The **Center for Clinical and Translational Science and Training (CCTST)** was established in 2005 as the University of Cincinnati (UC) academic home for clinical and translational research, providing "one-stop shopping" for investigators across the academic health center (AHC) and beyond in need of guidance, information, support, resources, and training. The CCTST spearheaded the AHC's submission of an NIH Clinical and Translational Science Award (CTSA) application in 2009, when it received an initial five-year award of nearly $23 million. The CCTST is currently in its 3rd cycle of funding, renewed again in 2020 with a $22.1 million, 5-year award plus an additional $4.1 million in funding for the KL2 Career Development Awards Program from the National Center for Advancing Translational Sciences (NCATS). UC and its partner institutions Cincinnati Children's Hospital Medical Center (CCHMC), and UC Health comprise the 39th member of the CTSA Consortium, which now includes ~60 sites. CCTST offices are centrally located in the CCHMC "Location S" research building, directly across the street from the UC Medical Sciences Building (MSB).

Investigators request methodologist consultation services through the CCTST's online **"Research Central"** portal and may qualify for a renewable voucher for more intensive support, described in the Biostatistics, Epidemiology and Research Design (BERD) section below. The CCTST website also features service descriptions, a searchable database of intramural funding opportunities, news, and a comprehensive AHC calendar of on-campus workshops, conferences, and lectures of interest to clinical/translational researchers. Faculty and community members can establish free CCTST membership online, required to obtain access to consultation services through Research Central as well as special funding, training, and networking opportunities. In return, members help promote CCTST goals and services, collaborate and share expertise with fellow researchers, cite CCTST assistance in publications as appropriate, and provide information for surveys and reports. To date, over 5,500 members have joined the CCTST, including over 570 community representatives.

The CCTST has promoted multi-disciplinary collaboration through **Integration Committee** consultations and topic-based studios, and by making multi-disciplinary teams a funding priority in CCTST grant programs. Since its inception in January 2013, the Committee has met with over 142 faculty and investigators/groups from across the AHC, UC undergraduate campus and the community to help define solutions for problems encountered during the course of their research efforts. One of the major strengths of the program is its longitudinal nature, which ensures that faculty on the Integration Committee serve as the "primary care doctor" for the participant, with frequent follow-up to ensure that solutions to any encountered obstacles can be developed and to encourage progress on projects and career development. There is interest at the UC leadership level to develop this program across the university and extend to the Colleges on the undergraduate campus (Engineering; Design, Art, Architecture and Planning; Arts and Sciences; Education and Criminal Justice).

The CCTST includes support for 2 optional modules which will advance clinical and translational research across the AHC:

- **Lifespan Data Integration Module.** The Lifespan Data Integration Module serves as a core resource for maternal and child health providers, policymakers, epidemiologists, and community agencies— ultimately, any stakeholder in maternal and infant health. The Lifespan Data Integration Module seeks to catalyze perinatal research efforts through engagement of additional multidisciplinary teams, both within and external to the CCTST community. This module focuses on local efforts to improve maternal health before and during pregnancy, discovers mechanisms to prevent prematurity and reduce intrauterine exposures to substances of abuse or other harmful environmental exposures, and tracks infant outcomes and healthcare utilization after birth. CCHMC and the UC Medical Center have an accomplished record of leading multidisciplinary research, as well as place-based collaborations focusing on improving perinatal health, including with the March of Dimes Ohio Collaborative, Cradle Cincinnati, and Start Strong-Avondale.

- **Learning Healthcare Systems to Accelerate Translation and Implementation Module.** A Learning Health System (LHS), in which patients, clinicians, and researchers work together to choose care based on best evidence and to drive discovery and learning as a natural outgrowth of every clinical encounter, can accelerate the translation of knowledge to outcomes. The overall goal of this module is

to accelerate research, translation, and implementation of new knowledge into improved outcomes. This module will develop, test, and refine interventions that facilitate the formation of an LHS within the Academic Health Center (AHC), starting with two pilot projects in the UC Gardner Neuroscience Institute and the CCHMC Mind, Brain, and Behavior Collaborative.

With CTSA and institutional funding, the CCTST provides resources in the major program areas described below:

Acute Care Research Council (ACRC). The ACRC is a high-impact collaboration of acute care research professionals across the CCTST member institutions, which has been meeting regularly since 2015. The ACRC has defined core competencies for clinical research coordinators (CRC) who work in this area and set up an online repository of regulatory documents (created by our Acute Care Research Regulatory Professionals Group). The ACRC is the most comprehensive AHC-based collaboration of acute care researchers in the nation. Throughout the past year, the ACRC provided support for acute care research initiatives, partnering with UC Emergency Medicine Service Center, CCHMC Collaborative Prehospital Care Committee, and UC Prehospital Trauma Research Group. This work included providing database management assistance, establishing regulatory processes with the Cincinnati Fire Department to facilitate research, and fostering collaborations across multiple AC settings. The ACRC includes an ACRC Pilot Grant award to fund ACR projects with the goal of transitioning to extramural funding and holds an ACRC Fall Symposium.

Center for Improvement Science (CIS). The CIS is a consultative and education service to support collaboration and Team Science. As a core of the CCTST, the CIS supports all faculty and staff of the UC, CCHMC, and UC Health. These services are also available to members of the community who collaborate with CCTST partner institutions. CIS helps with services such as collaboration, grant writing, grant and program evaluation, team building and Team Science training. Throughout the past year, the CIS identified its three areas of service as: 1) Team Science, 2) Qualitative and Mixed-Methods design and analysis, and 3) Program Evaluation. Wherever possible, the CIS is reaching out across the University, CCHMC, and UC Health to provide services to faculty and trainees pursuing research that would benefit from enhanced skills in team science. The CIS also disseminates their expertise in Team Science with KL2 and TL1 scholar presentations outside the local affiliates (e.g., University of Texas Health Sciences Center, Bahir Dar University of Ethiopia). The CIS is currently collaborating on projects with the UC Faculty Enrichment Center, the UC VP for Research, the College of Medicine Office of Research, the UC Staff Success Center, and the UC Digital Scholarship Center (among others). We were awarded an AAMC grant focused on *Building Trust and Confidence Through Partnerships*. The CIS is conducting primary research in team science and developing manuscripts to disseminate their work on: 1. Evaluation of Team Science Activities (Workshops, Consults, Presentations, and Grant Writing), 2. Creating a Team Science Infrastructure to Promote Interprofessional Collaboration, and 3. Andragogy in Practice. The CIS has a number of researchers with expertise in qualitative research methods.

Pilot Translational and Clinical Studies (PTCS). The CCTST offers five pilot funding mechanisms: Pilot Translational Research and Innovative Core grants, Just in Time (JIT) grants, Processes and Methods grants, and two grant programs organized by the Community Engagement Core (CEC), Community Health Grants and Partnership Development Grants (see CEC section for more details on the community grants).

There are three specific grant types within the Pilot Translational Research and Innovative Core grants program: Translational Research Grant (TRG), Mentored Translational Research Grant (MTRG), and Innovative Core Grant (ICG). The TRG supports established investigators seeking to conduct novel translational research. To focus on promoting mentored research by new investigators, mentees and mentors are paired in the MTRG to promote research education and help ensure career development. The ICG helps build adequate local infrastructure to support clinical and translational research by providing funds to establish new shared Core facilities with a clear translational focus.

The JIT grant program continues to address the barrier of increasing competition for a shrinking pool of external research funds. These awards are focused on supporting the use of cores for projects aiming to support resubmission of grants previously scored but not funded by the NIH or comparable grants through foundation sources. These funds have contributed substantially to publications and most importantly to successful extramural grant funding that has had a return on investment of >96. Finally, this year we added the

Magnetoencephalography Core to our list of pre-approved JIT cores.

The Processes and Methods grant program, a collaboration between PTCS, Biostatistics, Epidemiology and Research Design (BERD), and Ethics, Regulatory Knowledge, and Support (ERKS), enables investigators at all levels to explore ways to improve the efficiency and effectiveness of the processes and methods used in clinical and translational research. Since it began in 2010, we have awarded at UC, CCHMC, and the VA to advance methods necessary for science.

The CCTST provides Community Health (CHG) & Partnership Development Grants (PDG) have been used to fund academic-community partnership research projects. Grantees have leveraged over $10.3 million of external funds into community-based research projects and have resulted in publications and local and national presentations. The CHG and PDG program has impacted >52,000 individuals within our community-at-large.

Biostatistics, Epidemiology and Research Study Design (BERD). BERD provides services to CCTST investigators, ranging from advice on study design, grant application development, data management, and data analysis to career development support. BERD effectively interfaces with other CCTST programs and has served to generate methodologic research to advance clinical translational research (CTR). Methodologic advice, data management, and qualitative/quantitative statistical analysis have been coordinated through Research Central, a web-based, campus-wide hub that has become the "go-to" place to find expertise and collaborators.

The CCTST is recognized within the academic and local community from broad backgrounds (undergraduate and graduate, pre- and postdoctoral fellows, clinical fellows, faculty, and community members) where they can obtain support to create and complete high quality clinical/translational research. We continue to evolve in how we support investigators, to ensure we are helping the most promising trained investigators, as well as those who show promise during the early phases of their careers. We provide one-hour consultative services for any investigators seeking assistance, independent of their status/rank, including students, residents, fellows (with mentors), junior faculty, and senior faculty through our portal Research Central. This brief visit with one of our highly skilled "concierges" has helped to better define their needs so we can direct them to services supported by the CCTST or provided by other staff/faculty. For those investigators who are developing projects for extramural support, we provide vouchers for support beyond the one-hour consultation. We also provide vouchers for data management and analysis needs of K- and similar career development scholars. We have extended support for community-based projects that require skilled data management or statistical support and now support junior investigators pursuing an MS in Clinical and Translational Research.

Biomedical Informatics (BMI) offers resources and services to nearly all biomedically inclined investigators at both Cincinnati Children's Hospital Medical Center (CCHMC) and the University of Cincinnati (UC) College of Medicine, through several, closely integrated Shared Facilities. Collaborative bioinformatics core capabilities exist at both UC and CCHMC to integrate biostatistics and facilitate data science initiatives. The Division of Biomedical Informatics at CCHMC and the Department of Biomedical Informatics at the UC College of Medicine work in close collaboration. Research IT collaborates with the institution's Department of Information Services while maintaining its own IT infrastructure. The two groups have a long history of close collaboration to support research, with a highly granular matrix of responsibilities, shared use of network and data security personnel, and common set of policies and procedures as applicable. Research IT offers a broad set of resources and services, including:
- High performance, secure and scalable network, storage, databases, and servers
- Central Identity and Access management system
- High performance computational cluster and open-source analysis software
- Cloud computing infrastructure and collaboration platforms for research
- IT helpdesk for research

Data and Technology Services is a collaborative development unit with expertise in a number of different areas, including web- and mobile-based software development and database programming. Staff are accustomed to working on complex multi-center research projects with advanced informatics aims. BMI's Data and Technology Services offerings include:

- Developing software applications to support customized/personalized research workflows, as well as integrations with the electronic health record and other software/services
- Designing and hosting research databases, data marts, and registries
- Extracting electronic health record and other clinical information systems data for research purposes
- Developing web-based data reporting/visualization solutions
- Implementing custom data processing/analysis pipelines
- Developing customized research websites and web services compliant with industry and corporate standards

Operating at both CCHMC and UC, BMI Data Services specializes in complex extractions of data from the electronic health record (EHR) and other primary sources for research purposes. This group also helps to transform these data into common models for use in distributed research networks, and to develop and implement standards and infrastructure to support learning health systems, pending NIH Data Sharing and Management policies and other data and improvement networks. BMI Data Services oversees the development and implementation of the respective CCHMC and UC-based research data warehouses and develops data collection and reporting systems to support registries and multicenter learning networks, including serving as an honest broker and navigating investigators through compliance and data security issues.

The research data warehouses are also used to support CCHMC's/UC's participation in several distributed data sharing networks, including the Electronic Medical Records and Genomics (eMERGE) Network, the National Patient-Centered Clinical Research Network (PCORnet), and the Accrual for Clinical Trials (ACT) Network. Through these projects, staff in BMI Data Services have gained tremendous experience extracting data from the EHR and developing transformations into many of the most popular Common Data Models (CDMs), such as OHDSI/OMOP, i2b2, TriNetX and the PCORnet CDM. They have also gained experience developing and using analytical tools that are associated with each model. Additionally, the group oversees customizations of as well as complex extractions into and out of REDCap systems. The BMI Core continues to expand FHIR for transfer of data directly from the EHR to REDCap.

Bioinformatics Collaborative Services, (BCS), housed within the Division of Biomedical Informatics, serves as a collaborative nexus connecting bioinformaticians with basic/clinical researchers and provides bioinformatics services to Cincinnati Children's researchers, helping them achieve their scientific goals in a timely and dependable manner. The team consists of highly experienced bioinformaticians who aim to ensure that researchers have access to state-of-the-art methodologies and applications. Beyond providing bioinformatics support, the BCS promotes collaboration among various researchers and fosters a peer community for bioinformaticians throughout the institution. The BCS offers the following services:
- Bulk gene expression (RNA-seq, GSEA, expression arrays)
- Chromatin accessibility (ATAC-seq)
- Data storage and sharing
- Genotyping and variant calling (WGS, WES, genotyping arrays)
- Letters of support
- Protein-DNA interaction and Epigenetics (ChIP-seq, CUT&RUN-seq)
- Single-cell gene expression (scRNA-seq)
- Training

REDCap Support Services: The CCTST-supported REDCap (Research Electronic Data Capture) team aims to provide excellent translational research support to CCTST REDCap users. The team maintains a large, active REDCap instance (8,400 projects and 8,000+ users) and manages CCTST REDCap upgrades, installation, and external modules. REDCap access and support is fully subsidized by the CCTST and is provided free of charge to Cincinnati Children's, UC, and CCTST community researchers. The REDCap team also provides a robust training and assistance program to users free of charge, which includes:
- Weekly in-person training and workshops
- One-on-one user consultations
- An online public knowledge base for frequently asked questions
- REDCap-help ticket system covering day-to-day user requests and questions.

Ethics, Regulatory Knowledge & Support (ERKS). The ERKS program coordinates the resources of multiple initiatives centrally supported by the CCTST. The program provides institutional support to facilitate ethical, compliant research. Services include assistance with protocol development, data management, FDA filings, IRB applications, consent formulation, ethics consultations, as well as regulatory science and scientific integrity training. The ERKS led the development of the Cincinnati Ethics Center, linking local, academic, and business communities.

Participant and Clinical Interactions (PCI). The Schubert Research Clinic (SRC) at CCHMC remains a real-time laboratory for investigators to acquire practical knowledge about clinical/translational research. It provides resources that enable investigators to perform high-quality, patient-oriented research at various venues across the Academic Health Center and the community. The Schubert Research Clinic, which is located on the first floor of the Clinical Sciences Pavilion (aka "Location T") on the CCHMC main campus. The Schubert Research Clinic has 28 exam rooms: one preparatory lab with equipment for processing samples: a packaging and shipping room for clinical research samples: a metabolic kitchen for nutritional studies and teaching, body composition laboratory with DXA scanners: a vascular research laboratory and 3T magnetic resonance imaging. The Research Clinic can accommodate visits of less than ½ hour to greater than 10 hours and is equipped for subjects from infants to seniors. The clinic is fully staffed with highly trained and skilled nurses, dietitians, research assistants, and registration staff. The SRC also has admission privileges located on the main campus for overnight (23-hour short stays and sleep studies) and inpatient research admissions. Our SRC staff, in collaboration with faculty staffing and the CCTST's Research Central faculty and staff, register all approved protocols and provide excellent support in biostatistics, study design, regulatory and ethical challenges, data management, and services for optimal study performance that collectively encourage young investigators to pursue careers in clinical and translational research. Study start up average occurs in 14 days.

Community Engagement Core (CEC). The CEC initiated a cross-institutional initiative to establish a Community Engagement Network to share best practices and disseminate shared resources. The Community Leaders Institute (CLI) provides in-depth training in translational research over six weeks for community members and organization staff, a model that has been disseminated locally, regionally, nationally and across other CTSA hubs. The CE Program has leads the CIRTification training and is an active member of the Appalachian Translational Research Network including members from 10 CTSA hubs. Our practice-based research networks (PBRNs) are key stakeholder partnerships. The CEC houses the *Cincinnati Area Research and Improvement Group* (CARInG), led by Dr. Saundra Reagan, which includes 38 family medicine, general internal medicine and medicine/pediatric practices and Federally Qualified Health Centers (FQHCs). Our pediatric PBRN, *The Cincinnati Pediatric Research Group* (CPRG), led by Dr. William Brinkman, consists of 18 practices. The PBRNs are at the forefront of conducting research on disparities identified by community physicians and delivery of evidence-based care in community settings. The CE Core has helped transform the institutional environment to value and support community-engaged research. See below for activities related to the Research Participant Advisory Councils. The CEC continues to take leadership in our Diversity, Equity, and Inclusion Taskforce that provides researchers with the knowledge and skills necessary to reduce bias in research. The workgroup created and continues to build upon an online toolkit for resources to help researchers build knowledge and skills to enable them to conduct research that promotes health equity (https://www.cctst.org/antiracism).

- Research Participant Advisory Council. The first research-focused patient and family advisory council, the Research Participant Advisory Council (RPAC), established in January 2015, continues to meet monthly. This 25-member council aims to provide a platform for research participants to engage with and advise CCHMC administration, faculty, and staff on research and its conduct at the AHC. The second research-focused advisory group, established in June 2016, is a community-based advisory board in the West End (WE-CRAB), a low income, urban Cincinnati neighborhood. The focus of this group is to provide community perspective and feedback on community research issues. The group has worked on 9 research studies over the past year, including 3 that have been funded and include community partnership with the WE C-RAB.

Translational Workforce Development (TWD). The CCTST Translational Workforce Development Core manages the MS and Certificate programs in Clinical and Translational Research (CTR). The TWD offers a Clinical Research Professionals track in the MS program and developed a Community-Engaged Research for

Health Equity certificate program. TWD includes an R Club grant program that supports early career investigators preparing their first R application, which includes workshops, feedback on grant applications, and one-to-one in the development of grant applications. They have engaged clinical research professional and regulatory groups across the AHC to better define training and professional development pathways for study staff, including development of training competencies for acute care researchers, team science training in collaboration with the Center for Improvement Science, and continuing education credit for several existing seminar series and rounds. TWD supports the CTRonline, an online library of training modules designed to provide instruction on specific task-related activities such as Health Equity and Social Justice, Study Design, Community-Engaged Research, and other topics to provide a unique resource to our members to support their growth as more effective investigators. TWD hosts Health Science Cafes focused on engaging community members to increase awareness of health research conducted locally.

KL2/CT2 Career Development Awards. The CCTST is home to the KL2 Career Development Award Program. The vision of the KL2 program is to successfully train the next generation of diverse, multidisciplinary junior faculty leaders in clinical and translational research (CTR). These leaders will have the skills to: 1) conduct innovative, team-based, community-engaged clinical and translational research, 2) develop sustainable careers in clinical and translational research, and 3) disseminate and implement research findings that improve health outcomes and reduce disparities. The KL2 Program strongly encourages applications from members of underrepresented racial, ethnic, and socioeconomic groups as well as candidates with disabilities. The KL2 program provides financial support for salary and research-related expenses for up to 2 consecutive years to highly qualified junior faculty pursuing careers in CTR. During the award period, Scholars are expected to pursue their own K23 or similar individual career development awards or R series grants. The CCTST's KL2 program is closely linked with the TWD program. As such, KL2 Scholars can easily take courses in the MSCTR program or the Certificate in Clinical and Translational Research program. Many resources are available to KL2 Scholars in addition to their individual coursework, research, and mentoring experiences, including K Club and the K Scholars peer mentoring meetings. Anyone with a career development award, or who is planning to apply for a career development award, is invited to join the K Club, an informal forum for discussing topics of interest to attendees related to research, career development, and team science. The K Scholars meetings occur twice monthly and are peer mentoring sessions in which Scholars not only receive invaluable feedback on their current and planned research, but also learn to understand and value the perspectives of other clinical and translational researchers not in their field.