 1:00 PM in the library.

**Contact:** [Chat](#) with us during staffed hours. Call us: 708-216-9192. Email us: [hsl@luc.edu](mailto:hsl@luc.edu) Find us on [Facebook](#)

## **CLINICAL RESEARCH OFFICE (CRO)**

The Clinical Research Office is the umbrella organization for a diverse group of services essential to the support and conduct of clinical research.

**Biostatistics:** The Biostatistics Core of the Clinical Research Office (CRO) provides biostatistical consultative

support to investigators pursuing clinical and basic research. Masters and PhD biostatisticians offer services that include study design consultation and grant development, programming and database development, statistical analysis, and manuscript preparation.

**Clinical Research Support Services:** The CRO Clinical Research Support Services provide assistance with the contracting and budgeting phases of clinical trial start-up, completing the IRB submission process, sponsor regulatory approval processes, and providing study coordinator services. Services include pre-site and investigator meetings, study startup activities, consent preparation, assistance with all aspects of study conduct and maintenance of regulatory and study financial documents.

**Biorepository:** The IRB-approved CRO Biorepository provides a well-controlled, fully compliant, centralized location for patient sample collect storage and distribution for research. It serves as a resource for specimen collection as well as banking. The biobank staff interface with the clinical laboratories, clinics, and pathology to collect bio specimens according to established standard operating procedures (SOP). Samples are then processed per SOPs to ensure samples are handled/processed appropriately. Samples are labeled and managed via the sample management software, *Freezerworks*, which tracks specimens via a barcode system that provides a real time electronic inventory of samples and a link to user defined sample information. To assure samples are safe, all the freezers are monitored by two remote notification systems and have CO<sub>2</sub> back up. Additional demographic and phenotypic data are collected as appropriate per protocol and linked to stored samples using the commercial internet-based secure online database Research Electronic Data Capture (REDCap; <http://project-redcap.org/>). All data and specimens are de-identified and coded with a unique 12 digit SmartID based on donor variables making it consistent across studies. Samples and limited de-identified data sets are distributed via specific Usage Agreements. As a full service research core, related services available include assistance with IRB protocol drafting, submission and continuing reviews, protocol specific sample processing, specimen retrieval/distribution, consenting and clinical coordination training for study personnel. Confidentiality is protected under an NIH Certificate of Confidentiality (HG-2013-01, expiration 10/16/2022).

**Regulatory Compliance:** The CRO Regulatory team provides regulatory support and consultation to investigators including preparing and managing IRB submissions throughout the trial and conducting quality assurance activities for studies. Experienced staff maintain ClinicalTrials.gov compliance for applicable trials and manage IND applications, exemptions, and expanded access requests to the FDA.