Wright Center Boilerplate Language TOC

The Wright CCTR in the VCU Framework

The VCU Wright Center for Clinical and Translational Research was established in 2007 to integrate growing VCU multi-disciplinary medical research, providing resources and services that no other program has the scale or university support to provide. The Wright CCTR has recently been funded by the CTSA from May 2023 - April 2030.

CCTR Physical Space

Wright CCTR

The CCTR occupies a 12,000 square foot building centrally located on the VCU medical campus and provides a visible and easily accessible home for administrative services, the Research Innovator, Enterprise Informatics offices and work space, and conference and classroom space. Here the translational workforce across both campuses can access: informatics; education; clinical research services; community resources and information; consults on research projects; regulatory support; interactions with peers and mentors; and novel training quintessential to career development in multi-disciplinary science.

CRSU

The Clinical Research Services Unit (CRSU) at VCU was established in 1962 as a 10-bed GCRC and has operated continuously since then. The facility was renovated in 1997 with funds provided jointly by NCRR and VCUHS and occupies 10,000 square feet of space in centrally located North Hospital, a Joint Commission approved facility. Current CRSU capability for outpatient care includes 4 exam rooms; rooms for specialized testing; interview spaces; and infusion chairs.

Inpatient care resources include a telemetry capable metabolic chamber, 9 beds, a nurse manager, nurse clinician, RNs, LPNs, a registered dietician/bionutritionist, and administrative support. In addition to providing infrastructure for clinical research, the CRSU has played a crucial role in attracting new faculty at all levels.

Many of the investigators currently using the CRSU accepted positions at VCU only after ascertaining the availability of clinical research space. There are active protocols on the CRSU from investigators and co-investigators from specialties including cancer, dentistry, surgery, pediatrics, radiology, emergency medicine, ob-gyn, psychiatry, pharmacology, biochemistry, genetics, neurology, nursing, rehabilitation

medicine, internal medicine and physical therapy. Multi-center collaborative projects and industry sponsored research studies in healthy normal volunteers or in patient populations are currently underway using the CRSU.

CARI

Dr. Moeller, the PI of the CCTR, and director of the VCU Institute for Drug and Alcohol Studies (IDAS), has brought the IDAS Collaborative Advanced Research on Imaging (CARI) facility under the aegis of the CCTR. The CARI facility has over 6,000 square feet of research-dedicated space. Equipment includes a new research dedicated 3T Philips Ingenia MRI scanner with highly sensitive Philips' DirectDigital processing, purchased by VCU. The scanner was recently upgraded to accelerate fMRI or DTI (DWI) sequences by means of multi-band RF slice excitation and MB SENSE decoding during reconstruction, a feature utilized by the multi-site ABCD project. The CARI facility also has a mock scanner, a urine drug screen collection facility, multiple interview rooms, sound attenuated testing chambers for human behavioral laboratory testing, a physical exam room with ECG, and a dispensary for medication storage and dispensing. The CARI administrative space on the second floor features offices for faculty, workstations for trainees, and a video conference room. The CARI MRI Lab is two floors up from the imaging and research space and includes 3 Dell servers running Linux, 11 Dell workstations running Linux, 4 Dell Workstations running Windows, and 3 Apple Mac computers as well as an automated backup system to ensure data security. Software used in the CARI MRI Lab Includes SPM, FSL, and AFNI. Training and support for investigators in MR imaging who utilize the CARI program are available.

Wright CCTR Clinical Resources

VCU Hospital System (VCUHS)

Virginia Commonwealth University (VCU) Health System is an academic medical center comprised of the VCU Medical Center and Children's Hospital in Richmond, Tappahannock Hospital in Tappahannock, Community Memorial Hospital in South Hill, and over 60 outpatient and acute care locations across the state of Virginia. VCU Health believes in "Inventing better care, day by day by discovery." To aid with meeting this mission, VCU has health sciences schools of Pharmacy, Nursing, Medicine, Dentistry, and a College of Health Professions. Additionally, the health system has a Level 1 trauma center, one of two NCI-designated cancer centers in Virginia, the region's only full-service children's hospital, more than 800 physicians in 200 specialties, and dedicated research teams in every field.

The VCU Medical Center is the largest VCU Health facility. It includes an 837-bed hospital, outpatient clinics, and a 600-physician-faculty group practice. The MCV Campus also contains the Children's Hospital of Richmond at VCU (CHoR) that provides a full range of outpatient services for pediatrics, and the VCU Massey Cancer Center that provides the latest cancer therapies for the oncology population. For the fiscal year 2023, the Medical Center had 40,552 inpatient discharges, 101,604 Emergency Department visits, 1,877,536 outpatient clinic visits, and 29,880 total surgeries performed.

VCU Community Memorial Hospital (VCU-CMH)

Community Memorial Hospital (CMH) is a community-owned nonprofit hospital. It includes a 70-bed hospital and a long-term care facility with an additional 140 beds. For the fiscal year 2023, CMH had 3,228 inpatient discharges, 24,465 Emergency Department visits, 89,804 outpatient clinic visits, and 2,828 total surgeries.. Current research programs taking place at the VCU-CMH include cancer clinical

trials and recruitment for depression studies. VCU-CMH provides access to a more rural patient population than our other partner institutions.

Virginia Ambulatory Care Outcomes Research Network (ACORN)

ACORN is an Agency for Healthcare Research and Quality (AHRQ) established Practice Based Research Network (PBRN). It is a collaborative partnership between primary care practices supported by a multidisciplinary team of researchers from the VCU Department of Family Medicine and Population Health. The practices represent the full spectrum of primary care from single physician private practices to large multispecialty health system owned practices. Research in ACORN has leveraged this strength, successfully disseminating new innovations to become widely adopted across the state. With 181 primary care practices across Virginia, ACORN provides researchers at VCU with a platform for translation to practice and translation to community research.

McGuire Veterans Administration Hospital

The Richmond VAMC, as part of the Central Virginia Veteran Healthcare System, provides diagnostic and therapeutic services in medicine, surgery, neurology, rehabilitation medicine, spinal cord injury, psychiatry, and skilled nursing home care. This 399-bed tertiary care facility also serves as a major referral center for subspecialty treatment including advanced heart failure therapies and complex cardiovascular interventions, open-heart surgery, heart transplant, spinal cord injury, amputation care, vascular disease, oncology, and traumatic brain injury. Its ambulatory care facilities provide a full range of outpatient services. The Richmond VAMC currently follows 37,000 patients, is one of only 5 VA Polytrauma Centers in the US, is one of 23 spinal cord injury centers and is home to the nationwide Long-term Impact of Military-related Brain Injury Consortium (LIMBIC) research program. The VAMC maintains an intensive research program and provides administrative support, internal review and monitoring, and human studies oversight for all clinical trials. The population comprises approximately 68% white Americans, 27% African Americans, and 5% Latino Americans.

Wright CCTR Informatics Resources

EHR Data Mining

The current EHR data mining system consists of an Oracle repository for data storage, IBM DataStage for data movement activities and IBM Cognos for the generation of business intelligence reporting. The system is fed by many disparate data sources, which include registration, appointment scheduling, hospital billing, professional billing and clinical data from the electronic medical records. Data extractions run nightly and load replicated data from our billing system (IDX) and our EHR (Cerner). Special Oracle schemas have been created to support research teams. These schemas allow each of these teams to access the data required for research as well as extending the capability to build customized subject matter areas or data marts. Our Cognos implementation includes a semantic layer over the dataset as well as the Cerner Standby database. This tool can provide a real time EHR data feed as well as capability to pair EHR data with billing and registration data. **The data includes: 1.29 Million Distinct Patients; 17.6 Million Total Encounters; Encounter Records from: 1995; Clinical Data from: 2004; 7 Tb Total Database Storage.** This system will be the backbone of the operations enterprise data warehouse (EDW) (See Informatics Core).

Hospital Information Technology

Virginia Commonwealth University Health System (VCUHS) has been a leader in health IT enabled care for over 40 years. VCUHS currently has full EHR capability in both inpatient and outpatient settings as well as providing EHR access to community (non-VCUHS) providers. VCUHS Analytics has 20 technical and business staff using the analytical data warehouse to improve outcomes. VCUHS is a Cerner Development Partner and frequently develops and refines new innovative clinical technologies with industry, particularly in the area of integration. Two recent examples include developing an integration between the Helix genotype database and the EHR and the CernerHealth PHR and the EHR. VCUHS Information Services and the Office of Clinical Transformation together have almost 200 technical personal, support staff, nurse informaticists, and physician informaticists on staff. VCUHS has joined the regional and state health information exchange and is committed to sharing IT resources with community providers. VCUHS laboratories use next-generation sequencing and pipeline technology. Real Time Location Tracking Systems (tagging patients, staff and equipment) have been piloted in the observation unit and are live in two care settings. VCUHS has two local data centers and one remote data center hosting a total of 165 physical servers with about 2,200 CPU cores and 2PB storage (SAN), with 6PB of backed up data. Access to the data centers is ensured through a secure redundant, fiber telecommunications services.

Academic Information Technology

Virginia Commonwealth University Computer Facilities and Information Technology Support maintain a robust and highly flexible computing environment, drawing on local and remote resources. VCU Technology Services provide high quality IT products, services, and support for research and instructional activities. These resources and services include assistance in the use of University computer resources such as user accounts, E-mail, software downloads, security, Blackboard, web publishing, distance education, video conferencing, research computing (high performance computing, bioinformatics, statistical computing, database support), classroom support and IT consultation, formal courses in micro- and mainframe programming, advice on the acquisition and installation of computer equipment, data storage, data archiving, and data backup and recovery services. VCU also has a satellite hotsite facility to protect data and keep mission-critical systems functioning during unplanned power outages. Database services include installation of database software and patches, backup and recovery, security, and performance tuning. Two-factor authentication is required to access resources from off campus. The VCU University Computing Center has 550 physical servers, 1.7 PB storage, and over 2 PB of backed up data (backups performed nightly). Available software includes: DB2, SAS 9.3, SPSS , ESRI, S-PLUS, Sudaan, C, C++, IMSL, LISREL, PRELIS, Multilev, Perl, VI and Pico.

Research Information Technology

VCU Enterprise Informatics provides clinical data provisioning (including Honest Broker services), electronic data capture, survey and registry services, cohort discovery, and training; most at no cost to the investigator. Cerner Healthfacts EHR data (>100,000,000 patients over 15-year timeframe) is maintained and provided across the university for research and classroom use. Amazon cloud infrastructure (EC2) is used to quickly and efficiently share HIPAA compliant data along with statistical servers (SAS and R). VCU maintains the Digital Commons publication platform to share data, presentations, and publications. VCU research administration is completely electronic and recently overhauled for efficiency. IRB submission and maintenance, Grants and Contracts, and Clinical Trials Management are paperless.

VCU Center for High Performance Computing (CHiPC)

CHiPC, a component of the Center for the Study of Biological Complexity, has approximately 2000 sq. ft. of space devoted to high performance computing services for the VCU research community. The CHiPC maintains three major supercomputing clusters, each specialized for different computing environments: 1) teal.vcu.edu is the primary cluster for large scale parallel computing, and is especially well suited for applications such as molecular dynamics simulations, quantum chemistry and other physical science applications. Teal consists of ~3000 64 bit AMD compute cores, each with 2-4 GB RAM/core, 5 TB of total RAM, 36 TB of /home space, and tmp space of between 360 and 787 GB per node. High speed network infrastructure is provided by a 20 Gb/second infiniband architecture; 2) bach.vcu.edu is the cluster designated for serial and small parallel applications. Bach consists of a total of 1048 AMD 64 bit cores, each with a minimum of 2 GB/core RAM, 2 TB total RAM, 12 TB of /home space, and /tmp space of 360 GB per node. Networking infrastructure is gigabit Ethernet; 3) godel.vcu.edu is a cluster optimized for bioinformatics applications, with ~1200 Opteron 64 bit and Intel 64 bit cores, each with at least 3 GB RAM/core, 4.2TB of total RAM, 17 TB of /home space, tmp space of at least 180 GB/node, and 40 Gb/second infiniband networking; The three clusters are collectively served by nearly 1PB of networked nfs and GPFS high speed storage. To support this infrastructure, the CHiPC employs 6 FTE positions. In addition to maintaining the hardware, the CHiPC works collaboratively with the user base to maintain and optimize a large number of applications and development tools (BLAST, NAMD, Gaussian, Gromacs, Charm, C/C++, Fortran compilers, etc.)

Wright CCTR Informatics Core

In addition, VCU is investing in the infrastructure of the Informatics Core of the CCTR. By mid-summer the CCTR will have 800 TB of storage and a small Hadoop cluster dedicated to its use, with funds committed for expanding both later in the year; these will primarily be used for storing and analyzing genomic and other large ‘omic data sets.

Informatics Computing Resources

Informatics/Computing Resources at VCU

- **Commonwealth Center for Advanced Computing (CCAC) Virginia** recently authorized ~$7M funding for the VCU-led CCAC statewide initiative (previously C4) for acquiring high-performance computing tools such as advanced cloud computing. As part of the state funding, the CCAC has recently acquired as its centerpiece, an ~$3M IBM z16 system. The IBM z16™ is the latest iteration of IBM Z® mainframes with on-chip AI inferencing and industry-first quantum-safe technologies and is known for its AI accelerator, quantum-safe technology, and cyber resiliency. This system will be housed in the QTS Richmond facility. From what I understand, the market cost of the IBM Z16 is ~$20M but was specially discounted by IBM to VCU (academic rate) and we are perhaps the only or one of few universities in the country that may have this high-performance capability.
- The **VCU School of Medicine overseen Horizon system**: “virtual desktop infrastructure” (VDI) environment (nicknamed “Horizon”) specifically centered on secured research computing for VCU. The VDI infrastructure will provide an environment to support all health and science specialties such as (but not limited to): genomic analyses, drug discovery, pathology, radiology,

data visualization, informatics, data science, population health, public health, cancer research, knowledge workers, research labs, and data storage backups for instrument workstations.

- **VCU/VCUHealth Enterprise Data Warehouse in SnowFlake (Microsoft Azure)**: This data warehouse includes data from Epic (current VCUHS electronic health records system) and Cerner (historic VCUHS electronic health records system), spanning over 20 years. Currently supported research data models are i2b2 and OMOP. We are exploring the potentials of using native SnowFlake features for data science. The Wright Center informatics team is using this platform for their data warehousing needs.
- Seven professional staff from the Wright Center for Clinical and Translational Science and Massey Comprehensive Cancer Center are serving as **honest brokers** for VCUHealth system protected health information.
- The **Biostatistics, Epidemiology and Research Design (BERD)** core consists of member experts from VCU's Biostatistical Consulting Laboratory. The BERD core of the Wright Center (i) promotes health science research that is high quality, reproducible, transparent and translatable, (ii) establishes more and longer-lasting grant-supported research programs and (iii) generates peer-reviewed publications in top journals.
- **Biostatistics Shared Resource (BSSR)** provides biostatistical support beginning in the initial experimental design stage to the presentation of research findings and, ultimately, in the submission of scientific publications for peer review. Biostatisticians also participate in the oversight of cancer center protocols in the Protocol Review and Monitoring System (PRMS) and monitoring committees. The collaborative nature of this work optimizes the shared resources' effectiveness, resulting in support from peer-reviewed grants.
- The **Bioinformatics Core at VCU Massey Comprehensive Cancer Center** provides comprehensive, high-quality and cost-efficient bioinformatics service infrastructure to support Massey researchers in basic science, translational research and cancer control.
- The Wright Center has access to the **Virginia All-Payer Claims Database**, a program under authority of the Virginia Department of Health (VDH) that collects paid medical and pharmacy claims for roughly 5 million Virginia residents with commercial, Medicaid and Medicare coverage across all types of healthcare services.
- VCU participates in **TriNetX**, which combines real time access to longitudinal clinical data with state-of-the-art analytics to optimize protocol design and feasibility, site selection, patient recruitment, and enable discoveries through the generation of real-world evidence.
- The **VCU Collaborative Advanced Research Imaging (CARI) Center** houses 6,000 square feet of research space including our research-dedicated Philips Ingenia 3.0 Tesla MRI Scanner, a mock scanner, interview rooms, drug screening rooms, a dispensary and more. Additionally to fMRI use for research purposes, CARI faculty also provide image processing support.

BERD

Resources

The goals of the BERD are to (i) promote health science research that is high quality, reproducible, transparent and translatable, (ii) establish more and longer-lasting grant-supported research programs, and (iii) generate peer-reviewed publications in top journals. To achieve those aims, the BERD team provides numerous services to support quantitative health sciences research at VCU, including (i) study

and trial planning in grant proposal development, (ii) on-study database management, analysis and dissemination, and (iii) educational and training opportunities. Focusing on building long-term relationships, BERD members encourage “full-term” support, from refining research aims, crafting modern and advanced study designs, drafting grant proposals, ensuring that data capture, management and analysis protocols are aligned with current best practice, conducting reproducible and replicable biostatistical analyses, and drafting manuscripts for peer review. We especially encourage trainees and early-stage investigators to participate in the research process by providing general educational activities as well as one-on-one consultations to discuss biostatistical concepts and methods.

Study and Trial Planning

BERD members are excited to help you design your research study or trial and develop a grant proposal. In particular, members will work closely with researchers to:

- Refine research aims and ensure that hypotheses are testable
- Develop an appropriate and feasible study design in support of your research aims
- In particular, BERD members are experts in the design of adaptive trial and study designs, which are methods (such as response-adaptive randomization, early termination, sample size re-estimation) used to enable projects to end more quickly, more ethically and with more reproducibility than traditional designs.
- Define and phenotype measurements and observation schedules
- Draft the statistical analysis plan (SAP)
- Estimate and justify sample size
- Conduct light pilot analyses of preliminary data
- Plan budget and draft budget justification
- Help draft the proposal, particularly with respect to sections on study design, measurements, statistical analysis and sample size

These services will be provided by BERD members free of charge provided that BERD member efforts are sufficiently included in the project budget. If projects exceed the scope of Wright Center BERD members, they may be referred to the Biostatistical Consulting Laboratory or be subject to a fee schedule. BERD members reserve the right to deny assistance for projects that are ill conceived or do not allow sufficient time for completion.

On-Study Services

Consultations: BERD members provide consultations intended as one-time meetings to clarify and discuss statistical and study design concepts, tips for improving data management and analysis, guidance in interpreting statistical results and suggestions for improving manuscripts.

Collaborations: BERD members provide numerous collaborative services to help assure that research studies and trials are conducted in the most high-quality, reproducible, and translatable manners possible. In particular, we provide the following services for long-term collaborations.

Data Management

- Define and identify cohorts
- Plan and create a data management plan
- Provide data validation (range checks, missing data assessments, etc.)

- Collaborate and coordinate activities with Bioinformatics Core (BIC)
- Tools: SQL, MS SQL Server, Excel, REDCap
- Plan and create analysis set

Interim or Final Statistical Analysis

- Conduct participant allocation/randomization or generate a blinded randomization schedule
- Perform analyses for planned continual reassessments and design adaptations, such as response-adaptive allocation, early termination, dose/arm expansion and sample size re-estimation
- Statistical expertise: estimation and hypothesis testing, longitudinal data analysis, survival analysis, mixed effects modeling, generalized additive modeling, machine learning/artificial intelligence and Bayesian modelling

Dissemination

- Draft and review relevant sections for peer-reviewed manuscripts
- Support abstract, poster and oral presentation support

These services will be provided by BERD members free of charge provided that BERD member efforts are sufficiently included in the project budget. If projects exceed the scope of Wright Center BERD members, they may be referred to the Biostatistical Consulting Laboratory or be subject to a fee schedule. BERD members reserve the right to deny assistance for projects that are ill conceived or do not allow sufficient time for completion.

All projects supported by extramural funding must provide funding to cover the efforts of BERD members. If such support is made, BERD members will provide all on-study research activities described in the Statement of Work at no additional charge. Requests for projects that have been partially completed will be deprioritized, and BERD members reserve the right to deny assistance for projects that are ill conceived or do not allow sufficient time for completion.

Education and Training

Consultations: BERD members provide a free hour of one-on-one consultations. While these meetings are often to discuss particular aspects of papers or proposals, they can also be used to discuss statistical and study design concepts. Please provide in advance a specific list of topics and the reasons for the discussion, so that BERD members can make the best and most efficient use of that time. Fees will apply to repeated requests from particular researchers.

Workshops: BERD members provide several workshops on common and important statistical and study design topics throughout the year, which are free to the VCU research community. BERD members are also willing to discuss the potential for workshops on specific or uniquely tailored topics, or to smaller groups, though fees may apply. Rather than dull or dry lectures, our workshops are provided in lay, understandable language and will involve active participation from attendees.

Facilities

Laboratory:

N/A

Clinical:

N/A

Animal:

N/A

Computer:

Virginia Commonwealth University Computer Facilities and Information Technology Support.

VCU Technology Services provides high quality IT products services, and support for the research and instructional activities of VCU students, faculty and staff. These resources and services include assistance in the use of University computer resources such as user accounts, E-mail, software downloads, security, Blackboard, web publishing, distance education, video conferencing, research computing (high performance computing, bioinformatics, statistical computing, database support), classroom support and IT consultation,

formal courses in micro- and mainframe programming, advice on the acquisition and installation of computer equipment, data storage, data archiving, and data backup and recovery services. VCU also has a satellite hot-site facility to protect data and keep mission-critical systems functioning during unplanned power outages. Database services include installation of database software and patches, backup and recovery, security, and performance tuning.

Hardware and Networks:

All BERD faculty, research assistants and staff have access to laptops and desktop PCs for word processing and analysis of small to medium sized data sets. Each team member has access to physically secure servers, which follow appropriate multilevel access control protocols, and maintain long term data security via daily and monthly backup/restore procedures. All users are connected to a TCP/IP local area network within VCU web-VPN network or customized IP registered by specific user. Desktop resources, network storage, and email systems are protected from virus attacks via antivirus software that is automatically updated weekly. Desktop PCs and campus networks are behind appropriate firewalls. Desktops and their corresponding network resources follow appropriate multilevel access protocols; network data storage availability is assured via nightly and monthly archival procedures.

For more memory and computationally intensive tasks, there are many options. In particular, the VCU Department of Biostatistics houses a newly expanded Beowulf-style clusters, including:

- 54 Dell PE R620/R630 servers with CentOS 7.X 64 bits system
- 1336 cores/2672 threads using Intel Xeon 56XX processors (2.67GHz to 3.4GHz)
- 9TB RAM (80GB-200GB per node)
- 720TB parallel file system network storage running lustre on InfiniBand connection.
- Onsite daily backup for critical data
- 30TB internal disk storage (120GB-900GB per node)
- 40GB InfiniBand network connections to all nodes and storage
- Fail-over redundant master servers

Leveraging over 1000+ cores, the Linux Beowulf cluster system is configured to ensure multiple job types run efficiently. The cluster supports department faculty, research staff, and students working on intensive computation in both serial and parallel processing. All users are able to access cluster through VCU VPN for a secured connection. We expanded the network storage to double the size in 2018.

Software:

Software available on cluster includes:

- R 4.1.2 with CRAN packages and BIOCONDUCTOR packages
- R-Studio server
- C+/G+ and Fortran compilers
- JAVA compiler
- Perl compiler
- Python and Biopython compiler
- SAS-9.4 for Linux 64bit
- Mathematica
- Additional open source software upon user request

Additional computing resources: The servers at VCU Center for the Study of Biological Complexity Servers are important additional resources for intensive computing needs. Fields of specialization that reflect the interests of the faculty include design and analysis of algorithms, software development techniques, compilers, distributed computing, programming languages, database systems, artificial intelligence, computer graphics and vision, neural networks, large-scale simulation, biomedical computing applications, and bioinformatics.

These resources are available to current BERD faculty and staff.

1. bach.vcu.edu - Linux Beowulf cluster for computationally intensive applications, configured with 500 processors, 2.6 GHz Opteron, 4GB-32GB per node, 2TB direct attached Fiber Storage and 16.8 TB internal disk storage.
2. linn.vcu.edu -Linux Beowulf cluster for computationally intensive applications, configured with 54 processors, 3.06 GHz PIV, 64 GB RAM, 2.2TB internal disk storage and 17TB Network attached storage
3. watson.vcu.edu - Sun v880 for bioinformatics and statistical applications. Configured with 8 UltraSparcIII 750 MHz processors, 32 GB RAM , 360 GB internal disk storage and 2TB NAS
4. fenn.vcu.edu is a Linux bioinformatics cluster, configured with 70 processors 2 GHz G5, 140 GB RAM, 80GB disk storage per node
5. viz.vcu.edu - Sun v880 for visualization. Configured with 6 UltraSparcIV 1.2 HHz processors, 2 Graphics Pipes, 24 GB RAM, 180 GB internal disk storage and 1TB NAS

Office:

Department of Biostatistics. BERD members are currently located on the fifth and seventh floors of One Capitol Square at 830 East Main Street on the medical campus of VCU in Richmond, VA. The Department, which resides in the VCU School of Population Health, has 11,329 sq ft of space with 34 faculty and staff offices, 2 classrooms, 5 conference rooms, 5 storage rooms, and 2 large filing rooms.

Other Resources:

Virginia Commonwealth University Libraries. University Library Services (ULS) support and enrich the curriculum and research activities of VCU. ULS staff provides educational, informational, and reference assistance including bibliographic and other software instruction. ULS provides resources such as on-line bibliographic search services; interlibrary loans; and photocopying facilities. The Tompkins McCaw Library, located on the medical campus, contains a major health sciences collection of more than 200,000 volumes and 3,600 periodical titles. The collections of the Tompkins-McCaw Library include resources that support virtually every discipline of medical science. It is the largest health sciences collection in Virginia and ranks in the top 20 percent among U.S. medical libraries in print book titles and print serials. In addition to its own collections, ULS interlibrary loan departments obtain materials from other colleges and universities in Virginia, from institutions in other states, or from the National Library of Medicine.

VCU Research Registries

Mid Atlantic Twin Registry (MATR)

The Mid-Atlantic Twin Registry is a population-based registry comprised of over 50,000 twins of all ages and backgrounds. The MATR, which was established when the Virginia and North Carolina Twin Registries merged over a decade ago, is part of VCU's Office of Research & Innovation. For over thirty years, initially through the MCV Twin Studies and then as the VA & NC Twin Registries and now as the MATR, our twins have contributed to research endeavors in and outside the VCU community. The MATR now stands as a unique component of the VCU system and is a resource unmatched by any other college or university in the entire United States.

MATR welcomes research efforts from multiple areas of study and organizations (VCU and non-VCU). One of the main functions of the MATR is to act as a liaison between researchers and twins and their family members that are willing to consider participating in research. In addition to completing subject ascertainment, the MATR supports research goals in a variety of ways, including coordinating the logistics of data and/or sample collection. Studies involving twins are exceptional ways to learn about the genetic and environmental factors impacting our health. With a desire to maximize the capacity to learn from twins, Dr. Francis Macrina, VCU's former Vice President for Research, had a vision of a DNA repository in which MATR twins could participate. Through collaborations here at VCU, the vision of such a resource is now a reality. The MATR DNA repository is a tremendous scientific resource which will allow researchers to take twin studies to a new level of scientific knowledge. Not only will researchers be able to collect useful information from twins, they can now utilize the twins' DNA to truly realize the potential of studying genetic and environmental factors impacting our physical and mental health.

Research Alliance for Microbiome Science (RAMS) Registry

In 2013, the RAMS Registry was established coinciding with the beginning of the MOMS-PI project to permit banking of samples for future studies, re-contact of participants and linking of data between related multi-omic projects. The RAMS Registry is now recognized as an important university resource. The registry also has a relationship with a partner registry, the Global Alliance to Prevent Prematurity and Stillbirth (GAPPS) based at Seattle Children's that is coordinating enrollment for ~⅓ of the up to 2,000 participants for the MOMS-PI project. RAMS Registry Data Repository and Management System provides a sophisticated web-based data portal that hosts and integrates clinical metadata, sample

tracking and data generation progress, raw data (i.e.,16S rDNA metagenomic data, whole genome metagenomic sequence, and bacterial genome sequences) and the results from data analyses (e.g., microbiome profiles, clinical data, medical record abstractions, metadata, etc.). The clinical databases centralize data from a variety of sources (e.g., self-reported health surveys, diagnoses and vitals recorded by the clinical coordinators, abstraction of fields from medical record).

The RAMS Registry provides approved users with access to de-identified metadata to promote community-wide use of these data. Participants are consented in a manner to reflect these data access policies. ***The RAMS Registry Biorepository currently holds >120,000 samples collected from more than 7,000 women and 1,000 neonates***. Although most samples were collected at VCU, the repository holds samples from participants enrolled from at least 6 institutions includes GAPPS sites in Washington State, the Medical College of South Carolina, and the Virginia Department of Health, which has a high Hispanic population.

Spit for Science Registry

"Spit for Science" is a university-wide research opportunity for incoming VCU freshman, focused on understanding substance use and related mental health outcomes across the college years. All freshmen age 18 or older are invited to participate in an on-line survey at the beginning of fall semester of their first year. Upon completion of the survey, students go to a central site at the university to collect payment ($10 and a free "Spit for Science" t-shirt) and provide a saliva DNA sample (hence the "spit" in Spit for Science) for which they receive another $10. Students have the option of participating in the survey portion of the project and not the DNA component (though very few opt out of the DNA component, as detailed below). Students are informed that the study is longitudinal, and that they will be invited to participate in follow-up surveys each spring semester.

Follow-up surveys are sent by e-mail invitation with a link to the on-line survey, parallel to the fall data collection. Four consecutive cohorts of incoming freshman have been enrolled through this pipeline (N=9890), with both NIH and university funding. Participation has been remarkably high for college student surveys and consistent across the cohorts, with 67% participation rate across all freshman classes that have enrolled in the project, and 97% also participating in the DNA component. VCU is a diverse, urban university, and the sample of participants closely maps onto overall university demographics: 40% male in Spit for Science compared to 43% overall VCU; racial/ethnic distribution of the Spit for Science sample with the breakdown for the university shown in parentheses: 15% (14%) Asian, 20% (19%) African American, 7% (8%) Hispanic, 6% (5%) more than 1 race, and 50% (48%) White. Participation in the spring semester follow-up of the freshman year (~6mo follow-up) was 79% and 59% participation at the ~18 mo. follow-up (spring sophomore year).

VCU Centers and Institutes

The CCTR is an integral member of the Research Center and Institutes at VCU.

VCU's Board of Visitors determined the center framework (interdisciplinary, comprehensive, significantly externally funded with broad-based faculty collaboration) best suited to meet CTSA goals within our University's organizational structure. The CCTR was approved by the President and Vice Presidents, the University Council Academic Affairs Committee and full Council, and the VCU Board of Visitors in 2007.

VCU's Centers and Institutes (CIs) conduct cutting edge investigations in unique collaborations to add value to the university intellectual power, resources, extramural funding and resource development. CCTR interaction and integration with existing CIs serves the CCTR mission and benefits both the CIs and the university. Below VCU's CIs are listed and briefly described.

Massey Comprehensive Cancer Center

Massey's mission is to reduce the state cancer burden for all Virginians by addressing the confluence between biological, social and policy drivers through high-impact, cutting-edge research; person-centered care across the continuum, from prevention through survivorship; community integration; and training the next generation of community-centric researchers and health care professionals. As one of two NCI-designated Comprehensive Cancer Centers in Virginia, Massey is leading and shaping America's cancer research efforts. Nearly 150 research members span more than 38 academic departments and collaborate across three scientific research programs: Cancer Biology, Developmental Therapeutics and Cancer Prevention and Control.

Massey conducts cancer research at every level, including basic science (laboratory), translational, clinical and population sciences research. A major strength for Massey is in facilitating the translation and real-world application of research discoveries into improved treatments and patient care and advances in cancer prevention and control. A key part of the research cycle is developing and conducting clinical trials that test promising scientific breakthroughs, and Massey leads Virginia in offering one of the largest cancer clinical trials menus as well as a statewide clinical trials network that bring Massey's cutting-edge trials to patients throughout the Commonwealth. Massey is nationally recognized for its work in cancer disparities, studying the socioeconomic and cultural forces causing or contributing to disparities in cancer outcomes with a focus on minorities and the medically indigent. Massey also serves as a vital resource for education, offering academic programs and training for students, cancer researchers and oncology health care professionals as well as health outreach programs for cancer patients, caregivers and the community. ***Massey collaborates with the CCTR in process improvement, teaching, and participant recruitment into clinical trials using the CTED program developed by Massey. The CCTR Clinical Research Services Unit is one of the primary research sites for Massey outpatient studies.***

VCU Center on Health Disparities (CoHD)

The Virginia Commonwealth University Center on Health Disparities (VCU CoHD) was established in 2005 by the VCU Board of Visitors in response to emerging evidence of barriers to equitable health care at the local, state and national levels. The VCU CoHD supports multi-disciplinary, multi-level, integrated research projects to advance the understanding of the development and progression of diseases and disabilities that contribute to health disparities in racial and ethnic minority populations and other health disparity populations, including the medically underserved, by increasing and diversifying biomedical, behavioral, social science, and health services research, as well as cultural, linguistic and social epidemiology research conducted and supported by the National Institutes of Health.

Center for Rehabilitation Sciences and Engineering (CERSE)

The VCU Center for Rehabilitation Science and Engineering (VCU-CERSE) brings together researchers, clinicians, rehabilitation specialists, and academicians from the VCU Schools of Medicine, Allied Health, Education and Engineering, as well as the Hunter Holmes Veterans Administration Medical Center and the Virginia Department of Rehabilitative Services to promote research, education, physical medicine

and rehabilitation services, and clinical care for America's veterans, children and adults with disabilities. This site offers resources and initiatives aimed at improving the health, functional ability and quality of life of persons who experience a disability.

Center on Society and Health

The VCU Center on Society and Health is an academic research center that studies the health implications of social factors—such as education, income, neighborhood and community environmental conditions, and public policies. Its mission is to answer relevant questions that can "move the needle" to improve the health of Americans and present its work in formats and venues that are useful to decision-makers and change agents. It pursues these goals through collaboration with scholars in different disciplines at VCU and other institutions, and by nurturing partnerships with community, government, and private-sector stakeholders.

Institute for Drug and Alcohol Studies (IDAS)

The VCU Institute for Drug and Alcohol Studies seeks to explore the complex problems of drugs through multidisciplinary research and training, with a focus on the neuroscience of addictions and related neurobehavioral disorders. The institute is led by F. Gerard Moeller, M.D., a preeminent researcher with a focus on brain imaging in addiction medicine. Moeller's addiction research has been funded since 1996 by the National Institute on Drug Abuse. Moeller is also director of the Wright Center for Clinical and Translational Research and the university's associate vice president for clinical research.

Research Cores

VCU maintains a significant roster of centrally managed shared resource core laboratories to support and facilitate diverse research in the physical and biomedical sciences. Office of the Vice President for Research and Innovation (OVPRI) oversight ensures that core facilities are functional and provide state of the art technology. In most cases these resources provide services or access to instrumentation to VCU researchers on a subsidized fee-for-service basis, with rates set so as to be aggressively competitive with commercial alternatives. The CCTR falls under the OVPRI, contributing to shared resource support and management and providing a portal to access. We have solidified engagement with cores by hiring a Director of Research Infrastructure, Dr. Paul Fawcett, and two clerical staff members to oversee VCU's shared resource operations. Dr. Fawcett has rolled out the CORES software platform which now supports a growing number of shared resources in their operations, billing, and accountability reporting. The following is a summary of some the most significant shared resources and the services/instrumentation they provide:

- **The Center for Molecular Imaging** offers advanced imaging technologies to support molecular imaging and nanotechnology research. Preclinical imaging infrastructure includes: 1) PET/CT/SPECT; 2) Small animal MRI/MRS (7 Tesla magnet); 3) A Multispectral Optoacoustic Tomography (MSOT) photoaccostic system; 4) Multispectral Fluorescence; 5) Radiochemistry laboratory and cyclotron (operated by IBA Molecular in partnership with VCU); and 6) Clinical MRI/MRS (3 Tesla magnet) for human subjects. The high resolution (<1mm) PET/CT for rodents and primate animal imaging research has awake imaging capability and is the first such installation in the US.
- **The Flow Cytometry Core** provides a comprehensive instrumentation suite and technical services in support of cell sorting and analysis. Cell sorting capability includes two multi-laser BD

Aria II sorters, one enclosed in a Baker BioProtect Hood, for human and biohazardous tissues. Both have UV and violet laser capability. The core has a 4 laser Amnis MkII ImageStream analyzer which acquires images of cell populations. Flow analyzers include a two laser Beckman Canto II and a 5 laser BD Fortessa. The core maintains a Biacore T200 surface plasmon resonance instrument for determination of protein interaction constants.

- **The Chemical and Proteomic Mass Spectrometry Core** offers diverse mass spectrometry services, with specialization in proteomics. Routine proteomics is carried out on an AB SCIEX 5800 MALDI TOF-TOF, with off-line separations performed on an Easy nLC HPLC and a Leap Technologies spotter robot. More complex proteomics experiments are handled by a ThermoElectron Orbitrap Velos, interfaced to a Waters nanoAcuity UPLC. A state-of-the-art Waters Synapt G2si with electron mobility and ETD capability and NanoAcquity UPLC front end is ideal for the analysis of unlabeled clinical samples. The core provides data analysis including peptide identification and mapping.
- **The Transgenic Mouse Core** offers all stages of transgenic mouse production, including consulting, creation of targeting vectors, ES cell electroporation, screening of ES cell clones, blastocyst injection, and breeding of chimeras. The lab has extensive expertise in the mouse line re-derivation by embryo transfer, embryo and sperm cryopreservation, tail DNA preparation and genotyping. The core maintains an IVIS spectrum imager for live animal imaging. The Core can produce mice using revolutionary CRISPR/Cas9 technologies.
- **The Structural Biology Core** instrumentation and computational resources support macromolecular structure determination. 1) X-ray resources include a Rigaku Raxis-IV++ imaging plate system, MicroMax-007 rotating anode, and a crystallization robotics suite consisting of a Gryphon drop setter, a Minstrel/Gallery incubation system for crystallization trials and Alchemist liquid handling system; 2) NMR is supported by an Avance III 700 MHz instrument suitable for 1D, 2D, 3D or 4D homo- or hetero-nuclear experiments; 3) Molecular Modeling is supported by a suite of ApplePro and Linux graphics workstations, supplemented by the VCU Center for High Performance Computing.
- **The Macromolecule Core** produces biological macromolecules. Routine DNA preparations, insert purification, and DNA transformation, are augmented by the production of research grade vector virus particles (adenovirus, adeno-associated virus, retrovirus, and lentivirus), targeting vectors for knock-in/knock-out mice (in conjunction with the transgenic mouse core) and somatic cell lines, and other specialized or challenging custom DNA projects. The core offers: 1) a range of protein expression and purification services; 2) recombinant proteins from bacterial, yeast, insect, and mammalian origin; and 3) a paraffin embedding and sectioning service.
- **The Genomics Core** provides NextGen DNA sequencing and related genomics applications including transcriptomics, ChIP-seq, and methylation analysis. NextGen sequencing instrumentation includes a Life Technologies Ion Proton system, Illumina HiSeq2500 and miSeq machines, a Roche 454 GS-FLX Titanium, cBot workstation, and Covaris nebulizer. DNA microarray services provide transcriptomic and genotyping/SNP analysis, supported by a suite of instrumentation (fluidics workstation, hybe station, and scanner) and Affymetrix DNA arrays, as well as an Illumina Beadstation 500x.
- **The Center for High Performance Computing** maintains three major specialized supercomputing clusters: 1) teal is the primary cluster intended for large scale parallel computing and is especially well suited for applications such as molecular dynamics simulations. Teal consists of

~4000 64 bit AMD compute cores, each with 2-4 GB RAM/core, 8 TB of /home space, tmp space of 180 GB per node, and a 20 Gb/second infiniband architecture high speed network infrastructure; 2) bach is for serial and small parallel applications; 3) godel is a cluster optimized for bioinformatics applications. These clusters are collectively served by nearly 1PB of networked storage.

- **The Tissue and Data Analysis and Acquisition Core (TDAAC)** acquires human specimens and associated clinical and pathological data through 1) the VCU-IRB approved "Tissue Acquisition System to Support Cancer Research" protocol, which supplies specimens to a biorepository supporting cancer research; and 2) collection of tissue, hematopoietic and serum samples for investigator-initiated IRB approved projects.
- **The Microscopy Core** provides a comprehensive spectrum of imaging methods and techniques including: 1) electron microscopy (TEM, SEM) with a Jeol JEM-1230 TEM and a Zeiss EVO 50 XVP SEM; 2) confocal laser scanning microscopy systems: A Zeiss LSM 710 (inverted), a Zeiss LSM 700 (upright) and a Leica TCS-SP2 AOBS; 3) live cell confocal microscopy via a Zeiss Cell Observer SD spinning disc; 4) total internal reflection (TIRF) microscopy by an Olympus cellTIRF system; 5) five wide-field fluorescence microscopes, 6) a Nikon N-SIM Structured Illumination Microscope ("Ultra-Resolution"). The Core offers many imaging methods and services including: sample preparation; live-cell imaging; immuno-localization (fluorescence, EM); FRAP; and FRET.
- **The Nanomaterials Characterization Core** provides a comprehensive instrumentation suite for nanomaterials and surface characterization. The facility features a ThermoFisher ESCAlab 250 X-ray photoelectron spectrometer, a multitechnique platform for studying the surface of materials. The center also has three scanning electron microscopes and a transmission electron microscope: a Hitachi SU-70 FE-SEM, a Jeol JSM-5610 LV, Zeiss Auriga SEM/FIB, and Zeiss libra 120 TEM. The core additionally features: a VEECO ICON atomic force microscope, a Zeiss LSM-710 confocal microscope; a SkyScan 1173 u-CT scanner; a Quantum Design Versalab platform; a Viscotek GPCMax; a Rame-Hart Contact Angle, and a PANalytical X-ray fluorescence spectrometer.
- **The VCU Lipidomics and Metabolomics Core** provides mass spectrometry services built around two AB SCIEX 4000 QTRAPs, an AB SCIEX 5500 QTRAP, an AB SCIEX 6500 QTRAP, and a new AB SCIEX 5600+, which gives us the resolution and sensitivity for a broad range of qualitative and quantitative lipid and metabolite analyses required for exhaustive characterization of lipid signaling molecules and metabolic pathways.

VCU Students and Programs

VCU is the Commonwealth's largest university, enrolling the most diverse student body in Virginia, with more than 32,000 undergraduate, graduate and professional students. Our students are enrolled in more than 195 certificate, undergraduate, graduate, professional and doctoral programs. The University and the VCU Health System combined annual budget is $2.9 billion. The VCU medical campus has more than 4,000 students enrolled in the Schools of Allied Health (1,023), Dentistry (490), Medicine (1,292), Nursing (909), and Pharmacy (605) enrolled in 55 degree programs, with 22 at the Masters level and 17 at the doctoral level. The Monroe Park Campus comprises the College of Humanities and Sciences (including the Departments of Biology, Chemistry, and Psychology) and the Schools of the Arts, Business, Education (including the Department of Exercise Science), Engineering (including the Departments of Biomedical Engineering and Chemical and Life Sciences Engineering), the Wilder School of Government

and Public Affairs, Social Work, and VCU Life Sciences. Thirty-two VCU graduate and professional programs are ranked among the best in the nation in U.S. News & World Report's "America's Best Graduate Schools". VCU Faculty includes five members of the Institute of Medicine and one of the National Academy of Engineering. VCU is a comprehensive institution for life sciences in both budget and variety of programs and has a school in every health-related discipline, except Public Health.

Animal and Human Subjects Research

VCU's animal research program has been AAALAC accredited continuously since 1966. VCU's human subjects protection program has been fully accredited by AAHRPP since 2007. Submission, review, and operational oversight of both human and animal subject protocols are now fully electronic, using the ClickCommerce® platform. The animal platform was implemented in early 2012 and the human subjects platform was implemented in late 2013. Electronic management has decreased review times and permits real-time analysis of IACUC and IRB workload and performance. Total costs for deployment of these two systems exceeded $3 Million and was borne by the institution.