

The Integrative Biosciences Center (IBio) is a newly renovated, \$93 million, 207,000 square-foot building, located in the New Center area of Detroit, and in close proximity to the WSU main campus, hospitals, services, and core laboratories located in the Detroit Medical Center. This new research facility will encourage interdisciplinary work across a range of scientific areas with the goal of translating new discoveries to improve human health and society. More than 500 researchers, staff and principal investigators representing multiple programs in cardiovascular disease, metabolic disorders such as diabetes, hypertension and obesity, bioinformatics and computational biology and biomedical engineering will work out of the building, which will feature wet and dry laboratories, faculty and common areas, and clinical space.

The first floor will house both the clinical and administrative divisions of the Clinical Research Services Center (CRSC) and the School of Medicine's Pediatric Prevention Research Center (PPRU) as well as an advanced imaging team from the Henry Ford Health System's Bone and Joint Center. The NIH-IEHS P30 Center for Urban Responses to Environmental Stressors (CURES) program is located on the second floor in this building. The CURES program aims to combating health disparities and other specific health issues related to Detroit and the surrounding community with its attention to the interface of genes, environment, ethnicity and health. The third floor continues the open space configuration consisting of wet and dry labs, faculty offices, dedicated semi-private cubicles for research support personnel. WSU has announced a major initiative to recruit an additional 35-50 research faculty with thematic foci in imaging, biomedical engineering, informatics and systems biology, and cell biology and cellular structure.

The IBio facility has the full capability to host conferences, in face-to-face sessions as well as real-time video links, for small group interaction up to 100 participants. The large, multi-purpose conference center and each conference room is equipped to offer two-way video conferencing. All desktop computers can conduct Skype-linked conference connections.

All WSU faculty are provided with office space, office supplies, and access to a copier, printer, and fax machine. They are also provided a personal computer, which is linked to the Internet and WSU servers for daily backup. WSU has developed a reliable networking infrastructure that includes a high performance, fiber-optic cable in underground pathways that provide for electronic communication and high speed data transfer. Wayne State University's Computer & Information Technology (C&IT) division provides academic and administrative computing services including communication tools, hosting services, and hardware and software access. The C&IT is located in a secure facility with a raised floor, redundant power, network connectivity and systems monitoring.

Further, WSU has recently implemented the Researcher's Dashboard via WSU Pipeline (WSU's secure internet portal), which is a tool for researchers and department administrators to access a grant's administrative data and obtain up-to-date accounting summaries.

The Wayne State University (WSU) Clinical Research Services Center (CRSC) is currently housed in the IBio building. CRSC is a state-of-the-art research facility with a total area of 4,900 sq. ft., capable of conducting both pediatric and adult research. The area includes 4 exam rooms, 2 observation rooms, 2 community outreach conference rooms, 1 specimen processing/shipping laboratory, a research pharmacy, 1 metabolic assessment room and a data storage area that meets both FDA and NIH requirements. The exam rooms are equipped with beds, exam tables and infusion chairs. The Metabolic Assessment Room is equipped with the Parvo Medics TrueOne 2400 metabolic measurement system. The TruOne 2400 is an integrated system that has the capability to perform cardiopulmonary stress testing, indirect calorimetry, and measurement of maximal oxygen consumption (VO₂max). The TrueOne system has the capability to interface and control a TrackMaster TMX428 treadmill and Corival Lode cycle ergometer, allowing automated testing of participants with standard or customized exercise protocols. The system is also outfitted with a 12-

lead ECG, and the capacity to assess pulmonary function through measurements of spirometry including maximal voluntary ventilation and residual volume. The space is designed to conduct all facets of clinical research studies, drug studies inclusive of phase 1 pharmacokinetic studies, outpatient follow up visits, community engagement research as well as behavioral studies. It is designed to facilitate physical exams, as well as interviews, a pharmacy storage and dispensing facility, an additional blood draw and specimen processing laboratory. In addition, the CRSC has an operation center that consists of 1,636 sq. ft. This space consists of offices and 24 desk spaces with integrated university support services.

The CRSC is a service based entity designed to facilitate and promote inter disciplinary research. As such it is staffed with physicians, research nurses, study coordinators, regulatory coordinators, a nurse manager, grants management experts, a CRSC/OnCore Director, a Community Outreach Liaison and a Medical/Program Director. The research staff can conduct all aspects of clinical research including clinical assessments (blood pressure, measurements, height, weight, etc.), data collection, assistance with preparation and maintenance of IRB documents, and regulatory and document management.

The CRSC medical director is Phillip D. Levy, MD, MPH, a Tenure Professor of Emergency Medicine at Wayne State University. Dr. Levy has approved use of the clinical space for this project. The CRSC hours of operation are from 8 to 5 pm. Free parking is available in the lot attached to the building for participants coming to the unit for study visits. The CRSC suite includes a reception and entertainment area upon entry. In the event that a study patient develops an acute illness or cardiac arrest during any outpatient study, the unit staff will have the ability to provide advanced cardiac life support (ACLS) resuscitation measures and early critical care. The unit is equipped with a “crash cart” that contains airway and respiratory equipment (pocket masks, bag-valve mask ventilation equipment, laryngoscopes, intubating laryngeal mask airway (ILMA) devices, endotracheal tubes, and end-tidal CO2 monitoring devices), a ventilator, various emergency and rescue medications, and an automatic external defibrillator (AED). Patients who either cannot be stabilized or in whom an unexpected acute illness is beyond the scope of the CRSC will be immediately transferred to the emergency department at Detroit Receiving Hospital utilizing transport services (ambulances) that are able to provide ACLS. Should this occur, a detailed record including patient histories, study protocols, and study medication profiles will accompany the patient to the emergency department.

Forte OnCore Clinical Trial Data Management System - The CRSC uses the FORTE enterprise software to manage all aspects of the clinical research study. It has the ability to manage finance, regulatory and patient data. The OnCore Clinical Trial Data Management System (Forte Research, Madison, WI), has been in use at Wayne State University for cancer-related studies since 2006, and for non-cancer studies since 2010. The OnCore System is utilized by institutions throughout the United States for clinical trial data management, including over one-third of the NCI Comprehensive Cancer Centers. The OnCore System is linked to a Biorepository module for collection, storage, and tracking of samples, and integration with clinical data, including the option for high throughput genomic analysis. The OnCore System is internet accessible and structured for conduct of multi-institutional studies, including regulatory, enrollment, randomization, and study status for individual subjects at each institution, consistent with privacy and HIPAA regulations and guidelines.

The website is password protected and managed through the Wayne State University Informatics Department. In addition to the password restriction for access the data safety is maintained on backup recovery servers that have been validated and tested by Wayne State University Informatics Department. Access to the site is only granted once personnel are trained and have completed competencies. The data management allows site specific access for data entry and viewing based on privileges. The system functionality includes the creation of electronic data capture forms. Data quality can be monitored on the system by setting specific parameters for data capture fields. These can then be reviewed by the study

designated monitor. In addition, source documents can be uploaded and attached to the site specific patient for review and monitoring by the monitor.

Oncore Specimen Repository – The WSU BioBank (WSU BSB) has been established to support clinical and translational research locally, nationally, and internationally by storing sample collections of diverse type from research studies. Samples are shipped or carried to the WSU-BSB from the collection sites for research at WSU, distribution to other collaborating centers or/and for long-term storage.

The repository personnel will receive an email notification that samples will be transported to the WSU-BSB for storage. Samples that are not shipped from outside of WSU, but transported by staff of WSU, DMC and its affiliates to the BSB must be done by appropriately trained staff that have completed their packaging and shipping certification and carried in appropriate packaging. All samples received by the WSU-BSB will be examined, and documentation accompanying the package/samples reviewed. The samples will be placed immediately in a temporary appropriate temperature storage unit while reviewing the shipment inventory in order to allow for temperature stabilization of samples that may be received frozen. The sender of the samples will receive notification that the samples have arrived and will be notified of any problems that may have occurred during transportation. The inventory of the package content will be checked for concordance between the samples received and the list provided. Any discordance will be reported within 24 hours. Each sample will receive a bar code label and the sample will be scanned into the Oncore BioSpecimen Module (BSM). Data specific to each sample will be stored under this bar code designation in Oncore. The Oncore BSM system is set-up to allow the specimens to be cataloged into the appropriate freezer, shelf, box, and cell unit. These samples will be stored for the designated time allotted by the specific protocol in any of the 6 -80 °C freezers.

The PI will determine which study personnel can have access to the samples. If samples are needed, the Oncore BSM system will allow the appropriate personnel to submit a request for certain samples to be removed from the BioBank. When the BSB staff receives the notification of the request, the PI will be notified. The BSB staff will verify that the samples are available for request. The request will include which samples are being requested and the date they are needed. The PI and the BSB staff must both approve the request. When the request has been approved, the samples will be pulled from the storage unit by the BSB staff and placed in temporary storage to be scanned as being removed. The samples will be packaged appropriately by the BSB staff for transportation and an inventory slip will be generated by the Oncore BSB system. A Bill of Lading will be generated as to who received the samples and where the samples are going. Oncore BSB system will automatically open the storage unit spots as being available after the samples are marked as being "shipped". The software can track when assays are complete, as well as house data specific to patients once samples are analyzed.

Laboratory

Research Laboratory: The CRSC research laboratory is housed within the iBio building. This is ideal as the entire building is on dual power supply and a backup generator. The laboratory has the following dedicated equipment: 1 refrigerated centrifuges, 2 refrigerators, 6 -80 °C freezer as well as a specimen repository. The laboratory has the ability to bar code and store samples in the unit's freezers. Specimens can be stored and shipped as required by protocol.

Clinical Laboratory: The DMC/University Laboratories service provides a full range of routine and special diagnostic services 24 hours/day, 7 days/week. The laboratory is fully licensed and provides routine laboratory services required for safety monitoring during clinical trials. The laboratory provides services at discount rates for approved clinical research protocols.

Pharmacy: The Investigational Drug Service (IDS) maintained at the WSU CRSC is staffed by a pharmacist with oversight maintained by Dr. Levy. The WSU CRSC pharmacy is responsible for all

investigational drugs dispensed and administered in the unit. It is responsible for secure storage of all investigational drugs; maintenance of all records, inventory logs, and randomization codes; preparation and dispensing of investigational drugs upon order of the responsible investigator; and quality control of all investigational drugs.

Computers: The WSU CRSC has 8 Windows based PC, 5 printer/scanners/faxes and 1 network printer/photocopy/fax machine. The CRSC owns a variety of software applications for word processing, data management, spread sheet, graphics, pharmacokinetic/pharmacodynamic modeling, statistics and communications. In addition, each investigator has access to the Wayne State University Computing Services facility, which maintains full mainframe capabilities for data management, statistics, and graphics.