
CLEAR INSTITUTIONAL RESOURCES

UNIVERSITY OF ALABAMA AT BIRMINGHAM (UAB)

UAB is a comprehensive urban university with over 18,698 students from across the US and internationally. As a state-affiliated institution, UAB ranks among the top 15 public universities in federal research support, with a sponsored projects portfolio exceeding \$360 million (FY2014). The University of Alabama at Birmingham, one of three autonomous institutions within The University of Alabama System, is the only four-year, public university in the state's largest metropolitan area. The University spans more than 93 blocks in the city center with over 250 buildings providing over 10.5 million feet of assignable space. UAB is Alabama's largest employer with an annual economic impact exceeding \$4.56 billion. As of the fall of 2014 (most recent data), the University employed nearly 20,202 people, had a faculty of 2,436 (37 percent of whom are female), and had a student enrollment of 18,698 at the undergraduate through doctoral levels. The graduate student population is 64 percent female and 30% are among minority ethnicities. UAB is comprised of 10 academic colleges and schools in the health sciences and academic areas. The UAB Academic Health Center includes the Schools of Medicine, Dentistry, Nursing, Optometry, Public Health, Health Professions, the Graduate School, and the Lister Hill Library of the Health Sciences. The University's academic campus consists of the College of Arts and Sciences, the Collat School of Business, the Schools of Education and Engineering, the Graduate School, and the Mervyn Sterne Library. The university has 172 endowed chairs/professorships. The Institution has been ranked among the top quarter of all U.S. colleges and universities by The Princeton Review, and among the top 10 for diversity for four consecutive years.

Center for Clinical and Translational Science

To speed the translation of research into improved human health, the UAB CCTS and its Partner Network are committed to increasing research capacity, accelerating research processes, developing and supporting excellence in the research workforce and providing creative, innovative approaches to major health and health care delivery challenges. The CCTS offers access to a number of resources and capacities through its co-leadership of the Clinical Trials Initiative as well as the Research Commons and the Training Academy.

CCTS Partner Network – In synergy with the resource strengths available at UAB, the CCTS has established Institutional Partnerships to improve and accelerate translational research. The CCTS Partner Network crosses institutional boundaries to improve human health and health care delivery. This innovative partnership is well integrated into the fabric of the CCTS and provides the foundation for addressing health disparities through collaborative research and training efforts. Building on some initial relationships from the Deep South Network for Translational Research, we have significantly expanded to create new and more formal partnerships with regional institutions for mutual benefit. Regional partners are working together to facilitate and promote unique opportunities, including (but not limited to) drug discovery and development, genomics, advanced magnetic resonance imaging, population health and outcomes research. Partners include UAB (Hub), Southern Research, Auburn, South Alabama, HudsonAlpha, LSU, Mississippi Medical Ctr., Pennington, Tulane, Tuscaloosa, Tuskegee). See <http://www.uab.edu/ccts/partners>



Clinical Trials Initiative

(In partnership with UAB's School of Medicine and Research Administration)

The mission of the UAB Clinical Trials Initiative is to promote, foster, and enhance high-quality clinical research at the University of Alabama at Birmingham. UAB's initiative is to provide, support and direct the implementation of cutting-edge human subject research. By promoting clinical research, the effort will help the UAB community meet its mission goals of excellence in patient care, education, research, and community service. The Institution is committed to providing world-class patient care with innovative therapies to treat disease, promote health and wellness, and provide opportunity for patient participation in clinical research. As

an academic medical center, it is our responsibility to participate in research that leads to new discoveries and advances the art and science of medicine for future generations. This collaboration provides services to:

- UAB researchers and research teams, assisting with feasibility assessment, methodologic rigor, study start-up, implementation and reporting.
- Patients and the general public, providing opportunities for study participation.
- Sponsors, helping them identify UAB investigators for participation in their research.

As part of this effort, the CCTS mission addresses four programmatic tasks: 1) performance standards to meet and exceed national standards; 2) educated and knowledgeable workforce; 3) implementation of scientifically reproducible research; and 4) services to support rigorous design and interpretation.

CCTS Training Academy

The CCTS is committed to lifelong training. Its Training Academy offers research training and career development to investigators and their teams. In addition to the NIH-funded KL2 and TL1 programs (which are institutional training programs similar to K12 and T32 mechanisms), the CCTS offers the Clinical and Translational Science Training Program and the Research-Team Training Program (both certificate courses). The Clinical and Translational Science Training Program offers additional training in clinical and translational research over a six-month period (January-June) for two hours per week. Course content represents modules including clinical trials, epidemiology, biostatistics, ethics, clinical genetics research, behavioral research, outcomes research, dissemination of results, and grant writing and funding opportunities. All of the sessions are presented by experienced clinical and translational researchers or individuals with special expertise in areas such as grants and contracts and regulatory issues. Preceptors include faculty and research staff from across the Partner Network. The six-session Research-Team Training Program provides research staff (investigators, study coordinators, billing staff, regulatory coordinators, etc.) with the basics of implementing and managing a clinical trial with emphasis on good clinical practices (GCPs), research compliance, and other key topics. This Program has been expanded to become a regional training resource for the conduct of clinical trials.

The CCTS has also recently implemented a Summer Research Training Program in Patient-Centered Outcomes Research (PCOR) and Comparative Effectiveness Research (CER) for students at UAB and Partner Network institutions, as well as a CCTS/CTO Clinical Studies Seminars. The 8-week Summer Program provides mentored research training experiences in PCOR and CER for medical students or other clinically-oriented doctoral students that have completed their first year of training. Trainees must devote full-time effort (40 hours week) for the duration of the program (June and July). The CCTS/CTO Clinical Studies Seminars are offered the first and third Thursdays of each month from 12-1pm. Special topics are covered for all research study faculty and staff. Upcoming presentations include information on preparing for an FDA audit, the 1572 – what it means to be PI, and guidance on developing SOPs.

For mentoring and career development, the CCTS works with all learners to identify individual training needs and navigate the many resources available. Through individualized consults, learners identify additional competencies needed for specific clinical and translational research domains as well as the necessary training and research resources. The CCTS also provides assistance with Individual Development Plans (IDPs), which can facilitate dialogue between mentors and trainees as they establish training goals. An IDP is now strongly encouraged for many funding mechanisms. Information on creating IDPs is available on the CCTS website, along with information on related seminars and our entering mentoring curriculum.

Career development activities include the CCTS Forum, the PSDS (Professional Skills Development Series) and TIERS (Training Interdisciplinary Emerging Research Scholars). The CCTS Forum is a venue in which significant achievements and opportunities in translational research are explored in depth. It highlights individuals who have already advanced translational research or whose work has recognized potential to open new avenues of inquiry. Of particular interest are joint presentations by invited guests and their UAB colleagues whose collaborative or complementary work has contributed significantly to clinical or population science. The monthly PSDS is designed to provide practical assistance in the areas of scientific writing (such as the development of grants and scientific manuscripts), scientific presentations, team science and leadership. TIERS gathers junior faculty, postdoctoral fellows and professional students interested in

academic research careers. Its mission is to provide beneficial information on career planning and development including mentoring, presentation of findings, grant preparation, and project and team management. These topics are presented in a relaxed environment structured to promote collaborative learning and problem solving and to strengthen relationships in an effort to broaden the potential of each researcher both individually and collectively.

To assist with institutional awards, the CCTS provides a webpage with [resources for training grant directors](#), including a library of successful T32 applications and information on training in the Responsible Conduct of Research. For individual career development awards, the CCTS also offers assistance with personal statements and the career development plans – with the option of Panels to strengthen the scientific content.

The CCTS also provides training in specific content areas – most notably informatics, drug discovery, and biostatistics methodology. Informatics offers lectures and seminars, as well as an annual Summer Seminar Series. The Alabama Drug Discovery Alliance (ADDA), in collaboration with the CCTS, offers an annual Drug Discovery Seminar Series. Biostatistics methodology lectures have been provided, specifically targeting pilot program applicants. These lectures are archived and available through the CCTS website. Other training has also been provided related to biorepositories, data management, biostatistics, etc.

CCTS Research Commons

Through the Research Commons, investigators can access research-related services and resources available at UAB and our Partner Network institutions. The Commons provides individualized assistance to all investigators, from trainees to full professors. CCTS personnel direct investigators to appropriate services and resources and help identify related opportunities. They facilitate scientific connections between investigators and research capacities and among investigators to promote scientific interactions. One resource, especially useful to junior faculty and trainees, is the Panels Program. The CCTS offers a large, multi-disciplinary [Nascent Projects Panel \(NPP\)](#) and smaller, more agile [Panels Done Quickly \(PDQs\)](#). Both provide consultation in early phase project design, grant proposal development, evaluation and revision of unfunded grant proposals, implementation of research protocols, and interpretation and or dissemination of experimental results.

The NPP includes over a dozen faculty members and staff who are experts in their fields and are able to provide multi-disciplinary feedback in areas relevant to clinical and translational research including, but not limited to, epidemiology, exercise medicine, biostatistics, health economics, health disparities, comparative effectiveness research, and community-based participatory research. Each session also includes content-specific experts chosen after discussion with presenters. Presenters provide a brief overview of their research to the Panel, which is followed by a 20-30 minute session during which NPP members ask questions, discuss the project, and provide feedback. A written summary of the discussion is provided to presenters. The NPP Chair, other panel members, and members of the Research Commons later meet one-on-one with investigators to solicit feedback about the value of the NPP and to identify areas in which additional or ongoing assistance would be helpful.

For those who need a more rapid response mechanism, PDQs are available to address specific needs in a more targeted way. In contrast to the NPPs, PDQs are relevant for specific phases of research, such as project development, implementation, interpretation and/or dissemination. Consultation through PDQs can be requested through the Research Commons online portal or by direct personal request. Meetings are coordinated by the Commons and a member of the CCTS Executive Committee. Relevant materials are submitted for review and within 10 working days of the initial request, a PDQ is convened. As with the NPP, there is an emphasis on multiple viewpoints and content-specific expertise, but from a smaller group of experts (usually two to four). For those who seek additional opportunities to assess progress and identify opportunities for improvement, follow-up PDQs may be convened. In order to provide continuity, at least two of the original members serve as part of the follow-up PDQ. As with the NPP, written as well as oral feedback is provided to the investigator who requested the session.

The CCTS Research Commons is also the primary portal through which investigators can connect with important expertise including [Biostatistics](#), [Epidemiology and Research Design \(BERD\)](#), [informatics](#), [clinical research services](#) and other scientific capacities.

Clinical Research Services

A centralized hub provides a supportive environment for early phase and task-intensive clinical research in humans. The environment ensures safety and provides standardized pathways for the administration of investigational agents and the collection/management of valuable patient samples essential for translational advances. CCTS clinical services include the *Clinical Research Unit (CRU)*, the *Phase I Clinical Trials Unit*, the *Child Health Research Unit (CHRU)*, and the *Bionutrition Unit*. The Phase I Unit and the Bionutrition Unit are housed on the 15th floor of Jefferson Tower, in immediate proximity to the CRU, which was renovated to become the central location for CCTS clinical services. The CHRU is located on the UAB campus within Children's Hospital of Alabama.

Clinical Research Unit (CRU)

The CCTS has 15,450 square feet of dedicated clinical research space located on the 15th floor of Jefferson Tower. This space has two clinical units; The Clinical Research Unit (CRU) and the Phase I Unit. The CRU provides clinical services for investigator initiated clinical studies and Phase II and III clinical trials and the Phase I Unit provides services for Phase I clinical trials. The nursing staff support a wide range of clinical research including, but not limited to aging, Alzheimer's disease, diabetes, hepatic disease, obesity, pain, reproductive health, nutrition, and various cancers. These units are supported by two nurses stations and a pneumatic tube station to allow for quick transport of specimens to the hospital lab as well as receipt of some pharmaceuticals.

The CRU is located on the west wing of JT 15 and has four private rooms, one semi-private room, and an infusion suite with six infusion chairs. In addition, the west wing has storage space for equipment and/or supplies that are specific to investigator needs.

If inpatient care is required, the CRU has access to inpatient beds located on the 8th floor of UAB Hospital. Inpatient utilization focuses on studies requiring hospitalization of participants for proper study activities, ranging from 24 hour sample collection protocols to studies for which participant safety is best served by an inpatient setting.

L. Burt Nabors, MD, is the Medical Director of the CRU, and Jolene Lewis, MSN, serves as the Nurse Manager for the CRU. She has more than 10 years of service managing inpatient and outpatient research nursing staff. In addition to Ms. Lewis, the nursing staff includes four full-time nurses, one part-time nurse, and seven nurses who work on an as needed basis. CRU nurses have extensive research experience with the infusion of research medications, monitoring of participants, collection of PK, PD, PG, and biomarker samples, data collection, and use of scientific research equipment. All nurses complete required hospital competencies, human subjects training, certification on pharmacokinetics and Good Clinical Practice (GCP) training.

Child Health Research Unit (CHRU)

The CHRU was developed to provide a platform to improve our understanding of child health and childhood disease pathogenesis, and to accelerate the development of new treatments for diseases that are manifested in childhood. Its outpatient research unit is located on the 7th floor of Dearth Tower, which is part of Children's Hospital on the UAB campus. With a recent \$400 million expansion, Children's is one of the largest and busiest centers for child health care and the third largest pediatric hospital in the US. The outpatient unit includes an ancillary physician's office in proximity to the clinic, four outpatient beds (suitable for long-duration PK studies), a specimen processing laboratory (refrigerated centrifuge, microscope, hematocytometer, -80°C freezers, pipettes, etc), a state-of-the-art biospecimen storage facility with real-time monitoring and specimen-tracking capabilities, a nasal potential difference laboratory (2 setups, each capable of electronic and conventional data capture), and a third potential difference apparatus dedicated and optimized for the measurement of Potential Difference at other anatomic locations such as the lower airway (LAPD). Specialized equipment housed for CFTR clinical science are also housed in the CHRU, including two sweat iontophoresis devices (each compatible with the Macroduct collection system), two sweat evaporimeters (Cyberderm RG), a carbon monoxide monitor, a Lung Clearance Index measurement device (EcoMedics) for use by the nitrogen washout technique, nasal and exhaled nitric oxide measurement (EcoMedics), two spirometers with calibration equipment (NSpire), an EKG machine, a Code cart, and general laboratory supplies. The unit is separate from the outpatient clinical care areas,

which ensures that study subjects are separated from clinical care activities. Through the UAB Center for Clinical and Translational Science (CCTS) and in collaboration with the CRU and CRSP (described in the following section), the CHRU provides UAB child health researchers with the infrastructure to implement and conduct studies. The hours of utilization are flexible and can include after-hour visits.

Steven Rowe, MD, MSPH, and Alyssa Reddy, MD jointly serve as Co-Directors of the CHRU. In this capacity they oversee operations, set policies and procedures, assign project responsibilities, and in conjunction with the Clinical Trials Office, review budget development for industry contracts, review IRB submissions and renewals, and direct weekly team meetings that include junior investigators and evaluation of potential projects. Dr. Rowe serves as the CC-CHOC Point Person for the CTSA Consortium and also directs the Cystic Fibrosis (CF) Therapeutics Development Network at UAB, as well as is a member of the UAB Lung Health Center. He has broad training in Pediatrics, Internal Medicine, and Clinical Research, and is an expert on studies that address fundamental aspects of CF disease pathogenesis, including industry and investigator-initiated studies examining CFTR modulators, relationships between CFTR activity and CFTR biomarkers, and new assay development. Dr. Rowe also directs the Center for CFTR Detection and provides research quality conduct, support, and interpretation of CF research trials, supporting sites throughout the United States and Europe. Dr. Reddy, Professor of Pediatrics, Neurology, and Surgery, has extensive experience in conducting clinical trials. She also serves a leadership role in the Department of Defense-funded Neurofibromatosis Consortium, where UAB is both the Coordinating Center and a member site.

Phase I Clinical Trials Unit

In 2013 the CCTS expanded our CRU by adding a 7,950 square foot Phase I Clinical Trials Unit. The unit is located on the 15th floor of Jefferson Tower, adjacent to the existing CRU and the sample processing facility. It is comprised of five exam rooms for the administration of research agents. Each room has the flexibility to be used as private or semi-private to allow for maximum space utilization and appropriate participant monitoring. The unit also includes the capacity for the administration of standard of care drugs and routine infusions, which enhances the nurses' focus on the care given to those receiving Phase I agents. A centrally located nurses' station supports the unit. The Phase I Unit is led by Mansoor Saleh, MD, a Professor of Medicine and Medical Director of the UAB Clinical Trials Office. Prior to coming to UAB, he served as Director of Clinical Research for Georgia Cancer Specialists in Atlanta, the largest community-based oncology practice group in the Southeast. His research has been focused on translational research and targeted therapies for cancer. Dr. Saleh is nationally known for his work with monoclonal antibodies in the treatment of cancer as well as the treatment of idiopathic thrombocytopenic purpura (ITP) using novel agents.

Clinical Research Support Program (CRSP)

The current research environment has been impacted by the increase in regulatory requirements, the decrease in funding due to the economy, and the challenge for research sites to manage unexpected events. Additionally, novice research coordinators and limited educational experience of study coordinators leaves research sites unable to cope with these challenges. In late 2010, the Center for Clinical and Translational Science (CCTS) supported the development of a Clinical Research Support Program (CRSP) for the exclusive purpose of functioning as a modified institutional clinical research organization. This program was designed to provide any or all support for implementing a clinical (or non-clinical) study at UAB.

CRSP provides a pool of trained, certified research coordinators to assist investigators with study implementation, including interpretation and adherence to regulatory requirements, organizational and budget management, communication with sponsors, internal quality measures, and data management. Resource pooling provides flexibility and limits the need for individual investigators or programs to overstaff in order to handle sporadic needs. Additionally, trained, experienced research staff are capable of managing and implementing research studies more efficiently and effectively. CRSP personnel function in a flexible manner and provide services when and where needed. Most services and support are conducted at the study investigator's site. All staff received CCTS training, in addition to the standard human subjects training, certification on pharmacokinetics, and GCP training. Staff are also certified for working in UAB Hospital, the BVAMC, and Children's Hospital. Staff have experience in cardiology, cancer, endocrinology,

nephrology, neurology, pediatrics, School of Public Health, infectious diseases, pulmonary, CV surgery, GI, and continues to expand. CRSP personnel ensure that investigators have the required research implementation resources and that research teams have the knowledge and skills for conducting protocols. They assist with pre-study activities such as site and study feasibility assessments, staff education and training, budget development and negotiations, DSMB plans, regulatory preparation (e.g., IRB, IND/IDE, institutional requirements, sponsor requirements), site assessment visits, and study initiation meetings. They also provide study implementation services, which include subject visits and assessments, study report generation, maintenance of regulatory documents, budget maintenance, safety reporting, quality management assessments, monitoring/preparation for monitor visits, subject retention efforts, and data and specimen management. Finally, CRSP staff provide services related to study closure, including study closeout visits, reconciliation of final data, final study reports, and archiving.

Additionally, CRSP works in conjunction with the Clinical Trials Office (CTO) to better serve the research needs at UAB by building programs to increase education and training for all members of the investigative team. Some of the programs that have been implemented so far are weekly comprehensive research seminars that incorporate Good Clinical Practice training (GCPs), monthly research orientation and templates for Standard Operating Procedures (SOPs). Reasons for seeking CRSP support vary, but are reflective of the challenges in the current research environment. CRSP is focused on providing a 'best practice' environment extending the mission of the CCTS to facilitate the highest quality of clinical research across campus.

Specimen Processing and Analytical Nexus (SPAN)

SPAN is the central clearinghouse for sample collection, login, handling, and storage for clinical research studies at UAB. In addition, it provides access to cost-effective and high quality analytical measures of circulating analytes with an emphasis on markers of metabolic function and inflammation. SPAN also assists investigators in specimen distribution to other UAB analytical Cores, investigator laboratories and outside laboratories. SPAN consists of three laboratories on campus, all within a two-block radius. The primary specimen processing laboratory (450 sq ft) is located within the CRU, which allows for centralized collection and preparative activity. This laboratory is equipped for BSL2 level work in two laminar flow hoods and also contains three refrigerated centrifuges, two refrigerators, a non-cycling -20°C freezer and a -80°C freezer. A more sophisticated laboratory for processing and long-term storage is located in the Shelby Interdisciplinary Research Building (1,400 sq ft), and the analytical laboratory is located in the Webb Nutrition Sciences Building (1,300 sq ft). The latter is well equipped with both automated and manual analyzers for assessment of a variety of analytes. General equipment includes pipetting devices, a refrigerator, -70°C and -20°C freezers, two refrigerated centrifuges, water baths, a shaker, a rotating extractor, and an ALPCO microplate rotator. A water distillation and filtration system, cold rooms, and an ice machine are located adjacent to the facility, and are available for use in hormone/substrate analysis. Personnel are also available for assisting with research needs at other clinical intervention sites on campus that have existing laboratory facilities. All SPAN activities are fully integrated with CCTS clinical activities through the use of the recently implemented OnCore clinical trials management system.

SPAN actively works with investigators to develop specimen process protocols that meet the needs of each individual study and develops/implements new methods as required. Studies utilizing the core cover a broad range of translational research. SPAN protocols range from complex therapeutic clinical trials with PK/PD blood processing needs, to glucose tolerance tests in healthy controls with frequent blood sampling to simple phlebotomy of healthy controls for preparation of blood derived materials (serum, plasma, buffy coats, PBMC, DNA).

Biorepository

The CCTS Biorepository provides access to standard operating procedures for biobanking, an inventory of disease-specific biorepositories, and specimens from patients and from healthy individuals. It was designed to provide timely access to fresh blood for ex vivo studies; access to human plasma, serum and/or DNA samples from healthy participants; and access to biospecimens from patients with well-phenotypically-characterized disease. Housed in the more sophisticated SPAN laboratory, it includes an array of -80°C and liquid nitrogen cryogenic freezers. All freezers are centrally monitored and all cryogenic

freezers are equipped with automatic LN2 filling valves. Freezers are inventoried to the individual tube level using the Biospecimen Management module of OnCore

The CCTS Biorepository offers a centralized mechanism by which investigators can access healthy participants without incurring the costs associated with hiring a study coordinator and advertising. Studies may need access to fresh peripheral blood and benefit from access to a centralized resource with a cohort of available donors consented for recall. Others may only need banked blood derived materials. With donor consent, a biobank of human plasma, serum, buffy coats (cell pellets), DNA and transformed lymphoblastoid (EBV) lines from healthy participants is being created. Recognizing that many translational studies are being leveraged by tremendous advances in our understanding of the genetic variation that exists between individuals and underlies the genetic basis for disease, the Biorepository will provide, with appropriate IRB approvals, genotyping results on the healthy control cohort. As detailed below, there is a large collection of healthy control donors consented for recall, whose DNA has been included in large-scale genotyping studies. The availability of large scale genotyping results will greatly enhance the value of the healthy control cohort.

In addition to physical sample management, the CCTS has established TissueHub (tissuehub.org), an online, federated catalogue of biospecimen collections created in collaboration with CCTS Partner Network. By coordinating sample sets digitally, we can accomplish our goals of facilitating collaborations and stimulating new initiatives which can benefit from our network-wide tissue collections. TissueHub is currently a public site that collates summary information including clinical diagnosis, ethnicity, specimen type, repository size and contact to enable scientific investigation and enhance our capacity to serve our populations. It connects investigators does not obligate sample sharing; rather it connects investigators to determine whether they would like to pursue a collaborative relationship that may involve biospecimens.

Bionutrition Unit

The Bionutrition Unit, Clinical Research Unit (CRU), fosters the integration of nutrition into clinical and translational research by providing nutrition research expertise and resources for investigators. The Unit offers a number of core services:

- 1) Research design, development and implementation—this includes one-on-one assistance with the initial research design, calculating research diets, providing menus and meals as required by protocol, help with participant recruitment and retention, development of nutrition data collection forms, and data collection.
- 2) Nutrition education—assistance with educating participants about dietary protocols and assistance with specific diet prescriptions and other individual or group counseling as needed.
- 3) Body composition analysis—standardized height and weight measurements, anthropomorphic measurements (skinfold thickness and body circumferences), and bioelectric impedance analysis (BIA) to determine body composition (fat free mass, body fat mass, percent body fat), using a Tanita body composition analyzer TBF-310 and BC-418, a Scaletronic digital scale, a Biodynamics bio-impedance analyzer, a stadiometer to measure height electronically, and Lange calipers.
- 4) Nutrient Intake Analysis—analysis of 24-hour food recalls, multiple-pass food records using Nutrient Data System for Research (NDS-R) software, a comprehensive nutrient calculation software that can perform analyses of 139 nutrients, nutrient ratios and other food compounds.
- 5) A state-of-the-art Metabolic Kitchen that provides ideal infrastructure to prepare specially-designed research diets for participants in outpatient-based studies; a multi-purpose room is also available for nutrition studies that require on-site feeding. The staff includes two full-time research dietitians and four designated research cooks that have many years of experience implementing detailed nutrition interventions studies.

CCTS Biostatistics, Epidemiology and Research Design (BERD)

The CCTS Biostatistics, Epidemiology and Research Design (BERD) unit is a multidisciplinary team of biostatisticians, epidemiologists, and methodologists who collaborate with researchers to serve fundamental, clinical and translational research. The mission of BERD is to provide consultation, guidance, and expertise for study design, data management, and statistical analysis of research. Its goal is to gather methodological expertise as a single coordinated resource and match individual methodological skills and

interests with study-specific needs in order to advance research. BERD achieves this goal by providing methodological training (short courses, on-line video library), in-person directed consultation (walk-in clinics, scheduled expert consultation), methodology review of grant applications and clinical trials (panels), and collaborations for intermural and extramurally funded research .

The extent and intensity of services vary by study design. In support of study design, sample size and power calculations, data presentation and interpretation of results, the BERD has organized walk-in clinics. Responsive to investigator demand, these standing venues are available several days a week at multiple locations to enhance accessibility. For investigators who do not have the flexibility to attend a clinic, they may contact CCTS Research Commons to connect to methodological expertise by scheduled consultation. After preliminary consultation in weekly clinics, BERD methodologists are often engaged to a greater extent to ensure the scientific rigor. For independently funded clinical trials and other studies requiring sustained methodologic contributions, BERD experts participate as collaborators, effort for which is addressed through the grant / contract, to guide standard operating procedures and to ensure accuracy and reproducibility of scientific results.

BERD provides a large array of methodological services to clinical and translational researchers throughout the CCTS. The services provided are dependent upon the nature of either the mechanism being developed (Pilot Design, Clinical Trial, K Awards, R-series or Program Project Mechanisms) or mechanisms that are funded. BERD collaborates on the development of essential elements including specific aims, statistical analysis strategies, data management plans, and sample size/power calculations. Recognizing that sample size estimations differ between pilot / feasibility studies and large clinical trials, these calculations are customized for every mechanism to enable precision where appropriate and the power to detect clinically relevant effects where possible.

CCTS Informatics

CCTS Informatics provides a broad range of informatics services to CCTS investigators. Specifically, in support of the computational analysis needs of CCTS investigators, the CCTS formed the Informatics Consulting Service to provide consultation and collaborative assistance on the collection and analysis of data derived from basic biomedical research (Bioinformatics) to clinical, outcomes, public health, and health services research (Clinical and Health Informatics). Our expertise extends from traditional sequence and genomics analysis, microarray gene expression analysis, protein and RNA structural prediction, and the analysis of data from next generation sequencing (NGS) technologies, to the analysis of data derived from clinical research studies. We have extensive experience in the analysis of NGS data including data derived from whole genome and exome sequencing studies, genome methylation studies, RNASeq data, and microbiome and metagenomic analyses. CCTS Informatics currently employs 5 fulltime bioinformaticians (3 PhD level) and 3 Programmer/Analysts who support the consultation, analytical, training, and educational aims of the service. CCTS Informatics participates in the CCTS Partner Collaboratory, offering consultation services and collaborative opportunities across the CCTS Partner network.

CCTS Informatics personnel are located in offices in the Sparks building (900 sq. ft.) as well as the Bevell Biomedical Research Building (BBRB) building (200 sq. ft.). A small Data Center is located in BBRB (250 sq. ft.) that houses several development servers. Production servers are located in the central UAB IT Data Center (3,000 sq. ft.), and within the HIPAA-compliant Health System Data Centers, with the primary data center at a local off-site facility and the secondary facility (2400 sq. ft.) maintained on-site by the Health System Information Services (HSIS), both monitored 24 hours a day. A separate Data Center houses the UAB High Performance Computing infrastructure (1,500 sq. ft.).

The CCTS owns and leases access to a large collection of servers, storage systems, workstations, laptops and peripherals. Separate servers are utilized for production web sites, production database systems (MySQL, SQL Server, Oracle), data entry and curation databases, application development, database development, web site development, bioinformatics analysis, backup, and failover. Currently CCTS Informatics utilizes over 25 different servers comprising a mixture of dedicated hardware and cloud-based Virtual Machines with a combination of Windows, Linux, Solaris, and Macintosh operating systems are utilized. These systems include Dell PowerEdge (PE) server systems and Dell PowerVault (PV) storage

systems that provide in excess of 350 TB of disk storage. Hardware maintained directly by CCTS Informatics includes three Dell PE R710 servers, two with 192 GB RAM and 7 TB of storage and the third with 96 GB of RAM and 7 TB of storage; two PV NX3200 storage arrays, each with 48 TB of SAS disk storage; two PE R730x systems each with 72TB of SAS storage; one PV MD3400 with 96TB of SAS storage; and 4 PE 2950/2850 servers. All servers are connected to the campus network backbone using 1GigE (gigabit per second) network connections (soon to be upgraded to 10GigE connections). As detailed below, additional petabyte-scale storage is available locally within the UAB Research Computing infrastructure. All servers are backed up on a daily basis using a combination of a LTO tape backup system (Dell TL2000 library with two LTO-4 drives) and network-attached disk storage arrays. All data maintained by CCTS Informatics that contains PHI (protected health information) is housed either within the HSIS HIPAA-compliant data processing facility or the UAB-IT Assured Computing Platform. All other systems outside of these secured facilities contain only non-PHI, de-identified datasets.

One of the major initiatives of CCTS-Informatics has been to develop a Natural Language Processing (NLP) infrastructure to support the processing and analysis of unstructured medical records. This has been initially deployed within the UAB Health System to support the State of Alabama Cancer Registry reporting requirements. This NLP Infrastructure is used to facilitate cancer case detection by reviewing and processing all UAB Health System Pathology reports in real time to detect cancer concepts as defined by the National Association of American Cancer Registries (NAACR). We have improved cancer case detection throughput by 41%. Currently, approximately 1,000 cases are processed through this NLP platform each month. From the beginning, we built this platform with extensibility in mind and have extended its use to support cohort detection for retrospective research and active detection of participants for clinical trial enrollment. For example, this NLP infrastructure is currently being used to support the identification of patients in a Multiple Myeloma research study. Development of this infrastructure through a partnership with the UAB Department of Computer and Information Sciences has also included utilization of NLP to improve the medical documentation skills of our medical students, and we are currently exploring opportunities to utilize NLP to facilitate national reporting in our transplant programs. We are also working on extending these tools to support the processing of records derived from clinical research studies to both support the research goals of the study as well as to support the entry of NLP-derived structured data directly into patient's electronic health record.

UAB Institutional Research Environment in Clinical and Translational Science

School of Medicine (est. 1945; Selwyn M. Vickers, MD, Dean and Senior Vice President)

As the largest School within the University of Alabama at Birmingham, one of the South's premier research universities, the School of Medicine is dedicated to the education of physicians and scientists in all of the disciplines of medicine and biomedical investigation. The school provides medical education and internship opportunities for students throughout the world. Its comprehensive approach to teaching future physicians covers all facets of medicine, including medical education, research, and patient care -- delivered in one of the most technologically advanced medical facilities in the country. The SOM has nationally recognized clinical programs in many areas including, but not limited to, Oncology, Neurology, Psychiatry, and Immunology/Rheumatology. UAB is also a national leader in organ transplantation. Many of UAB's most productive extramurally-funded research centers, including the Comprehensive Cancer Center, Comprehensive Diabetes Center, Center for Aids Research, and others are based in the SOM and report to the Dean. The School of Medicine is also a national leader in research, and has been ranked in the top 30 of NIH funded Schools of Medicine for more than 20 years.

School of Public Health (est. 1981; Max Michael, III, MD, Dean)

The UAB School of Public Health (SOPH) offers the opportunity to join a vibrant community of professionals and scholars whose world-class research and scholarship is exploring complex problems like HIV/AIDS, obesity, and therapeutic intervention in creative and unusual ways. The interests of the faculty and staff extend from community organization in the Black Belt regions of rural Alabama to understanding the dynamics of the HIV epidemic in Sub-Saharan Africa. The institution offers a highly interdisciplinary, collaborative atmosphere

to support the missions of training and research excellence. With active research programs in diabetes, cardiovascular diseases, cancer, infectious diseases, and Alzheimer's disease, SOPH faculty interact with key researchers within the CCTS Network Partnership. The Department of Epidemiology offers a Master of Science in Public Health in Clinical and Translational Research, a one year MSPH program available for CCTS TL1 trainees to complete during their training (please see TL1 description).

School of Health Professions (est. 1969; Harold P. Jones, PhD, Dean)

The School of Health Professions in the UAB academic health center is one of the nation's largest such organizations with more than 1,900 students enrolled in over 20 different academic programs. Several graduate programs are nationally-ranked and the school is consistently rated at or near the top among all allied health schools for NIH funding. As a national leader, the school is dedicated to providing the best in professional education at the undergraduate and graduate levels. The school's research programs are nationally renowned, especially in the areas of nutrition and obesity. Graduates are well prepared to become outstanding practitioners who provide leadership to their communities and disciplines, as well as quality care to their clients. SHP is also recognized for its efforts in preparing top-level healthcare executives.

School of Dentistry (est. 1945; Michael S. Reddy, DMD, Dean)

The University of Alabama at Birmingham School of Dentistry was created by an act of the state legislature in 1945, the same year that the School of Medicine moved to Birmingham from the university campus in Tuscaloosa, and became a four-year school. The School of Dentistry admitted its first class of students in October 1948. In addition to its first professional degree (D.M.D.) program, the school offers accredited postdoctoral programs in twelve areas of study. Building on these foundations, the School is committed to training, research and refinement in prosthodontics and restorative dentistry. In this frame, the goal is to ensure that the UAB School of Dentistry remains a visible contemporary model for healthcare innovation.

Collat School of Business (est. 1971; Eric P. Jack, PhD, Dean)

Located in the heart of Alabama's business center, the UAB School of Business offers an engaging learning environment with classrooms extending well beyond the walls of the UAB campus. Integrating practical experiences of the State's leading companies - from Fortune 500 corporations to entrepreneurial startups - into the classroom, students gain valuable, real-world experience through a wide variety of internships and other opportunities in the business community. Business faculty are accomplished researchers, contributing to the ever-growing body of knowledge within the business disciplines. They are also deeply experienced professionals, having worked for some of the world's leading companies: Ford, Deloitte, United Airlines, Motorola, Procter & Gamble and U.S. Steel to name a few.

College of Arts and Sciences (est. 2010; Robert Palazzo, PhD, Dean)

The UAB College of Arts and Sciences was founded in 2009 with the integration of the schools of Arts and Humanities, Social and Behavioral Sciences, Natural Science and Mathematics, and Education. Serving over 6,500 students pursuing degrees, the college includes 20 academic departments offering 58 baccalaureate majors and 36 programs leading to a masters or doctoral degree. Nearly every student pursuing a baccalaureate degree at UAB takes classes in the College of Arts and Sciences where the majority of general education core curriculum courses are offered. The professoriate of the college includes more than 350 full time faculty members, approximately 59% percent of whom are tenured.

School of Education (est. 1971; Deborah L. Voltz, EdD, Dean)

The School of Education is distinct from yet synergistic with the College of Arts and Sciences to provide an innovative environment that promotes teaching methods in collaboration with the content experts in the academic areas to insure the best preparation for students pursuing careers in the field of education. This unique configuration is emblematic of UAB's interdisciplinary, collaborative culture, strengthening cooperation between departments and programs for excellence in research and scholarship where students can thrive in an open environment with a bold, innovative approach to education.

School of Engineering (est. 1971; J. Iwan D. Alexander, PhD, Dean)

The UAB School of Engineering embraces a collaborative mission, supporting projects that bring engineers together with medical professionals, business leaders, and fellow scientists from other disciplines, in order to push the envelope and discover new, innovative solutions for the challenges in the world. It is likewise

committed to training at the undergraduate and graduate levels, where student engagement in design projects is prioritized throughout the curriculum.

School of Nursing (est. 1969, Doreen C. Harper, PhD, RN, FAAN, Dean)

The UAB School of Nursing offers innovative bachelor's, master's, and doctoral programs under the leadership of an interdisciplinary clinical and research faculty vested in developing the next generation of compassionate nurses committed to contributing to the improvement of the health and quality of care for individuals, families, and populations. Among these are the state's only PhD in Nursing and joint Doctor of Nursing Practice (DNP) degrees, more than 10 specialty and/or subspecialty nurse practitioner and clinical nurse specialist majors, dual degree options, advanced nursing executive majors in administration and informatics, and an Accelerated Master's in Nursing Pathway (AMNP) program for students who already have one degree. Some courses are taught completely in a distance-accessible format, where students can complete course requirements without traveling to campus, and some courses have online content combined with live sessions on campus. The UAB School of Nursing offers students opportunities to learn and investigate with faculty and student teams from nursing, medicine, dentistry, health professions, public health, and optometry.

School of Optometry (est. 1969; Kelly K. Nichols, OD, MPH, PhD, FAAO, Dean)

The School of Optometry was established in 1969. Since that time, the School has grown to include graduate degrees (M.S., Ph.D.) in Vision Science and post-doctoral residency education. One of the smaller Optometry Schools in the country, it has a competitive enrollment that benefits the world-class educational environment. Optometry has a first rate reputation for educating optometrists and vision scientists. Their faculty is among the best known in the country through their lectures, research and publications including many textbooks. Their clinical service is widely respected for the excellent patient care provided in the recently renovated clinic "UAB Eye Care," a 34,000 square foot state-of-the-art facility that covers everything from primary eye care, including the dispensing of glasses and contacts, to the treatment of ocular disease, as well as low vision rehabilitation and pediatric vision care. Collectively, these commitments help the School in its mission to educate optometry students, residents, and future scientists; to discover and broadly communicate new principles and concepts in eye care and vision science; to translate these ideas into clinical practice; and deliver health care with integrity and compassion.

Joint Health Sciences

Within the academic health system, the Joint Health Sciences (JHS) represents a set of coordinated units embraced by the Schools of Medicine, Optometry and Dentistry that are based on shared goals in teaching and research missions. These include the Departments of Biochemistry & Molecular Genetics; Biomedical Engineering (in the School of Engineering); Cellular, Developmental, and Integrative Biology; Genetics; Microbiology; Neurobiology; Nutrition Sciences (in School of Health Professions); Pathology; and Pharmacology & Toxicology. In an effort to leverage the expertise throughout these programs, the JHS Departments provide faculty leadership in graduate/ first professional training, mentorship, curricula development, interdisciplinary research as well as participating in institutional roles in multiple schools.

Libraries (est.1945, John Meador, Dean)

The *Lister Hill Library of the Health Sciences* - Centrally located in the heart of the academic medical center, the Library provides a variety of reference and educational services plus extensive educational opportunities through one-on-one instruction at point of need or in scheduled workshops on using library resources or searching for information. Established in 1945, LHL is the largest biomedical library in Alabama. The library also maintains two satellite operations to be even more accessible. The Lister Hill Library at University Hospital (LHL@UH) is located in the West Pavilion to provide onsite support for education, research, and patient care. The Kirklin Clinic Patient Resource Library is located on the 2nd floor of The Kirklin Clinic and provides access to quality health information services and resources for patients of the UAB Health System. Additionally, the library offers an extensive digital collection supporting the research enterprise.

Mervyn H. Sterne Library-Entering its 40th year in operation, the Mervyn H. Sterne Library maintains a collection of over one-million items that enables teaching and research in arts and humanities, business, education, engineering, natural science and mathematics, and social and behavioral sciences. The facility has special collections, including books, periodicals, and access to electronic titles, seminar rooms, collaborative study spaces, computers, printers and copiers, and seating for 1,350 users. In addition to serving the

University community, the Library provides support to users from schools and businesses within the city and the state through various reciprocal borrowing agreements.

Reynolds Historical Library - Located on the UAB campus, the Reynolds Historical Library is a nationally respected collection of rare and important books, manuscripts and artifacts in the medical sciences.

Graduate School (est. 1970; Lori McMahon, PhD, Dean)

Established in 1970, the UAB Graduate School offers competitive annual recruitment funding awards to Masters and PhD entry programs to be used for enhancement of recruitment practices, including recruitment advertising, website upgrades, support of head-start summer programs, participation in diversity recruiting events, interview visit support and others. The Graduate School also hosts the annual Opportunity Zone recruitment event for regional undergraduates, collaborates with the UAB Office of Undergraduate Research to sponsor an annual Undergraduate Research Day and summer research intern events, and liaises with various departmental honors programs as well as the university-wide Science and Technology Honors Program. It also hosts the UAB McNair Scholars Program and the NIH-funded UAB PREP post baccalaureate program, and provides recruitment and ongoing mentoring programs for minority graduate students.

University-Wide Interdisciplinary Research Centers

University-wide thematic centers provide a framework for research and training. These multidisciplinary centers are open to all investigators with interests consistent with the mission of the given center. The centers assist in coordinating thematically-oriented efforts for extramural grants and contracts, in developing center-associated core facilities and in integrating enrichment programs that are important trainee resources. Centers require sponsorship from at least three UAB schools, substantive interdisciplinary faculty involvement; contribution to the intellectual environment in order to enhance faculty and student recruitment, development, and retention; an extramural financial base to support center and core activities; internal and external review processes to ensure quality and productivity; and leadership in the integration of research and service including community outreach or partnerships. Through a competitive review process, the Deans of sponsoring Schools and the Provost provide modest funds for research cores, pilot and feasibility studies and selective enrichment activities. The Center for Clinical and Translational Science, a university-wide center, integrates essential resources and services for clinical and translational research for all faculty and centers and has developed a jointly sponsored pilot program in translational research.

UAB Research Administration

In support of the research endeavors of a dynamic institution, the administration reporting to the Office of the Vice President for Research develops and improves processes and services that promote research and scholarship by faculty, staff, and trainees, that foster an environment of integrity in research and scholarship, that improve the quality of research, and that enhance economic development. Administrative units include the Office of Sponsored Programs (OSP), Conflict of Interest Review Board (CIRB), Institutional Review Board (IRB), Animal Resources Program (ARP), Institutional Animal Care & Use Committee (IACUC), The UAB Research Foundation (UABRF), Occupational Health and Safety (OH&S) and the Office of Sponsored International Programs (OSIP). Working in close affiliation with UAB Research Administration and individual Offices, the CCTS serves translational researchers to optimize business and oversight practices in support of research and training.

UAB Institute for Innovation and Entrepreneurship

The responsibility of the UAB Institute for Innovation and Entrepreneurship (IIE) is to serve as the nexus for UAB innovation, entrepreneurial educational models, applied research, management of intellectual property and an entry point for industries seeking collaborations with UAB. The UAB Research Foundation operates under the umbrella of the IIE.

Innovation Depot

Innovation Depot is a business incubator facility and program in Birmingham, AL, that resulted from a public-private economic development effort funded by the Birmingham regional business community, the Community Foundation of Greater Birmingham and other local private foundations, UAB, the City of Birmingham, and Jefferson County. Centrally located within close proximity of the UAB academic health center, the financial district, and the entrepreneurial district, Innovation Depot provides a broad support infrastructure to emerging

biotechnology / life science start-ups, information technology operations and service businesses in collaboration with UAB.

Informatics Institute

UAB's Informatics Institute, under the leadership of Dr. James Cimino is building a world class team of faculty and technologists to address four key informatics activities: (1) Biomedical Research: provide researchers with access to clinical and biological data and offer tools and expertise for their analysis and interpretation; (2) Patient Care: to work with the UAB Health System to apply informatics solutions to deliver research knowledge to improve the care experience, including quality and outcomes, of patients and their providers; (3) Informatics Research: to discover and develop new approaches, techniques and tools that will improve the quality and efficiency of biomedical research and patient care; and (4) Education: expand our informatics education to train researchers and practitioners to apply informatics solutions to their work and to train the next generation of institutional and national leaders in informatics.

At its core, this Institute is catalyzing the understanding and use of data, as well as the ability to use data to bring innovative solutions to the strategic and operational objectives across the academic medical center. Both the learning healthcare system and predictive, preventive, personalized and participatory (P4) medicine rely on the effective collection, analysis and use of data and the transformation of data to information and insight that strengthens our patient care, research and education. The knowledge necessary to control cost, to manage the health of patient populations, to improve in-hospital care through the reduction of errors and variations in clinical practice, is a direct result of an institution's data and analytics infrastructure. Through the Institute, the learning healthcare system and Personalized Medicine promote the integration of research and clinical practice in a mutually beneficial cycle of knowledge and understanding.

Information Technology (UAB IT)

UAB Information Technology Operations - The responsibility for the campus network, IT resources, and IT security resides with the UAB Office of the Vice President for Information Technology. UAB Health System IT operations are provided by the Health System Information Services (HSIS) unit. The CCTS utilizes services and resources provided by both UAB-IT and HSIS. The services and resources available to the CCTS are outlined below.

Integrated Research Administration - UAB has implemented an Integrated Research Administration Portal (IRAP). The underlying software consists of a suite of modules developed by InfoEd Global Inc. When fully implemented IRAP will support electronic submission of funding applications and compliance forms and will seamlessly connect the operations of the Office of Sponsored Programs (OSP), Institutional Review Board for Human Use (IRB), Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), Chemical Safety Committee, Radiation Safety Committee, Conflict of Interest Review Board and UAB Research Foundation. Other features of the system provide access to potential collaborators and automated notification of funding opportunities meeting criteria users set.

UAB Network Infrastructure

- *Campus High Speed Network Connectivity* The campus network backbone is based on a 10 gigabit redundant Ethernet network with 480 gigabit/second backplanes on the core L2/L3 Switch/Routers. For efficient management, a collapsed backbone design is used. Each campus building is connected using Gigabit Ethernet (GE) links over single mode optical fiber. Within multi-floor buildings, a gigabit Ethernet building backbone over multimode optical fiber is utilized. Category 5 or better unshielded twisted pair wiring is used to connect desktops to the network. Computer server clusters are connected to the building entrance using Gigabit Ethernet. All CCTS servers and desktops have 1 GE connections. The campus wireless network blankets classrooms, common areas and most academic office buildings.
- *UAB 10GigE Research Network* The UAB Research Network is currently a dedicated 10/40 GE optical connection between the UAB Shared HPC Facility and the RUST Campus Data Center. The network supports direct connection to high-bandwidth regional networks and has the capability to connect data intensive research facilities across the institution with the high performance computing services of the Research Computing System. This network can support very high speed secure connectivity between nodes connected to it for high speed file transfer of very large data sets without the concerns of interfering with other traffic on the campus backbone; thus ensuring predictable latencies.

- *Off-campus Network Connections* UAB connects to the Internet2 via the University of Alabama System Regional Optical Network (UASRON), a University of Alabama System owned and operated DWDM Network offering 10G Ethernet to the Southern Light Rail (SLR)/Southern Crossroads (SoX) in Atlanta, Ga. The UASRON also connects UAB to UA, and UAH, the other two University of Alabama System institutions, and the Alabama Supercomputer Center utilizing Gigabit Ethernet speeds. UAB is also connected to other universities and schools through AREN (Alabama Research and Education Network). Connection to the commodity Internet is via Gigabit Ethernet, of which UAB currently uses approximately 3.0 Giga-bits-per-second (Gbps).
- UAB was recently awarded an NSF CC*DNI Networking Infrastructure grant (CC-NIE-1541310) to establish a dedicated high-speed research network (UAB Science DMZ) that establishes a 40Gbps networking core and provides researchers at UAB with 10Gbps connections from selected computers to the shared computational facility. During 2016, the UASRON will be upgraded to support 100Gbps connections.

High Performance Computing Resources

The UAB Shared High Performance Computing (HPC) Facility provides UAB and the CCTS with a shared software and hardware infrastructure along with the necessary support for the high performance parallel and distributed computing, numerical tools and information technology-based computing environments, and computational simulation to UAB researchers. Expansion and use of the Cheaha computational and storage infrastructure is subsidized by UAB-IT and the office of the Vice President for Research. Through these subsidies, investigators are provided access to these shared HPC resources at no cost for routine processing needs (such as for the analysis of next generation sequence data).

The core compute resources for the Research Computing System is Cheaha, a commodity cluster with four generations of hardware (generations 1 and 2 have been retired) totaling 3,144 cores with fourteen data rate (FDR), quad data rate (QDR), and dual data rate (DDR) InfiniBand networks. This cluster is rated at more than 110 Teraflop/s computing capacity. The currently available generations of hardware include:

- Gen6: 97 nodes with 2 cpu/node, 12 cores/cpu (2328 cores total), 2.5 GHz Intel Xeon E2650 compute nodes. 44 nodes with 5GB RAM per core (128GB RAM total), 39 nodes with 10GB RAM per core (256GB RAM total) and 14 nodes with 16GB RAM per core (384 GB RAM total). FDR InfiniBand access to a high-performance GPFS parallel file system running on a 6.6PB (5.2PB usable) DDN disk array.
- Gen5: 12 nodes with 2 cpu/node, 8 cores/cpu (192 cores total) 2.0 GHz Intel Xeon E2680 compute nodes, QDR InfiniBand access to a high-performance GPFS parallel file system running on a 6.6PB (5.2PB usable) DDN disk array
- Gen4: 3 2x8 core (48 cores total) 2.70 GHz Intel Xeon compute nodes with 384GB RAM per node (24GB per core), QDR InfiniBand access to a high-performance GPFS parallel file system running on a 6.6PB (5.2PB usable) DDN disk array
- Gen3: 48 2x6 core (576 cores total) 2.66 GHz Intel Xeon compute nodes with 48GB RAM per node (4GB per core), quad data rate InfiniBand, ScaleMP, and QDR InfiniBand access to a high-performance GPFS parallel file system running on a 6.6PB (5.2PB usable) DDN disk array. (Supported by NIH grant S10RR026723-01.)

In addition to the 6.6PB GPFS parallel file system, an additional 400TB of storage is available for Cheaha users and this storage system uses OpenStack and Ceph to provide a cloud-centric HPC environment.

HPC Software Tools. CCTS Informatics has installed and supports a variety of bioinformatics tools that are available to be run from Cheaha. The Galaxy tool suite is available to provide web-based access to tools for analysis of next generation sequence data and analytical workflows. In addition, standalone packages are available for quality control (fastQC, Picard Tools), alignment (Abyss, Velvet, BWA, Bowtie) visualization (IGV), variant calling (GATK, SnpEff, annoVar), RNAseq (Cufflinks, Cuffdiff, TopHat) and microbiome and metagenomic analysis (QIIME, HUMAnN, MEGAN). These are just a few of the tools available from Cheaha.

Other Available High Performance Computing Resources

UAB is a member of the SURAGrid Virtual Organization (SGVO) on the Open Science Grid (OSG) (<http://opensciencegrid.org>). This is a national computer network and consists of nearly 80,000 computer cores aggregated across national facilities and contributing member sites. The OSG provides operational support for the interconnection middleware and facilitates research and operational engagement between members.

The *Alabama Supercomputer Center (ASC)* is a State-wide resource located in Huntsville, Alabama. The ASC provides UAB investigators with access to a variety of high performance computing resources. These resources include:

- An SGI Altix Cluster with 162 CPU cores, 1340 GB of shared memory, and 19 terabytes in the Panasas file system. Each CPU is a 64 bit Intel Itanium 2 processor. The system consists of a SGI Altix 350 front end node with 1.4 GHz processors and Altix 450 nodes with dual core 1.6 GHz and 9.67 GHz processors. This gives the entire system a floating point performance of 1035 GigaFLOPS. Sets of from 6 to 72 CPUs are grouped together into shared memory nodes. There are multiple networks connecting the processors. These include: NUMalink for sharing memory, Infiniband for file system access, gigabit ethernet for internet connectivity, and a secondary ethernet connection as a redundant fail over and management network.
- A Dense Memory Cluster (DMC) HPC system has 2216 CPU cores and 16 terabytes of distributed memory. Each compute node has a local disk (up to 1.9 terabytes of which are accessible as /tmp). Also attached to the DMC is a high performance Panasas file server, which has 17 terabytes of high performance storage accessible as /scratch from each node. Home directories as well as third party applications use a separate Panasas Filesystem and share 47 terabytes of storage. The machine is physically configured as a set of 8, 16, or 20 CPU core SMP boards. Forty nodes have 2.3 GHz quad-core AMD 8-core Opterons and 128 gigabytes of memory. Ninety-six nodes have 2.26 GHz Intel quad-core Nehalem processors. The DMC has 32 NVIDIA GPU (Graphic Processing Unit) chips. These are a combination of: two Tesla S1070 units (external GPUs connected in pairs to four DMC nodes); four DMC nodes configured with a pair of Tesla M2070 cards each, and four DMC nodes configured with four Tesla K20m cards each. These multicore GPU chips are similar to those in video cards, but are installed as math coprocessors.
- A large number of software packages are installed supporting a variety of analyses including programs for Computational Structural Analysis, Design Analysis, Quantum Chemistry, Molecular Mechanics/Dynamics, Crystallography, Fluid Dynamics, Statistics, Visualization, and Bioinformatics.

The UAB Assured Computing Platform

The UAB Assured Computing Platform (ACP) provides hosting, applications management, infrastructure support, and operation and maintenance services to UAB and CCTS Investigators. The ACP maintains an information assurance level that satisfies the Federal Information Processing Standard (FIPS) security impact of moderate. Primary services include hardware, OS software, storage, application management, testing, monitoring, patching, incident management/response, problem resolution, upgrades, security, disaster recovery, and help desk services. Information systems are customized to meet tenant compute requirements.

The ACP provides:

- An accredited Information System receiving ATO's from NASA and the NIH-NHLBI
- An audit by a third party (April 2014) for FISMA moderate security assurance
- Security standards that meet NIST SP800-53r4
- Dedicated firewall appliances
- Dedicated VPN appliances
- Multiple layers of IDS / IPS
- Multiple layers of vulnerability management
- Multiple layers of system level monitoring
- Active Directory / DNS services
- Enterprise PKI
- Patch and update services through System Center Configuration Manager
- Performance and resource management through System Center Operations Manger

- Dedicated SIEM platforms
- Two-factor authentication

The current hardware construction of the ACP includes:

- 11 Dell Server hosts
 - 92 CPU cores
 - 2.9 TB RAM
- 32 TB Hitachi NAS storage
- Redundant Palo Alto firewalls
- Dedicated network switches

The hardware architecture is scalable to meet customer requirements. Customer systems are constructed within the VMWare private cloud.

Operational Healthcare Information Systems

The UAB Health System (UABHS) through HSIS houses and supports over 2000 servers across 350+ applications and databases in a mostly virtualized computing infrastructure with a mix of operating systems including Windows, AIX, Linux (both Red Hat and SUSE), Solaris, zOS and Macintosh. The current storage for UABHS resides mostly on Hitachi Data Systems and provides 2 Petabytes of storage across a redundant fiber channel network. Both data centers run on a 10Gig backbone, utilizing Cisco Nexus equipment, and have redundant 40 Gig connections between the primary and secondary data centers. Backups are done on tape and multiple disk arrays.

- Clinical, financial, and administrative data are managed on behalf of the UAB Health System and include patient demographics records available in the Enterprise Master Member Index (EMMI) system; lab results dating back over ten years; documents dating back over ten years; encounter records, showing paths of patients across the UAB Health System; clinical images, including CT, MRI, X-rays, and more; user audit trails, showing the usage of the data by operational and clinical staff. Multiple systems are in place, and an active program to enhance integration / interoperability has been underway for several years.
- Horizon is a UAB-developed web portal used across the UAB Health System. Horizon includes all inpatient discharge and operative notes, all The Kirklin Clinic outpatient documents and notes and all laboratory and imaging results, each of which is integrated with EMMI to ensure valid patient demographics on the front end of the process. No documents can be created without first selecting a valid EMMI patient, and this occurs via a self-developed CORBA PIDS (Patient Identification Service) implementation wrapped around EMMI.
- The Cerner Millennium Core Clinical system is used as our core clinical system, supporting a complete clinical environment, with medication management, bedside device integration, and clinical decision support via alerts and content as some of the primary features. Cerner Millennium objects allows for object based access to the Cerner system for the purpose of integration. Although we have direct database access as well, this is a preferred abstraction layer that protects both Cerner and their customers from breakage due to changes in the database layer.
- The Cerner PowerInsight Clinical Data Warehouse is used to support reporting, analytics, quality measures and data extraction for research, clinical and administrative operations within UABHS. PowerInsight feeds data into our i2b2/SHRINE (version 1.7) informatics framework.
- Oracle SiteMinder supports clinical trials with tools for scheduling patient visits, tracking completion targets, and tracking expenses and billings to enhance optimal protocol performance and appropriate financial management for the study sponsor. To date, the major focus has been financial management.
- Forte Systems OnCore eClinical Solution is used by the Comprehensive Cancer Center and the CCTS Clinical Research Unit for management of clinical trials.

Software Licenses (Partial Listing)

A variety of software packages are available through institutional licenses maintained by UAB-IT. These include:

- Institutional campus-wide license for Oracle RDBMS.

- Institutional campus-wide Microsoft Campus Agreement and Microsoft Select programs that provide licenses for operating system upgrades, SQL Server, Microsoft Office, and Microsoft program development tools.
- Institutional campus-wide licenses for EndNote, MATLAB, LabView, IBM/SPSS, SAS, and others.
- The Section on Statistical Genetics provides investigators with access to a wide range of statistical software including SAS, S-plus, SPSS, and R. They also maintain many more specialized software programs including some specifically for statistical genetics such as SAGE, SIMWALK, ALLEGRO, DANDELION, GENEHUNTER, MERLIN, MX, PEDCHECK, PHASE, PREST, SOLAR, FASTLINK, VITESSE, SIMLA, and SUPERLINK amongst others. For software development purposes, the group has access to compilers for Fortran, C/C++, Perl, and Java as well as Fortran and Java IMSL libraries.
- CCTS Informatics maintains licenses and provides investigators with access to the Ingenuity Pathway Analysis tool suite and database that provides the ability to mine genomic and other – omics data for information on pertinent biological systems, networks, and pathways.

UAB and UAB Health System (UABHS) Security Policies and Practices

UAB-IT and the HSIS maintain a unified and comprehensive privacy and information security program that preserves and protects the confidentiality, availability and integrity of all information assets including patients, research, customer and business data. The integrated security program upholds values and provides high standards of service, trust, confidentiality and responsiveness to patients, customers, employees and business associates. The IT Security program encompasses regulatory requirements in a practical approach that preserves and protects the confidentiality, availability and integrity of information assets including patient, customer and business data.

The security program includes the following:

- IT security policies designed to help ensure a secure state of operations and information management.
- Technical security standards that document baseline security requirements for key technologies and platforms such as major operating systems, databases, network device operating systems, firewalls, web-server security, email, encryption, secure file transfer protocols, virus defense, media reuse and media disposal.
- A comprehensive qualitative risk management program.
- A computer security incident response plan that is supported by cross-functional response and recovery teams.
- User system access that is tightly controlled and meets standards required by various regulations and accrediting agencies such as HIPAA, JCAHO and CAP. Two-factor authentication is utilized for access to all shared systems. Users must agree to maintain password confidentiality, log-off terminals at the end of each user session and alert management when security violations become known. We also must routinely demonstrate compliance with Federal granting agencies and the corresponding security requirements such as the NIH, FISMA and the VA.
- An Institutional Firewall for perimeter and layered protection.
- Network Intrusion Detection Systems (NIDS) have been strategically deployed to continuously monitor Internet, Extranet and Internal communications.
- Zero Day Desktop and Server Centralized Microsoft Patch Update Services.
- A centralized firewall protected Email Microsoft Exchange system with Spam Scoring and Virus Scanning.
- 168bit 3DES encrypted IPSec tunnels for business associates, staff remote access, or partner VPN connectivity,
- Capability to support encrypted secure file transfers.
- Virus protection agents and comprehensive patch management programs installed on all computer workstations and servers to protect against malware infections.
- PGP whole disk encryption software that is required for all portable and high risk devices
- In-depth security training that is provided for all Faculty, Staff and students.

UAB has an extensive infrastructure to secure HIPAA-defined Electronic Protected Health Information (ePHI) from its creation and throughout its lifecycle. Secure web portals are utilized to make the required information accessible only to those who need access. The existing wireless infrastructure and secure VLAN architecture make the required ePHI portable but secure. Portable devices do not cache the data local to the device and transmissions are encrypted.

UAB/UABHS applications are designed and developed using a comprehensive set of security standards. Areas addressed within application security standards include: password construction, strength and control, browser technologies authentication and access control, security administration, and logging, auditing, and monitoring.

Internet applications mandate TLS encryption with strong cipher suites for the transmission of any sensitive data. Before going into production, all new Internet applications must be submitted for security testing. All identified security issues that could impact the confidentiality or integrity of our data must be corrected prior to production release. Applications are retested on a regular schedule that coincides with major release cycles. A comprehensive change management system is utilized for updates, production changes, quality control and revision management.

Physical security is controlled by the following:

- Access to data center facilities is electronically controlled using card access systems. The access to computing facilities is granted on an as needed basis based upon the employee's job function.
- Access to the data center is removed as soon as the employee leaves or changes jobs within the UAB/UABHS. Authorizing approvers perform periodic reviews of employees with data center access. All IT personnel are required to submit to pre-employment security background screening.
- Access of personnel entering the data center area is monitored by operators in the Control Room. Operators are authorized to permit access of individuals such as vendors who may be required to support a system in the data center, but do not have a card that permits them access, and provide escort while on site.
- A video surveillance system is in place in hallways, main areas, electrical and NOC entrances, and the main data centers. This system is managed and monitored by physical security personnel.

Environmental security is integral at each data center. All data centers are equipped with smoke and heat alarm systems, water sensors, fire suppression systems, fire extinguishers, emergency lights, air conditioning, humidity control systems, and backup power (UPS and Emergency Generators). UAB/UABHS has comprehensive provisions for Business Continuity and Recovery Systems. UAB contracts with third party vendors for rapid emergency equipment shipping, and are currently implementing a "hot site" alternative-processing center. Supplemented by on-site technical and administrative personnel, this solution will facilitate the exercise of a recovery plan, thus enabling the institution to rebound from an unplanned outage should a critical IT disruption occur.

Core Facilities

UAB's shared Core Facilities offer state-of-the-art instruments, resources and technologies that are beyond the reach of the individual laboratory, available to investigators and trainees throughout the Hub and Partner Network research enterprise. Scientific capacities that include animal models, biomolecular analysis, imaging, genomics, proteomics and metabolomics, exercise medicine, structural biology, biological sample repositories and many others are available to CCTS investigators to support fundamental and translational research. Selected examples are listed below:

Biomolecular Analysis – To assist in the characterization of molecular interactions, signal transduction pathways and other fundamental analyses, Core expertise and technology are available to help define mechanisms of action and clinical and translational applications of research discovery.

- *Pharmacokinetic and Pharmacodynamic Shared Facility* – The PK/PD Shared Facility offers pre-clinical and clinical trial design to support sample analyses for drug and metabolite quantitation as well as PK/PD determinations. Data analysis and interpretation is also available.

- *Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Expression Core* – The CFTR assists investigators interested in CF with the complex technology necessary to efficiently express CFTR in experimental systems. It maintains a repository of reagents for studying CFTR, including over 50 constructs containing mutations that lead to disease and CFTR plasmid molecules used as part of gene therapy protocols in CF patients in the past. Expertise is available to assist with expression using vaccinia, adenovirus or other methodologies and to detect expression using antibody directed against CF related gene products.
- *Islet Resource Facility* – The Islet Resource Facility provides state-of-the-art islet isolation and in vitro/in vivo assessment of functionality. The Islet Resource Facility is equipped to process human and non-human tissues and isolating islets. A complementary facility, the Beta Cell Biology Core assists investigators with islet morphology and measurements of whole pancreas beta cell mass, whole pancreas insulin content, whole pancreas beta cell morphometry, and whole pancreas islet visualization (stitching).
- *UAB Vector Production Facility* - The UAB Vector Production Facility provides the UAB translational research community with the capability of producing viral vectors and cell-based proteins in compliance with current Good Manufacturing Practices (cGMP) for FDA-directed preclinical studies and early phase human clinical trials of cancer.
- *Tissue and Immunopathology Core Facility* - The Tissue and Immunopathology Core Facility has extensive experience in collecting, processing, storing/banking, and distributing a wide range of cancer-related tissues. The Core has established a bank of well characterized tumor specimens and matching normal/control specimens from patients who have given informed consent for their tissues to be used in genetic and other types of research so tissue can be supplied to investigators along with clinical data including outcome and familial histories of ovarian, breast, and related tumors. Fresh, frozen and paraffin preparations of tissues can be supplied as well as unstained tissue slides, tissue matrix arrays, microdissection and other histology services. The Core also provides light microscopic and immunocytochemical interpretation of animal and human tissues and cytologic materials including methods to detect gene products within transfected cells and adjacent tissues.
- *Multidisciplinary Molecular Interaction (Biacore) Core (MMIC)* – The MMIC uses a GE Biacore T200 optical biosensor to detect biomolecular interactions of proteins, nucleic acids, carbohydrates and lipids. Characterization of interactions includes binding specificities, kinetics, affinity, concentration and epitope mapping.
- *Comprehensive Flow Cytometry Core* - The Comprehensive Flow Cytometry Core provides instrumentation and expertise to support fundamental mechanistic studies of disease and the identification of new biomarkers for disease diagnosis and the development of novel treatments. The facility is equipped with two BD FACSAria II, two BD LSR II, two FACSCalibur instruments, a Tecan Infinite M200 Pro multifunctional microplate reader that can provide a variety of measures including fluorescence intensity, time resolved fluorescence, fluorescence energy transfer, flash fluorescence, absorbance, glow fluorescence, bioluminescent resonance energy transfer in 6 to 384-well microplates, and a GUAVA EasyCyte flow cytometer that is available for simple flow cytometry analysis. High throughput flow cytometry is enabled using a high-throughput flow cytometry platform interfaced with a FACSCalibur flow cytometer. A BioPlex Suspension Array System (a flexible multiplex analysis system permits the simultaneous analysis of up to 100 different biomolecules (proteins, peptides, or nucleic acids) in a single microplate well.
- *Targeted Metabolomics and Proteomics Laboratory* –Complementing proteomics capacities, the Targeted Metabolomics Laboratory is organized to provide a variety of analytical and technical services using mass spectrometry to UAB investigators. The laboratory is well equipped to analyze the metabolome, including five mass spectrometers two triple quadrupole instruments (AB Sciex 3200 and 4000) and a quadrupole-linear ion trap instrument (AB Sciex 4000Qtrap), a quadrupole-TOF (AB Sciex 5600) and a Varian gas chromatography-MS. The ABSciex 5600 is particularly powerful for comprehensive and targeted lipidomics and metabolomics. This technology is instrumental in characterizing the host molecules as well as those produced by bacteria, which may represent the link between the microbiome and chronic diseases such as cancer, diabetes and obesity.

Southeastern Biosafety Laboratory (SEBLAB) - Southeastern Biosafety Laboratory is a 43,500 s.f. facility that houses state-of-the-art biosafety level 2 and level 3 laboratories as well as animal biosafety level 3 laboratories. SEBLAB's design includes flexible and secure laboratories, animal housing and procedure space,

and laboratory support space. Specialized resources at SEBLAB include an aerobiology suite, imaging suite, irradiator, vaporized H₂O₂ decontamination and a decontamination chamber.

UAB Heflin Center Genetics / Genomics –UAB cores support fundamental, routine capacities in sequencing and genotyping, DNA Sequencing as well as leading-edge technologies in next-generation genomics on a low-throughput scale to establish proof-of-concept among a broad research portfolio.

Laboratory

The Genomics Core is dedicated to basic and applied research in genomics and genetics. The Core, which opened in 2001, is housed on the fourth floor of the Kaul Human Genetics Building and the facility is well-equipped state-of-the-art laboratories. The Core laboratory is 2,500 square feet in area and has bench and desk space for all the staff required to run the facility and all the standard equipment for molecular biology, genetics, and genomics work, including refrigerators, freezers, centrifuges, incubators, water baths, etc. The Core provides the necessary expertise in Next-Generation Sequencing library production. To that end, the core has the Covaris S2 sonicator and the cBot cluster station housed in a separate room on the 4th floor of the Kaul building. The S2 is used for DNA fragmentation, while the cBot is used to generate the clusters of DNA for sequencing on the flowcells for both Illumina GAIIx and HiSeq2500). A large equipment room located on the 7th floor of the Shelby Interdisciplinary Biomedical Research Building houses the Illumina GAIIx, HiSeq2500 and two Illumina miSeq sequencers and supporting computers.

Computer

The Core utilizes a local install of the Galaxy software suite for sequencing data analysis on UAB's Cheaha compute cluster (described High Performance Computing Resources above). In addition to the Cheaha cluster the UAB Stem Cell institute maintains the iComputer system from Illumina. The data obtained from the sequencing instruments is sent directly to the IlluminaCompute (iCompute) server. The iComputer is comprised of 3 Dell R610 servers with 8 CPU Cores and 48GB of RAM, each with 48TB of Isilon IQ12000x storage. The iComputer runs CASAVA 1.8 for data analysis. The iCompute is also on a 1Gbps data lines within the university for easier data transfer between the iCompute and the Cheaha cluster.

Major Equipment

- An Illumina Genome Analyzer IIx instrument includes a paired-end module and has the capacity of approximately 90Gb of sequence data per instrument run. The instrument is located in a dedicated equipment room and fully staffed by a team of experienced technicians.
- An Illumina HiSeq2500 sequencer, which has positions for two flowcells that can be run independently and can provide up to 600Gb of DNA sequence per instrument run, co-located with the GAIIx and two Illumina miSeq instruments.
- cBot Cluster Station. The cBot cluster station provides the platform necessary to generate the flowcells for both the GAIIx and the HiSeq2000 instruments.
- Covaris S2 Sonicator. The Covaris S2 sonicator provides the mechanism to fragment DNA molecules for library generation for Illumina sequencing. The Covaris has a dedicated laptop computer to run the instrument.
- Affymetrix GeneChip system: The system includes the GeneChip Scanner 3000 7G with 48 position autoloader capable of scanning up to 48 microarrays unattended. The scanner can image the high-density 5µm GeneChip arrays, including exon, tiling and genotyping arrays (at their respective resolutions. Two Fluidics Station 450s capable of processing 8 GeneChip arrays simultaneously (32 arrays per day); and two Hybridization Oven 640s capable of hybridizing up to 128 GeneChip arrays.
- An Illumina BeadXpress and iScan instruments. Located in a dedicated equipment room adjacent pre-PCR room, the Illumina scanners include full robotics and are staffed by a team of three dedicated technicians.
- Tecan Evo robot for liquid handling and Illumina microarray processing.
- One Axon GenePix 4000B glass-slide microarray scanners (located in the computer lab): The scanner is capable of scanning a single glass slide microarray in approximately 10 minutes at a resolution of 5µm.
- Roche 480 LightCycler for real-time quantitative PCR using with Taq-man or fluorescent detection.

- Beckman BioMek FX single-arm liquid handling robot: Capable of automated liquid transfers, dispense and aspirate procedures using almost any variety of plate, tube or container.
- Applied Biosystems 3730 Genetic Analyzer. The 3730 is used to process samples for Sanger Sequencing and fragment analysis. It is housed in the main core laboratory and is staffed by a dedicated technician.

Animal Models - To enable proof of principle investigation and studies of biological function / significance, model systems play an essential role in clinical and translational science. UAB has established essential Cores to enable the use of animals to model human disease. The human to animal model (H2M) consultative service, championed by the CCTS, won an AAMC innovative practices award in 2014. The facilities below operate in close cooperation with the UAB Animal Resources Program which is accredited by the AAALAC, is registered as a research facility by the USDA, and has an Assurance of Compliance on file with the Public Health Service Office of laboratory Animal Welfare

- *UAB Animal Model Systems Facility*– Genetically modified murine models continue to be the most tractable system to examine the role of an identified genetic variant associated with human disease, as well as creating much needed translational models for developing novel therapeutics. The facility provides expertise and technical service related to the creation of genetically modified rodent models. The Core works with investigators to devise targeting strategies and will facilitate DNA or ES cell microinjection, ES cell gene targeting, assisted reproduction and line cryopreservation. Additionally, it provides unique services for in vitro fertilization, embryo cryopreservation, sperm cryopreservation, long-term storage of cryopreserved embryos and sperm, and assistance with reproduction / re-derivation of transgenic animals.
- *UAB Zebrafish Facility Resource* - This resource includes a recirculation aquaria system with a central water conditioning/purification system supplying 27 racks (>2200 aquaria) to support the use of Zebrafish as an investigative model of human development. The *in vitro* manipulation laboratory includes four embryo processing stations equipped with dissection microscopes, injectors, and micromanipulators; incubators; a pipette puller; and a fluorescent microscope, as well as other smaller equipment to be used for embryo manipulation.
- *Small Animal Microsurgical Core* – The major goals of this unit aim to provide investigators with the expertise and technology to develop animal models of human disease that provide important insights that can help to define the impact(s) of therapeutic interventions and preventative approaches. The core supports the development and evaluation of rodent models of acute kidney injury specifically in the setting of ischemia/reperfusion injury, sepsis and renal transplantation. It also provides access to multi-modality imaging of small animals, as well as microsurgical techniques and measurements of GFR, tubular reabsorption, renal hemodynamics with assessment of tubulo-glomerular feedback, metabolic assessment of kidney oxygen consumption and nitric oxide in rodents. It provides surgical expertise and facilities to UAB investigators interested in various aspects of organ injury and repair. Services offered include heterotopic heart transplantation, orthotopic kidney transplantation, orthotopic abdominal aortic transplantation, ischemia/reperfusion models for lung, kidney and heart.
- *Animal Physiology and Imaging Shared Facility* - This facility provides body composition assessment of non-human primates and rodent models by chemical analysis, DXA, QMR, and micro-computed tomography. The core can also evaluate energy balance by measurement of metabolic rate, food intake, fecal output, activity and body temperature as well as cardiovascular assessment with echocardiography and blood pressure. It can also facilitate animal imaging including bioluminescence and fluorescence imaging, gamma ray imaging, SPECT/CT, microPET/CT, bioluminescence, fluorescence, magnetic resonance (MR) imaging and ultrasound imaging. This technology has been used to detect tumor location and mass, receptor expression (tumors, brain, etc.), organ function, metabolism, perfusion, and response to therapy.
- *Behavioral Assessment Core* - The Behavioral Assessment Core provides a facility for the behavioral testing of mice and rats. Newly created transgenic mice can be analyzed using the most-accepted battery of behavioral tests, including a primary neurological screen, sensory and motor tests (including rotorod, spontaneous locomotor activity, walking coordination, etc.), an open field test for emotional and exploratory activity, and an elevated plus maze for anxiety. Motor function testing is available, and cognitive testing is provided with the Morris water maze, Barnes maze, holeboard maze and eight-arm radial maze tasks. Other, more complex, tasks are also available.

- **Gnotobiotic Animal Core** - The microbiota in an organism can exert both beneficial as well as deleterious effects on their animal hosts. The Gnotobiotic Animal Core provides the expertise, sterile technology (e.g., isolators) and standard operating procedures / quality control protocols to develop animal models ideally suited to characterize the role of the microbiome in pathology. The Core is also equipped to assist investigators in the development of transgenic models in a germ-free environment.

Imaging - These facilities offer pre-clinical research support with a range of cutting-edge imaging modalities and assistance with protocol development and analyses. The resources are available to CCTS Partner network investigators, trainees and partners. These core capacities support imaging across the research spectrum.

- *High Resolution Imaging Facility* – The High Resolution Imaging Facility provides access to instrumentation and expertise that supports fundamental mechanistic studies and the development and testing of new biomarkers and treatments for disease. The facility offers multiphoton laser scanning microscopy, confocal laser scanning microscopy, multi-photon imaging, an Amnis Imagestream imaging cytometer, Ca²⁺ imaging, FRET, FRAP and FLIM imaging, digital microscopy equipment configured with deconvolution software, and image processing programs. The facility also includes an FEI TEM and FEI environmental scanning EM and is staffed by experienced technical specialists who are able to offer assistance at each stage of an imaging experiment.
- *Functional Neuroimaging Laboratory* – Replacing a 3T Siemens Allegra instrument, a new 3T Siemens Prisma whole body fMRI scanner will be available for structural and functional imaging in 2015. The facility is supported by highly trained personnel, including a full-time MR technologist, to enable research protocols involving imaging and image processing in intellectual and developmental disabilities, and neurological disease research. The laboratory has state-of-the-art equipment for audio/visual stimulus presentation and response devices to monitor behavior during scanning.
- *Advanced Imaging Facility* - The Advanced Imaging Facility, which includes the Radiopharmaceutical and Materials Laboratory, is designed to develop custom radiopharmaceuticals for SPECT and PET imaging, thus enabling immediate capacity in basic and preclinical efforts. The facility includes a tracer preparation laboratory and radiopharmaceutical laboratories. The centerpiece of the facility is a newly-acquired TR24 cyclotron, manufactured by Advanced Cyclotron Systems (ACS), a division of EBCO, which operates at 24MeV and has current capacity of 300uA. This instrument enables UAB investigators to produce many different radionuclides with appreciable yields including PET radioisotopes, SPECT radioisotopes, radiotherapeutic isotopes, and radioisotopes for research applications for SPECT animal imaging that could be correlated with MRI. The cyclotron and associated radiopharmaceutical laboratories are adjacent to a new GE PET/MR imaging system (coming in 2015) which will provide a significant enhancement of UAB's translational research capabilities.

Structural Biology - A comprehensive structural biology capacity at UAB has been developed, leveraging the robust expertise and technological investment to enable high resolution microscopy and proteomics, including mass spectrometry, post-translational modification analysis, X-ray crystallography and high-field NMR. Together, these bioanalytical resources are a critical feature available to the biomarker and drug-discovery initiatives.

- *Mass Spectrometry/Proteomics (MSP) Shared Facility* - Mass Spectrometry and Proteomics Facilities are organized to provide a variety of analytical and technical services using mass spectrometry to UAB investigators. These include clinical proteomics, 2D-proteomics, quantitative small molecule and peptide analysis, and high resolution mass spectrometry. In addition to standard sample preparation and separation equipment, the Facilities are equipped with an array of mass spectrometers: two triple quadrupole instruments (AB Sciex 3200 and 4000); a quadrupole-linear ion trap instrument (AB Sciex 4000Qtrap); a quadrupole-TOF (AB Sciex 5600); a Varian gas chromatography-MS, two fourier transform-ion cyclotron resonance instruments; and a Bruker MALDI TOF-TOF instrument.
- *UAB High Field NMR Facility* - The UAB High-Field NMR Facility provides instrumentation and expertise for elucidating the structure and dynamic behavior of macromolecules. It provides a capacity to analyze molecular interactions critical for both understanding basic mechanistic structures and using that information to refine potential therapeutics for a variety of diseases. The facility is equipped with Bruker 600 (Avance III), 700 (Avance II) and 850 (Avance III) MHz NMR spectrometers with cryoprobes. A 500 MHz Bruker Avance NMR Spectrometer with TXI and TBI probes is also available.

- *X-ray Crystallography Shared Facility* – Cutting-edge technology and expertise is available to enable differential scanning and isothermal calorimetry, high-throughput aqueous and membrane protein crystallization, and structure determination via in-house or synchrotron x-ray systems.
- *Cryo-Electron Microscopy* – High resolution electron microscopy and tomography of stained and unstained specimens, including cryo-EM of fully-hydrated samples, such as protein complexes, viruses, fibers, liposomes and whole prokaryotic cells is available in this shared resource. FEI Tecnai F20 200kV field-emission gun microscope equipped with a high-sensitivity Gatan 4k x 4k CCD camera and tomographic acquisition software, supported by highly trained staff as well as robotic sample preparation tools and Leica ultracut UC6 cryo-ultramicrotome enable high caliber images.

Data Resources available to CCTS Investigators and Trainees (examples)

1. Medicare, Medicaid, and Administrative Databases from Private Insurers

CCTS HUB faculty (Curtis, Kilgore, and Muntner) have considerable experience in managing and analyzing the Medicare 5% sample and (50 state) Medicaid (MAX) data. Work to date has predominately focused on the epidemiology of osteoporosis, bone mass measurement, the longitudinal comparative effectiveness and safety of biologic medicines, and the prevention and treatment of cardiovascular disease. The data management and analysis team includes 14 faculty members in the Schools of Public Health and Medicine, supported by a senior systems analyst, 2 senior statisticians, and 19 statistician/analysts. Data management and analysis tasks and resolution of study design and statistical analysis issues are coordinated through monthly Medicare/Medicaid Data Group meetings, attended by investigators and project staff and weekly meetings dedicated to specific projects.

One strength of Medicare and Medicaid is that the computerized pharmacy records provide an objective, detailed, high-quality, and relatively low-cost measure of drug exposure. Inpatient, outpatient, nursing home, and other files provide information on outcomes and other important study variables. Although the limitations of these data always must be considered, Medicare and Medicaid databases have long been recognized as an essential resource for pharmacoepidemiology and health services research.

CMS encourages researchers to use its diagnosis and treatment database. They will provide a file that contains all records submitted with date of birth, gender and date of death information. The Medicare ID returned on this file is an encrypted ID that contains no identifying information including no component of the SSN. The encryption is uniquely created for this proposed study and does not correspond in any way to Medicare data obtained for other studies. CMS has well established, secure procedures for linking research subjects' identifiers to Medicare files for purposes such as this. They uniquely encrypt IDs for each project. Thus, the Medicare data received cannot be combined with Medicare data from any other source or project without CMS assistance.

The Medicare component of this resource includes (1) 1999-2014 claims on a national sample of over 3.3 million beneficiaries, including all claims from inpatient, outpatient, physician, skilled nursing, home health and hospice providers; (2) 2006-2014 claims data for 7 million beneficiaries with osteoporosis; (3) Medicare data on over 18,000 subjects included in a large prospective cohort study of stroke and other medical conditions; (4) Medicare data on subjects with autoimmune disorders included in a large retrospective cohort study; (5) Medicare data linked to Surveillance Epidemiology and End Results (SEER) cancer registry data on over 400,000 cancer patients diagnosed during the period 1999-2005; and (6) 100% cohort of 585,000 MI (myocardial infarction) Medicare beneficiaries from 2006-2012. The Medicaid database includes: (1) national claims data on over 55 million beneficiaries for 1999-2002; (2) claims data on over 490,000 Medicare/Medicaid dual-eligible beneficiaries for 2003-2005; (3) claims data on over 9 million beneficiaries with autoimmune diseases and ADHD for 2006-2010; and (4) claims data on subjects included in the special cohorts mentioned above. In addition, we have Medicare Part D data for 2006-2014 on the 5% national sample of beneficiaries. We also have medical and pharmacy claims data on over 100,000 VIVA Health members for 2010-2014.

Computing resources are housed in the Multimedia Information and Technology services facility in the School of Public Health. The facility is locked and all servers and drives are physically secured. Entry into sensitive areas requires appropriate identification and passwords for access. Computing resources available in the UAB PEER Group consist of multiple Dell PowerEdge (PE) servers, tape drive units, network switches and software for word processing, data management, and statistical analyses. The primary file servers on which analyses will be run are Dell PowerEdge R510s, each with 64gb of RAM and dual-core processors running Microsoft Windows 2008 R2 server operating system. These servers are clustered together to provide both redundancy and system integrity in the event of hardware malfunctions. Approximately 48tb of disk space is available for data storage and is optimized for storing large SAS datasets across separate drive arrays. A Dell robotic tape library is used to back up data on a nightly basis. Additional Dell servers are used for Active Directory, Web server, and other system management tasks. Software available for projects includes SAS versions 9.3 and 9.4, R version 3.0.3, Stata version 12, Microsoft Office 2010, and other utility software.

Data security and integrity is accomplished by a combination of hardware and software protocols. Comodo and Microsoft firewall software packages are used to prevent access from unauthorized computers. Microsoft Forefront is used to provide anti-virus protection. Access to the server is restricted to computers located on the UAB campus with specific IP addresses. Data containing individually identifiable data are stored in encrypted, password-protected datasets that can only be accessed through a Remote Desktop Connection to the server. Data integrity is accomplished by a nightly backup routine and by replicating the data to a secure, off-site server. The UAB Office of Internal Audit conducted an audit of the facility where the data are housed. Based on their recommendations, additional security protocols were implemented and the User Authorization Agreement was amended to reflect stricter CMS guidelines. The auditor was pleased with the attention to detail and also gave suggestions for maintaining a secure environment. All project personnel are required to have current IRB and HIPAA training and will be signatories to Data Use Agreements in order to access any research identifiable data.

2. Coronary Artery Risk Development in Young Adults (CARDIA)

The Coronary Artery Risk Development in Young Adults (CARDIA) Study examines how heart disease develops in adults. In 1986, it began with a group of 5,115 African-American and Caucasian men and women aged 18-30 years. The participants were selected so that there would be approximately the same number of people in subgroups of race, gender, education (high school or less and more than high school) and age (18-24 and 25-30) in Birmingham, AL; Chicago, IL; Minneapolis, MN; and Oakland, CA. These same participants were asked to participate in follow-up examinations during 1987-1988 (Year 2), 1990-1991 (Year 5), 1992-1993 (Year 7), 1995-1996 (Year 10), 2000-2001 (Year 15), and 2005-2006 (Year 20). A majority of the group has been examined at each of the follow-up examinations (90%, 86%, 81%, 79%, 74%, and 72%, respectively).

While the specifics of each examination has differed somewhat, data have been collected on a variety of factors believed to be related to heart disease. These include conditions with clear links to heart disease such as blood pressure, cholesterol and other lipids. Data have also been collected on physical measurements such as weight and skinfold fat, as well as lifestyle factors such as substance use (tobacco and alcohol), dietary and exercise patterns, behavioral and psychological variables, medical and family history, and other chemistries (e.g., insulin and glucose). In addition, subclinical atherosclerosis was measured via echocardiography during Years 5 and 10, computed tomography during Years 15 and 20, and carotid ultrasound during Year 20. Safford, Lewis, and K. Saag have mentored trainees using CARDIA data.

3. Consortium for the Longitudinal Evaluation of African Americans with Early RA (CLEAR)

The CLEAR Registry and Repository is a National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)-funded project established through a contract in 2000 and renewed in 2006. The goals of this registry were to compile extensive demographic, socioeconomic, clinical, and radiographic data on African-Americans with rheumatoid arthritis and to collect biological samples (genomic DNA, RNA, serum) to allow a comprehensive analysis of factors influencing disease susceptibility and severity in African-Americans with RA. The CLEAR Registry provides a unique and valuable resource for the scientific community to explore genetic and non-genetic factors that influence disease occurrence and outcomes. The CLEAR Registry is composed of African-Americans RA patients with both early disease (≤ 2 years) who were followed longitudinally, as well as a cross-sectional cohort at various disease durations. CLEAR was a collaborative effort among five institutions: University of Alabama at Birmingham (Coordinating Center), Grady Hospital/Emory University, Atlanta, GA, University of North Carolina, Chapel Hill, NC, Medical University of South Carolina, Charleston, SC, and Washington University, St. Louis, MO. The CLEAR Registry is the largest available cohort of African-American RA and has a wealth of data, including radiographic, genetic, and autoantibody data.

4. (ENCOURAGE): Evaluating Community Peer Advisors and Diabetes Outcomes in Rural Alabama

ENCOURAGE is a group-randomized, controlled implementation trial in partnership with the UAB DRTC and established community coalitions. It is designed to improve diabetes health outcomes in adult patients (> 18 years of age) with uncontrolled diabetes living in Alabama's Black Belt region. Peer advisors with diabetes or familiar with its management will counsel and link patients to clinical care and community resources. Part of the 12-month, weekly intervention for 8 weeks, followed by monthly contacts for the remainder of the year, is empowering/activating patients to self-manage their diabetes. Four community coordinators, 36 peer advisors,

and 424 research participants were enrolled for the full study. The infrastructure established through the initial study has led to four additional projects. The first is examining the cost-effectiveness of using peer advisors. The second will assess peer support intervention for patients with diabetes and chronic pain. The third will examine peer advisor roles and integration into a larger health care team. Finally, investigators will look to implement the program in Birmingham. All of these projects will provide junior investigators with the opportunity to conduct research in disadvantage areas and engage both patients and other community stakeholders in research.

5. The Global Longitudinal Study of Osteoporosis in Women (GLOW)

GLOW is an international study that collects, analyzes and distributes data to understand ways in which practice patterns influence the care of patients at risk for osteoporotic fragility fractures. GLOW is a prospective, longitudinal, observational study of women 55 years of age and older who visited a primary care physician during the two years prior to the study. A major study objective is to characterize the clinical and demographic attributes of patients at risk of fracture from representative sites in Europe, North America and Australia in order to improve patient outcomes. Data on osteoporosis risk factors, treatment approaches, patient behavior, and fracture outcomes with an annual patient survey over a 5 year period are collected. GLOW participants are from 10 countries, 17 regional sites with 706 (337 in the US) physicians enrolled and 60,461 (31,074 in the US) women enrolled. K. Saag has mentored trainees using GLOW data.

6. The Osteoporotic Fractures in Men (MrOS) Study

The Osteoporotic Fractures in Men (MrOS) Study (Lewis, CE PI) funded by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Aging (NIA), and the National Cancer Institute (NCI), began in July 1999. MrOS a 7-year multi-center prospective, longitudinal, observational study examining risk factors for vertebral and all non-vertebral fractures in older men, and of the sequelae of fractures in men enrolled approximately 6000 men aged 65 and older). The specific aims of the MrOS study include: (1) to define the skeletal determinants of fracture risk in older men, (2) to define lifestyle and medical factors related to fracture risk, (3) to establish the contribution of fall frequency to fracture risk in older men, (4) to determine to what extent androgen and estrogen concentrations influence fracture risk, (5) to examine the effects of fractures on quality of life, (6) to identify sex differences in the predictors and outcomes of fracture, (7) to collect and store serum, urine and DNA for future analyses as directed by emerging evidence in the fields of aging and skeletal health, and (8) define the extent to which bone mass/fracture risk and prostate diseases are linked. Lewis and Curtis have mentored trainees using this cohort.

7. The Multicenter Osteoarthritis Study (MOST) Study

Since inception in 2002, The Multicenter Osteoarthritis Study (MOST) Study, funded by a grant from the National Institute On Aging (Cora Elizabeth Lewis PI, UAB), is a cohort of 3,026 adults aged 50 to 79 years from the community with either symptomatic knee osteoarthritis or high risk of knee osteoarthritis based on obesity, knee pain, or previous knee injury. This large, multifaceted and comprehensive study of persons with knee OA, or at high risk of disease, examines the relation of potentially important risk factors to the development or progression of a major disabling disease and to provide new insights into disease biology and potential opportunities for prevention. Lewis and Curtis have mentored trainees using this cohort.

8. Reasons for Geographic And Racial Differences in Stroke (REGARDS)

Funded in 2003 (R01) by the National Institute of Neurological Disorders and Stroke (NINDS), the Reasons for Geographic And Racial Differences in Stroke (REGARDS) cohort, is a prospective study of 30,239 community-dwelling Caucasian and African American adults aged 45+ who were sampled from 1,866 of the approximate 3,000 counties in the continental US. The cohort was oversampled for African Americans (~42%) and residents of the Southeastern Stroke belt (~56%). G. Howard is the principal investigator of the REGARDS study. The purpose of the REGARDS project is to understand why people in some parts of the country develop more strokes than people in other parts of the country, and why African-Americans develop more strokes than whites. However, the study has been enriched by approximately 67 funded ancillary studies, both adding new and novel exposures (childhood socio-economic status, air pollution, direct measures of physical activity, kidney biomarkers, etc.) and outcomes (cognitive change, myocardial infarction, sepsis, venous thrombosis, etc.). Participants are randomly sampled with recruitment by mail then telephone, where data on stroke risk factors, socio-demographic, lifestyle, and psychosocial characteristics are collected. Written informed consent, physical and physiological measures, and fasting samples are collected during a subsequent in-home visit.

Participants are followed via telephone at 6-month intervals for identification of stroke events. A second in-home assessment approximately 10 years after the baseline assessment is currently being completed on approximately 15,000 of the participants. The novel aspects of the REGARDS study allow for the creation of a national cohort to address geographic and ethnic differences in a wide range of diseases.

9. Systolic Blood Pressure Intervention Trial (SPRINT)

The University of Alabama at Birmingham serves as one of the NIH/NHLBI Clinical Center Networks (CCN; Oparil, PI; Lewis, Co-PI) and Tulane serves as one of the clinic sites (Krousel-Wood, Site-PI) for the Systolic Blood Pressure Intervention Trial (SPRINT). The Systolic Blood Pressure Intervention Trial is a multicenter, randomized, controlled trial that compares two strategies for treating systolic blood pressure: one targets the standard target of <140 mm Hg, and the other targets a more intensive target of <120 mm Hg. Enrollment focused on volunteers of age ≥ 50 years (no upper limit) with an average baseline systolic blood pressure ≥ 130 mm Hg and evidence of cardiovascular disease, chronic kidney disease, 10-year Framingham cardiovascular disease risk score $\geq 15\%$, or age ≥ 75 years. The Systolic Blood Pressure Intervention Trial recruitment also targeted three pre-specified subgroups: participants with chronic kidney disease (estimated glomerular filtration rate < 60 mL/min/1.73 m²), participants with a history of cardiovascular disease, and participants 75 years of age or older. The primary outcome is first the occurrence of a myocardial infarction (MI), acute coronary syndrome, stroke, heart failure, or cardiovascular disease death. Secondary outcomes include all-cause mortality, decline in kidney function or development of end-stage renal disease, incident dementia, decline in cognitive function, and small-vessel cerebral ischemic disease. For the trial, 9361 people from 102 clinics were recruited and randomized. This includes 3331 women, 2648 with chronic kidney disease, 1877 with a history of cardiovascular disease, 3962 minorities, and 2636 ≥ 75 years of age. Oparil, Lewis, Krousel-Wood, and Muntner are available to mentor trainees using this cohort.

10. UAB 1917 HIV Clinic Cohort

The 1917 clinic cohort is a prospective, observational HIV clinical cohort study established in 1992 through support by CFAR. It includes extremely well characterized patients (>7000 overall, 1700 active). In 1999, the database was expanded to include real-time collection of clinic utilization data, thereby allowing cost / expenditure analyses. In August 2004, the UAB 1917 Clinic deployed a client-server based point-of-care electronic medical record system (1917 EMR) developed within the clinic to its own specifications. The 1917 EMR system allows for real-time collection of medication, laboratory, clinical, behavioral, and health care utilization data. Over the years numerous clinical and behavioral comparative effectiveness studies have been conducted through the cohort. These include evaluation of the "efficacy vs. effectiveness" of initial ART regimens in patients treated in clinical trials vs. routine care.

The UAB 1917 Clinic Cohort is housed at the UAB 1917 HIV/AIDS Clinic on a Dell PowerEdge 2300 server, which is part of a seven server farm that provides the 1917 Clinic IT infrastructure. This structure allows for flexible and comprehensive data query capabilities. The current storage capability exceeds 500 GB and contingency/disaster recovery procedures are in place with remote real-time back-up of data at two additional sites. Over 100 users utilizing our 93 personal computers (including 4 computers dedicated to trainees) regularly access the applications housed in this secured environment. Additionally, 7 exam rooms are outfitted with touch screen computers linked to a web-based platform for completion, transmission and secure storage of Patient Reported Outcomes (PROs) questionnaires completed routinely during clinic visits. Shared conference rooms, fax machines, scanners, and copy machines are co-located and readily available to 1917 Clinic Cohort personnel and trainees on the first floor of the Community Care Building. M. Saag and Mugavero are available to mentor trainees using this Cohort.

11. Study of Aging (SOA)

The Study of Aging is a prospective, observational study of a population-based sample of 1000 community-dwelling Medicare beneficiaries, stratified by sex, race, and urban/rural residence now beginning its 3rd cycle of R01 funding from NIA. The hypothesis underlying this major research initiative is that potentially modifiable factors predict mobility (life-space) trajectories associated with aging among community-dwelling African Americans and whites. Brown and Locher have mentored trainees using this cohort.

12. Healthcare Cost and Utilization Project (HCUP)

The Healthcare Cost and Utilization Project (HCUP) is a family of health care databases and related software tools developed through a Federal-State-Industry partnership to build a multi-State health data system for health care research and decision making. HCUP is sponsored by the Agency for Healthcare Research and Quality (AHRQ) as part of its mission to improve the quality, safety, efficiency, and effectiveness of the Nation's health care system.

HCUP databases bring together the data collection efforts of State data organizations, hospital associations, private data organizations, and the Federal government to create a national information resource of patient-level health care data. HCUP includes the largest collection of longitudinal hospital care data in the United States, with all-payer, encounter-level information beginning in 1988. These databases enable research on a broad range of health policy issues, including cost and quality of health services, medical practice patterns, access to health care programs, and outcomes of treatments at the national, State, and local market levels.

The Lister Hill Center at CCTS HUB (Muntner, Director) has HCUP and National Inpatient Sample (NIS) data through 2008. It is available to all Lister Hill scholars and trainees through a sponsoring Lister Hill Scholar. Kilgore has expertise and experience mentoring trainees using this data.

13. Atlanta Census Research Data Center (ACRDC)

Located at the Federal Reserve Bank of Atlanta, the Atlanta Census Research Data Center (ACRDC) seeks to provide qualified researchers in Atlanta, and around the Southeast, with the opportunity to perform statistical analysis on non-public Census microdata. The ACRDC, established 2011, is 1 of 8 centers in the United States and is a partnership between the U.S. Census Bureau and a consortium that includes Georgia State University, the Federal Reserve Bank of Atlanta, the Centers for Disease Control and Prevention (CDC), Emory University, Georgia Tech, the University of Alabama at Birmingham, and the University of Georgia. There are four general categories of data on which qualified researchers may perform statistical analysis inside the secure ACRDC: 1) Economic Data; 2) Demographic Data; 3) Mixed Data; and 4) Health data.

14. Cancer Care Outcomes Research and Surveillance Consortium (CanCORS)

The CCTS HUB serves as a Primary Data Collection and Research (PDCR) site in the NCI-funded Colorectal and Lung Cancer CanCORS consortium (Fouad, PI). This research consortium of eight grantees measures the quality of cancer care and associated health outcomes in the United States. The project supports prospective research in a cohort of approximately 10,000 patients with newly diagnosed lung cancer or colorectal cancer recruited from geographically diverse populations and health care systems. The CCTS HUB PDCR site is for newly diagnosed cases of both lung and colorectal cancer with special emphasis on African Americans. Fouad is an author of the publication that introduced the goals and methods of the Consortium to the broader community of cancer researchers and clinicians; several manuscripts elucidating the findings of the consortium with regards to ovarian cancer and the recruitment of patients to cancer clinical trials are in the process of being submitted for publication. Fouad has mentored trainees using this cohort.

15. OsteoArthritis Initiative (OAI)

The Osteoarthritis Initiative (OAI) is a nationwide, multi-center, longitudinal, prospective observational research study of men and women. The overall aim of the OAI is to develop a public domain research resource to facilitate the scientific evaluation of biomarkers for osteoarthritis as potential surrogate endpoints for disease onset and progression. Osteoarthritis (OA) is the most common form of arthritis and the major cause of activity limitation and physical disability in older people.

Four clinical centers and a data coordinating center conducted the Osteoarthritis Initiative (OAI), a public-private partnership that brought together new resources and commitment to help find biochemical, genetic and imaging biomarkers for development and progression of OA. The OAI established and maintain a natural history database for osteoarthritis that will include clinical evaluation data, radiological (x-ray and magnetic resonance) images, and a biospecimen repository from 4796 men and women ages 45-79. The seven-year project enrolled participants who have, and those who were at high risk for developing, symptomatic knee osteoarthritis. All data and images collected is available to researchers worldwide to help quicken the pace of biomarker identification, scientific investigation and OA drug development. Access to biospecimens is by application to the National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS).

16. Cohort Study of Medication Adherence among Older Adults (CoSMO)

The mission of the Tulane led Cohort Study of Medication Adherence among Older Adults (CoSMO) is to lay the groundwork for interventions to improve medication adherence and clinical outcomes in older adults with hypertension and will increase our understanding of factors contributing to therapeutic outcomes in the use of medications by these patients.

The goal of Cohort Study of Medication Adherence among Older Adults (CoSMO) with essential hypertension (HTN) in a managed care setting is to investigate the multiple factors that influence antihypertensive medication adherence (via validated self-report and pharmacy fill measures). The specific aims of this cohort study are as follows:

1. to assess the impact of psychosocial, behavioral, health, quality of life, sexual function, medication class, and clinical factors measured at baseline on subsequent change in antihypertensive medication adherence over 2 years of follow-up
2. to assess health care system issues (perception of primary care provider, satisfaction with access and communication), use of prescribed and over-the-counter and unconventional medications and lifestyle modifications on anti-hypertensive medication adherence and change in adherence
3. to determine the relationship of antihypertensive medication adherence at baseline with future medical and psychosocial outcomes such as blood pressure control, cardiovascular disease incidence and all-cause mortality, quality of life, utilization
4. to explore differences in aims 1-3 with regards to gender and race.

To address these specific aims, a random, race-and gender-diverse sample of 2194 HTN patients > 65 years of age who met the study eligibility requirements from the pool of all hypertensive patients enrolled in a large southern managed care organization. Study participant's medication adherence, demographic, behavioral, treatment (i.e. medication class), quality of life, duration of hypertension, psycho-social factors and perceptions of primary care provider, and satisfaction with access to care were assessed at baseline and after 1 and 2 years of follow-up via telephone-administered surveys.

Rigorous quality control procedures have been implemented to assure high quality data. Blood pressure control, severity of hypertension, cardiovascular outcomes, healthcare utilization at baseline and follow-up have been collected. Models predicting change in medication adherence, blood pressure control, utilization, and cardiovascular events are under development. Krousel-Wood and Muntner have experience mentoring trainees using this cohort.

17. Jackson Heart Study

Since there is a greater prevalence of cardiovascular disease among African Americans, the purpose of the Jackson Heart Study (JHS) is to explore the reasons for this disparity and to uncover new approaches to reduce it. The JHS is a large, community-based, observational study whose 5301 participants were recruited from among the non-institutionalized African-American adults from urban and rural areas of the three counties (Hinds, Madison, and Rankin) that make up the Jackson, MS, metropolitan statistical area (MSA). Jackson is the capital of Mississippi, the state with the largest percentage (36.3%) of African Americans in the United States.

The primary objective of the Jackson Heart Study was to investigate the causes of cardiovascular disease (CVD) in African Americans to learn how to best prevent this group of diseases in the future. More specific objectives included:

1. Identification of factors, which influence the development, and worsening of CVD in African Americans, with an emphasis on manifestations related to high blood pressure (such as remodeling of the left ventricle of the heart, coronary artery disease, heart failure, stroke and disorders affecting the blood vessels of the kidney).
2. Building research capabilities in minority institutions at the undergraduate and graduate level by developing partnerships between minority and majority institutions and enhancing participation of minority investigators in large-scale epidemiologic studies.
3. Attracting minority students to and preparing them for careers in health sciences.

The JHS design included participants from the Jackson ARIC study who had originally been recruited through random selection from a drivers' license registry. Approximately six months before the JHS was to begin, an amendment to the federal Driver's Privacy Protection Act was passed that changed the level of consent for public release of personal information from driver's license lists from an "opt out" to an "opt in" basis. The Mississippi Highway Patrol was no longer able to release a complete listing of all persons with driver's licenses or state identification cards, which prevented its use in the JHS. New JHS participants were chosen randomly from the Accudata America commercial listing, which provides householder name, address, zip code, phone number (if available), age group in decades, and family components. The Accudata® list was deemed to provide the most complete count of households for individuals aged 55 years and older in the Jackson MSA. A structured volunteer sample was also included in which demographic cells for recruitment were designed to mirror the eligible population. Enrollment was opened to volunteers who met census-derived age, sex, and socioeconomic status (SES) eligibility criteria for the Jackson MSA.

In addition, a family component was included in the JHS. The sampling frame for the family study was a participant in any one of the ARIC, random, or volunteer samples whose family size met eligibility requirements. Eligibility included having at least two full siblings and four first degree relatives (parents, siblings, children over the age of 21) who lived in the Jackson MSA and who were willing to participate in the study. No upper age limit was placed on the family sample. Known contact information was obtained during the baseline clinic examination from the index family member with a verbal pedigree format to identify name(s), age(s), address(es), and telephone number(s).

Recruitment was limited to persons 35-84 years old except in the family cohort, where those 21 years old and above were eligible. Only persons who otherwise met study criteria but were deemed to be physically or mentally incompetent by trained recruiters were excluded from study eligibility. Beech, Correa, Crook, and Muntner are available to mentor mentees interested in using this cohort.

18. Pulmonary biospecimen collection

The Pulmonary Biospecimen Repository (PBR) at the CCTS Hub was launched in 2009. The purpose of the PBR is to provide investigators within the pulmonary community at CCTS Hub and elsewhere with clinical samples derived from multiple lung diseases, including transplant recipients, idiopathic pulmonary fibrosis, chronic obstructive pulmonary disease, cystic fibrosis, and asthma. Cell and fluid samples isolated from bronchoalveolar lavage (BAL), plasma, and serum are collected and stored; samples are assessed routinely for viability. Each sample is linked directly with the respective patient information via the Pulmonary Translational Research and Clinical Database, a Health Insurance Portability and Accountability Act compliant database that includes detailed information allowing for the study of specific patient cohorts. To date, more than 800 patients have provided approximately 7,000 BAL, serum and plasma fluid, and cell samples. Over the past 4 years, nearly 800 of these samples have been distributed to investigators at the CCTS Hub and elsewhere. Future plans for the PBR include expanding sample collection to additional pulmonary diseases, such as mycobacterial infections, increasing the number of sample users and obtaining external funding to ensure its continued sustainability. Dr. Eric Sorscher is available to mentor trainees interested in working with this collection.

19. Cooperative Human Tissue Network (CHTN) –Southern Division

The CHTN –Southern Division at the CCTS Hub is one of six member institutions funded by the National Cancer Institute to prospectively collect, process and distribute remnant human tissue specimens to IRB-approved biomedical researchers. The CHTN operates through a shared networking system which allows investigators greater access to available research specimens. CHTN offers a variety of preparation and preservation techniques to ensure investigators are receiving the quality specimens needed for research. Remnant human tissue specimens (including normal, benign, malignant, or diseased) from routine surgical resections and autopsies are procured to the specifications of the investigator. Frozen aliquots of fluid (serum, plasma, buffy coat, urine, saliva) as well as paraffin blocks and/or slides may also be made available. Although the CHTN operates as a network, each CHTN division is responsible for primary coordination and intake of applications from investigators based upon the investigator's geographic location. The Southern Division encompasses Kentucky and all states south and west from the Carolinas to Texas.

Clinical Care and Medical Training

UAB Medicine

Partnering with UAB and the School of Medicine to provide resources for clinical care and training for medical professionals, the entities listed below highlight the diversity of the UAB network and showcase the advances made since its inception. UAB Medicine unites UAB Hospital, The Kirklin Clinic, UAB Health Centers, the Callahan Eye Foundation, and VIVA Health (a health maintenance organization and subsidiary of Triton Health Systems, LLC, owned by UAB Medicine that provides quality, reliable health care).

Facilities - Partnering with UAB and the School of Medicine to provide avenues for clinical care and training for medical professionals, the entities listed below are part of the broad patient care network on the UAB campus.

- *UAB Hospital* - Established in 1945 as the teaching hospital for the School of Medicine, UAB Hospital is the largest comprehensive medical facility in Alabama. Encompassing five city blocks, 13 major buildings and 2.1 million square feet of space, it excels in the areas of emergency care transport, heart and kidney diseases, cancer, spinal cord injuries, diabetes, arthritis, organ transplantation, and cardiac surgery. It is licensed for more than 900 beds and serves approximately 35,000 patients each year. UAB Hospital has almost 900 of Alabama's most outstanding physicians on staff. Because UAB Hospital is at the forefront of medical innovation, it draws referrals from community hospitals throughout Alabama, as well as many other states and a number of foreign countries. The 885,000 square-foot, 11-story North Pavilion opened in 2004 and has 37 operating suites, 3 medical surgical units, 4 intensive care units (trauma and burn, surgical, neuroscience, and cardiovascular), and a 44,000 square-foot Emergency Department.

UAB Hospital is among a select group of hospitals across the nation recognized as "centers for excellence in nursing." It was the first hospital in Alabama – and one of only 17 in the southeastern U.S. – to earn Magnet recognition, a designation awarded by the American Nurses Association to fewer than 210 of the nation's top 5,500 hospitals. The book *The Best in Medicine* ranked UAB Hospital among the top three in the United States, and 74 physicians who work with UAB Hospital earned a prestigious listing in the second edition of the book *The Best Doctors in America*. Four UAB Hospital specialty programs are among the nation's top 50, with two in the top 25 (Rheumatology and Urology), of the 16 categories evaluated at near 5,000 hospitals by U.S. News & World Report in the 2012-2013 review.

- *The Kirklin Clinic* - The Kirklin Clinic® (TKC) opened in 1992 as a premier outpatient facility to provide examination and treatment rooms for physicians representing almost every specialty in adult medicine. The five-story facility covers a full city block with 454,000 square feet, more than 30 distinct clinical units of multidisciplinary teams, and an adjacent covered parking deck that accommodates 1,450 vehicles. The Kirklin Clinic® at Acton Road provides a wide array of patient care services south of Birmingham, established in the suburban community.
- *1917 Outpatient AIDS Clinic* - The 1917 Clinic provides care to individuals infected with HIV. The Clinic's mission is to provide comprehensive and compassionate health care for people with HIV infection by: 1) delivering world-class, state-of-the-art primary HIV treatment; 2) offering specialty clinics for HIV patients with needs in dermatology, oncology, neurology, addiction recovery, and palliative care; 3) providing social service support; 4) offering chaplain services; 5) facilitating interactions between laboratory scientists and the Clinic by providing clinical specimens from well-characterized patients; 6) providing ongoing medical education; 7) establishing a vital link between the activities of the Clinic and the community; and 8) conducting clinical trials of new approaches to treatment
- *Spain Rehabilitation Center* - As one of the Southeast's premier providers of comprehensive rehabilitation care, the nationally recognized programs available at Spain Rehabilitation Center are designed to address every aspect of a patient's rehabilitation, including physical, social and psychological health. Specialists are devoted exclusively to the practice of rehabilitation medicine, utilizing advanced research, technology, and expertise to provide the highest level of patient care.

Interdisciplinary treatment integrates specialists from all areas of the UAB Health System to bring together unique skills and expertise to form care teams that evaluate and treat each patient. These efforts result in a comprehensive care plan that coordinates treatment to meet each patient's individual needs.

- **UAB Highlands** - UAB Highlands is a 219-bed general acute facility with community-based and university physicians on staff covering a full range of general, medical, and surgical specialties. These services include orthopedics, plastic surgery, ENT, gynecological oncology, urology, oral and general surgery, internal medicine, cardiology, pulmonary, and gastrointestinal services. Annually, UAB Highlands has approximately 3,000 admissions, almost 9,000 emergency room visits, and over 6,500 inpatient and outpatient surgeries. The hospital is located on the southwest edge of the UAB campus, and has conference and office space with ample parking for staff and medical patients. In addition to receiving expert, compassionate care from the UAB Highlands physicians and staff, the facility houses *The Workplace*, a comprehensive injury management and rehabilitation center; a pain management center; a sleep disorders center; the state's only Gamma Knife Radiosurgery treatment center; the Heart College, a comprehensive cardiac care program; and a full range of modern diagnostic testing modalities. UAB Highlands also offers a 24-hour Level III emergency room, which frees the University Hospital emergency room for more complex and high-acuity emergency care. Additionally, The Callahan Eye Foundation Hospital will move to UAB Highlands to provide inpatient and outpatient ophthalmology services.
- **UAB Women and Infants Center** - UAB's newest facility, the UAB Women and Infants Center is a world-class health care facility dedicated solely to the care of women and infants. Whether it's inpatient surgical care or a routine outpatient office visit, the Center provides complete care, all under one roof. The 400,000-square-foot-hospital is one of the first in the Southeast with all private neonatal intensive care nursery and continuing care nursery rooms. It also offers private labor, antepartum, postpartum, and gynecology patient rooms. The private room design enhances maternal, family, and infant bonding. Specialized isolation rooms and rooms designed for twins and triplets further enhance the family atmosphere. UAB's highly-trained and compassionate physicians, nurses and other health professionals utilize advanced services and sophisticated state-of-the-art medical technology dedicated to the care of healthy and high-risk pregnant women, healthy and high-risk newborns, and women receiving care for a variety of gynecological challenges, including gynecological cancers.

Health Services Foundation

UA Health Services Foundation is a nonprofit, group physician practice including The Kirklin Clinic and The Kirklin Clinic at Acton Road. The HSF was founded by pioneering heart surgeon John W. Kirklin, M.D., in 1973. Since that time, the Foundation has achieved national prominence for high quality patient care services and the unique knowledge, dedication and compassion of its employees.

HSF General Endowment Fund - The University of Alabama Health Services Foundation (UAHSF) General Endowment Fund (GEF) provides capital on a competitive, peer-reviewed basis, to enhance the infrastructure of the UAB academic health center for laboratory research, patient-oriented efforts, clinical care program development, and medical education initiatives. In general, funds from the HSF-GEF are invested in research, educational, and clinical programs that are deemed in the best interest of the UAB Medical Center and for UAB university-wide projects which are consistent with institutional priorities.

UAB Eye Care - Exemplary patient care is provided in the recently renovated clinic "UAB Eye Care," a 34,000 square foot state-of-the-art facility that covers everything from primary eye care, including the dispensing of glasses and contacts, to the treatment of ocular disease, as well as low vision rehabilitation and pediatric vision care.

Callahan Eye Foundation Hospital - The UAB Callahan Eye Hospital (CEH) is the state's only facility dedicated to providing quality medical and surgical eye care to the people of Alabama and the Southeast. Callahan's primary business consists of outpatient ophthalmology and ambulatory surgery, making it one of the busiest ophthalmology surgery centers in the country. Moreover, the hospital offers a 24-hour, 7 day a week

eye emergency room and is the region's only Level I Ocular Trauma Center. With exceptional healthcare professionals, dedicated surgery suites, and state-of-the-art equipment, more than 70,000 surgical procedures have been performed at Callahan to date. The hospital offers nine superbly equipped ophthalmology operating rooms and provides the full spectrum of specialized eye care. UAB Callahan Eye Hospital is also home to a comprehensive eye research program via partnership with the UAB Department of Ophthalmology and provides the state's only accredited (Accreditation Council for Graduate Medical Education, ACGME) ophthalmology training program.

Hospitals on UAB Campus Involving UAB Faculty

In addition to the UAB Medicine components listed above, two additional hospitals are physically part of UAB's main campus in Birmingham, and the UAB faculty provides both clinical and investigative expertise.

- *Children's Hospital of Alabama* - The Children's Hospital of Alabama, part of the Children's Health System, provides pediatric care while serving as the primary site for education in pediatrics at UAB. The private, not-for-profit hospital is home to a full array of specialists treating more than 634,000 outpatient and nearly 14,000 inpatient visits each year to Children's from every county in Alabama and from 47 other states. For the past three years, Children's has been ranked among the best children's hospital programs in the nation by US News & World Report, and ranked nationally in 10 pediatric specialties. With more than 2 million square feet, including dedicated space for the CCTS Child Health Research Unit, it is the third-largest pediatric medical facility in the U.S. In 2012, Children's opened two new facilities, strengthening its ability to serve pediatric patients statewide. The Benjamin Russell Hospital for Children, a 12-story, 760,000-square-foot, \$400 million expansion allows Children's to increase its licensed beds from 275 to 332, ranking Children's in the top 10 pediatric medical centers based on bed count. The hospital also opened the Joseph S. Bruno Pediatric Heart Center, which includes a 20-room cardiovascular intensive care unit, two dedicated surgical suites, three heart and vascular catheterization labs, and four dedicated extracorporeal membrane oxygenation (ECMO) rooms. The floor connects directly via skywalk to the new UAB Women and Infants Center to provide quick and efficient access for the physicians and surgeons to their pediatric patients, as well as for the immediate transport of newborns requiring specialized care for congenital heart ailments. At the cornerstone of the Bruno Heart Center is its innovative pediatric hybrid catheterization suite, the only one of its kind in the state of Alabama. The hybrid cath lab is equipped with \$3 million worth of state-of-the-art technology that allows it to be immediately converted to a cardiovascular surgical suite, eliminating the need to bring children out of anesthesia for a second procedure in a different room.
- *Birmingham VA Medical Center* – Also situated in the heart of the UAB academic research center and interconnected with UAB research and health care delivery facilities since 1975, the Birmingham Veterans Affairs Medical Center (BVAMC) is an acute care facility with 136 beds currently in operation. The facility provides acute tertiary medical and surgical care to veterans of Alabama and surrounding states. It provides health care services to eligible veterans in the VA Southeast Network Veterans Integrated Service Network. Recent construction provides state-of-the-art facilities and equipment in all clinical programs. Care is provided in practically all medical and surgical specialties and subspecialties. Most staff physicians have joint appointments with VA and its primary affiliation, UAB. The BVAMC operates eight Community Based Outpatient Clinics in North Alabama.

Regional Networks of Clinical and Translational Research

- *Dental Practice-based Research Network* - The UAB-led Dental Practice-Based Research Network (DPBRN) is a consortium of participating practices and dental organizations committed to advancing knowledge of dental practice and ways to improve it. The Network strives to improve oral health by conducting dental practice-based research and by serving dental professionals and their patients through education and collegiality. It assists in the translation of scientific discovery into clinical practice. DPBRN's major source of funding is the National Institute of Dental and Craniofacial Research (NIH/NIDCR). Clinical studies embrace four approaches: studies that may involve practitioners and / or their patients: retrospective studies using dental records; observational studies of routine care activities, case-control studies, and clinical trials comparing alternative treatment strategies. Practitioner-investigators help design clinical studies, assess the implications of study results for practitioners and patients in different practice settings, and disseminate research results.

- *Deep South Network for Cancer Control (DSN)*– Mindful of the elevated risk of cancer and lower outcomes in the African American community, UAB has established the Deep South Network for Cancer Control, which builds on an established community and institutional capacity in order to eliminate cancer health disparities by conducting community-based participatory education, training and research. The goals of the DSN are to improve access to and utilization of proven beneficial cancer interventions. DSN serves two underserved rural areas - the Black Belt of Alabama and the Delta of Mississippi - and two urban underserved areas - Jefferson County, Alabama, and Hattiesburg/Laurel Metro, Mississippi. This project focuses on breast, cervical and colon cancers.

Graduate Education and Post-graduate Training Infrastructure

Graduate School (est., 1970; Bryan D. Noe, PhD, Dean)

Established in 1970, the UAB Graduate School offers competitive annual recruitment funding awards to Masters and PhD entry programs to be used for enhancement of recruitment practices, including recruitment advertising, website upgrades, support of head-start summer programs, participation in diversity recruiting events, interview visit support and others. The Graduate School also hosts the annual Opportunity Zone recruitment event for regional undergraduates, collaborates with the UAB Office of Undergraduate Research to sponsor an annual Undergraduate Research Day and summer research intern events, and liaises with various departmental honors programs as well as the university-wide Science and Technology Honors Program. In its commitment to diversity in UAB Graduate Programs, the School contributes to the development, coordination, implementation and assessment of a comprehensive array of programs to enhance opportunities for underrepresented groups. Featured in this effort are the UAB McNair Scholars Program and the NIH-funded UAB PREP post baccalaureate program, and provides recruitment and ongoing mentoring programs for minority graduate students.

Graduate Program in Biological Sciences (S. Rich, PhD, Sr. Associate Dean) - The Graduate Biomedical Sciences (GBS) community at UAB encompasses approximately 475 graduate students and 350 faculty. With guidance from the GBS Steering and Oversight Committee, Chaired by CCTS Executive Committee member Dr. David Chaplin, trainees participate in multiple interdisciplinary thematic programs that integrate more than 25 departments in the School of Medicine, partner Schools throughout the university, and Southern Research, an affiliated drug discovery and development institute. UAB is consistently among the top 25 institutions in the US for NIH research funding. The GBS Program provides its graduate students the flexibility, guidance, resources and training to become highly competitive for outstanding postdoctoral and professional positions. UAB offers interdisciplinary training pathways in the Graduate Biomedical Sciences, including; Biochemistry, Structural & Stem Cell Biology; Cancer Biology; Cell, Molecular and Developmental Biology; Genetics, Genomics and Bioinformatics; Immunology; Microbiology; Neuroscience; and Pathobiology & Molecular Medicine. Working closely with the GBS Program, the CCTS has been instrumental in developing certificate programs in Translational Science and Molecular Medicine and in Bioinformatics to enhance the graduate curriculum.

UAB Division of Continuing Medical Education (M. Safford, MD, Assistant Dean)

The Division of Continuing Medical Education (CME) at UAB strives to be a national leader in defining and delivering meaningful learning opportunities for healthcare professionals to improve patient and community health. The Division's CME program strengthens the UAB Health System through the quality, scope, and diversity of its educational activities. Topics include traditional areas of basic science, clinical medicine, patient care, and public health, as well as more contemporary themes of quality improvement, patient-centered care, leadership, and others within the Accreditation Council for Graduate Medical Education's professional core competencies. The mission of the Division of CME is to develop and provide a professional development program for physicians and physicians-in-training that is effective in increasing knowledge, awareness, and competence; enhances physician performance; and improves patient and community health. The CME group supports the broader School of Medicine's tri-part mission of research, education, and clinical practice, working together with other units within the spectrum of medical education, faculty development, and quality improvement.