Resources and Environment

The following is a detailed description of facilities and resources at UC and CCHMC available to the PD/PI. The document is organized in broad categories, as listed below. The parts most relevant to the PD/PI's application are highlighted in red.

- I. University of Cincinnati Academic Health Center and its affiliates
- II. CCTST/CTSA
- III. Training Programs
- IV. Graduate Programs in Biomedical Sciences
- V. Affiliates
- VI. Patient Resources Available for Research
- VII. Informatics Infrastructure
- VIII. Core facilities
- IX. Department of Internal Medicine

I. University of Cincinnati Academic Health Center and its affiliates

The University of Cincinnati (UC) Academic Health Center (AHC) traces its origins to the Medical College of Ohio, the first medical school west of the Alleghenies, founded in 1819 in Cincinnati through the efforts of Dr. Daniel Drake. Dr. Drake originated the academic health center concept of a single organization encompassing a medical school, other health professional colleges, and teaching hospitals. The Medical College of Ohio joined UC in 1896, merged with the Miami Medical College in 1908, and was renamed the College of Medicine (CoM) in 1919. UC became a state-supported institution in 1977.

Our University is classified as a "very high research activity" institution by the Carnegie Commission and is ranked 25th among public institutions by the National Science Foundation in federally-financed research and development expenditures; **28**_{th} in all R&D expenditures among public institutions; **46**_{th} in R&D expenditures among all colleges and universities; and **47**_{th} overall in federally-financed R&D expenditures. From all sources, UC, as of FY2020, received \$273.1 million in sponsored program funding. Nearly 83% of the \$175,4 million in UC research



awards was from federal sources, including \$114.1 million from the NIH. The College of Medicine in FY2022 was ranked by Blue Ridge in the top 41% of medical schools in overall federal research grant holdings. Full-time, part-time, and adjunct/volunteer/visiting faculty (904 physicians, 499 advanced practice providers, 288

PhD) at the College of Medicine (COM) (excluding pediatrics) number *4,104 (Faculty: 61% male, 39% female; 70.9% white, 23.7 Asian, 3.9% Black, 1.7% Hispanic/Latino),* distributed among five basic science and 18 clinical departments. There are 15 robust core facilities to support research within the COM.

The UC AHC includes the Colleges of Medicine, Nursing, Pharmacy, and Allied Health Sciences, Hoxworth Blood Center, UC Cancer Institute, UC Neuroscience Institute, Center for Addiction Research, and Center for Integrative Health and Wellness. In 2021, UC Health initiated a \$221 million expansion that will double the size of the emergency department at the University of Cincinnati Medical Center, the region's main trauma center. Teaching, research, and patient care affiliates include UC Health (encompassing UC Medical Center [formerly University Hospital], West Chester Hospital, Daniel Drake Center for Post-Acute Care, Lindner Center of HOPE, Bridgeway Pointe, and UC Physicians), Cincinnati Children's Hospital Medical Center (CCHMC), Cincinnati Veterans Affairs Medical Center (VAMC), Shriners Hospital for Children–Cincinnati, Christ Hospital, and Jewish Hospital.

The AHC campus includes 16 buildings spanning nearly 2.5 million gross sq. ft. on 56 acres in the central Cincinnati neighborhoods of Avondale and Corryville. The Medical Sciences Building (MSB), at the center of the AHC, comprises 917,000 gross sq. ft., with 200 research laboratories totaling over 210,000 sq. ft., as well as all the preclinical and clinical departments of the CoM (except Pediatrics), the health sciences library, classrooms, teaching laboratories, and animal facilities. The MSB is physically joined to the 771-bed UC Medical Center. The attached 9-story, 240,000 gross sq. ft. Center for Academic & Research Excellence (CARE)-Crawley wing, which opened in September 2008, encompasses over 70,000 sq, ft, of laboratories as well as a library, administrative, meeting, and recreational space. The \$60 million Gardner Neuroscience Institute on the AHC main campus was opened in April 2019. The 114,000 sq. ft. building consolidates patient care and education and 215 faculty physicians, researchers, and staff in a single location. A \$34 million renovation of the Winkle College of Pharmacy's home in Kowalewski Hall was completed in the summer 2019. These upgrades foster the continued growth of the AHC's biomedical research grants and contracts, just as the addition of the MSB, the Cardiovascular Research Center (1996), and the free-standing Vontz Center for Molecular Studies (1999). The Reading Campus is located 8 miles north of the AHC and comprised of 10 buildings containing over 382,000 gross sq. ft. of laboratory and office space on a 25-acre campus. It houses research faculty in the Metabolic Diseases Institute, focusing on diabetes and obesity, lipids and arteriosclerosis, and cancer metabolism. The Campus includes about 30 principal investigators and over 300 staff.

The James L. Winkle College of Pharmacy, the first college of pharmacy west of the Alleghenies, was established in 1850 as a private, independent college of pharmacy and joined UC in 1954. It assumed its current name in 2007 to recognize a \$10 million gift to fund scholarships, research and faculty recruitment. The College has 55 faculty members. The College's research-intensive MS/PhD program has 36 students across 6 disciplines: Biopharmaceutics, Pharmacokinetics, Cosmetic Science (including an online degree program option, one of only 2 nationally), Drug Development, Pharmacology, and Social and Administrative Sciences. The College has 389 students in its 4-year PharmD program, and 144 graduate students. Extramural faculty research funding was \$8.9 million in 2016. Areas of interest include health outcomes research, cancer, dermatology, drug penetration, drug delivery technology, cosmetic science, cardiovascular disease, infectious disease, and neuropharmacology. The research faculty moved into renovated research labs in the Medical Sciences Building in 2015 and 2016. A \$34 million renovation of the College's home in Kowalewski Hall was completed in summer 2017.

Founded in 1889, the **College of Nursing** is ranked among the top U.S. Nursing schools by *U.S. News & World Report.* The first college to offer a baccalaureate degree in nursing (1916), it has offered a doctorate program since 1990, the same year in which a Center for Nursing Research, now the Institute for Nursing Research and Scholarship, was developed. Additional programs include an RN to BSN online program, an accelerated program, and a master of science in nursing program with a spectrum of online and onsite specialties available. In 2003, it became the first college of nursing in Ohio to offer a cooperative education program, which now includes University of Cincinnati Medical Center and CCHMC. The College's 70 faculty received over \$3.9 million in extramural funding in 2016, a nearly 206% increase from 2015. Programs and research are supported by organizations such as the Midwest Nursing Research Society, Sigma Theta Tau, the Transcultural Nurses Society and various federal agencies within the U.S. Department of HHS including

the CDC and HRSA. Research areas include nursing education innovations, interpersonal violence, vulnerable populations and health disparities, aging, and co-morbid conditions. Enrollment includes 2,653 undergraduate and graduate students. The 26 PhD students focus on specific research interests and methodologies, under the direction of senior faculty nurse scientists. Established in fall 2010 with CCTST/CTSA support, the Doctorate of Nursing Practice (DNP) program emphasizes the advanced practice of nursing, utilizing best evidence in the delivery of nursing practice and leadership in complex healthcare systems. The College is a leader in leveraging technology in healthcare education and in providing diverse educational opportunities for nurses, including nurse scientists and nurse educators.

Formed in 1998, the **College of Allied Health Sciences** has 264 faculty and 2,993 students, including Master's and doctoral students. The College houses the Departments of Analytical and Diagnostic Sciences, Communication Sciences and Disorders, Health Informatics, Nutritional Sciences, and Rehabilitation Sciences, as well as the School of Social Work. Research areas of interest are specific to each program and include child language development, traumatic brain injury, stroke, maternal, childhood and adolescent nutrition, and deafness. Faculty extramural research support in FY2016 was nearly \$1.6 million, an increase of over 14% from the previous year. The College offers a 5-year MD/MS in Nutrition dual degree program with the College of Medicine, which allows medical students to develop a comprehensive knowledge of human nutrition as well as skills in research design and implementation. A new, 117,000 sq. ft. free-standing home for the College of Allied Health Sciences was completed in 2019.

Commitment to Diversity:

Commitment in General of the University of Cincinnati

UC recognizes a very broad and inclusive concept of diversity that includes commonly recognized considerations such as race, ethnicity, gender, age, disability status, socioeconomic status, gender identity and expression, sexual identity, sexual orientation, religion, and regional or national origin. A diversity plan was adopted in 2007, which included as major goals: 1) attract, retain and graduate academically prepared, diverse students; 2) attract, retain and promote an increased number of historically underrepresented and other diverse faculty in tenure and clinical track positions; and 3) develop/strengthen partnerships with diverse communities and groups locally, nationally and internationally. As a part of the University of Cincinnati's Creating Our Third Century plan, as of December, 2015, UC is investing more than \$40 million in building, supporting and sustaining faculty diversity through the Strategic Hiring Opportunity Program, dual career assistance and a cluster hiring initiative. In addition, an additional \$1 million in new scholarships has been earmarked to enhance the recruitment, retention and graduation of underrepresented minority students. As of July 1, 2016, the university requests a Diversity and Inclusion statement of all applicants for faculty and staff positions, as part of the university's overall hiring process. Almost every campus unit and college now have a Diversity and Inclusion Committee working among, engaging with, providing programming and serving as a resource among students, faculty and staff. The UC Graduate School offers the Provost Graduate Fellowship for promising new PhD students whose presence diversifies our institution and the academy. These awards signify the commitment of UC's leadership to making graduate education mirror the demographics of American society. The Graduate School offers three PGF awards per year to incoming PhD students, with each winner receiving three years of a full-tuition scholarship in addition to a yearly living stipend of \$25,000. These efforts and others have resulted in genuine improvements: UC opened its academic year (2021-22) with a undergraduate enrollment, 35,339 students: the percentage of minority students at UC is 32.9 percent, 8.2% African-American, and 55% are female. In the incoming fall 2016 baccalaureate class, first-generation college students comprised 21 percent, and in 2021 there was 32% increase in first-generation students in the incoming class. Pell-eligible students accounted for 28.2 percent of UC's first-time, degree-seeking undergraduates. In short, UC asan overall institution is clearly committed in tangible and real ways to fostering diversity and the College of Medicine, a subset of UC is similarly committed.

Commitment by the UCCOM

UCCOM employs multiple mechanisms to enhance the recruitment of underrepresented minorities and students with disabilities. Diversity is a key component of the new UCCOM strategic plan. UCCOM's Office of Research and Graduate Education in collaboration with the Office of Diversity and Inclusion (ODI) is committed to increasing the number of qualified underrepresented minority medical students, graduate students, residents postdoctoral fellows, and faculty at UCCOM. In 2022, the COM welcomed a new Assistant Dean for Graduate

Diversity, Brittany Allison, PhD. She was charged with directing all diversity, equity, and inclusion efforts in the Office of Graduate Education, as well as leading the Summer Undergraduate Research Fellowship Program (SURF), providing training grant support, and serving as a liaison between the graduate office and the undergraduate Medical Sciences program. She will also be responsible for providing ethics training and being a co-principal investigator for the Post-baccalaureate Research Education Program (PREP), which helps prepare underrepresented minority or disabled college graduates for entrance into biomedical science doctoral programs. The ODI provides centralized support for the recruitment of underrepresented minorities into the COM; in collaboration with the Office of Graduate Education in UCCOM, the ODI recruits at national and regional conferences for all of the programs, including the AAMC, SNMA (Student National Medical Association), LMSA (Latino Medical Student Association) and APAMSA (Asian Pacific American Medical student association). Furthermore, the ODI works with several local pipelines at UC and local high schools to encourage and mentor students in science disciplines and, eventually medicine. As amechanism to document a genuine focus on diversity issues that would be both attractive to applicants and enhance their experience as UC students, cultural competence has been incorporated into the medical school curriculum to educate students on the care of a growing diverse patient population. Finally, the recruitment of students with disabilities is also a priority at UC. Mr. Mike Southern, leader of our Disability Services Office (http://www.uc.edu/aess/disability.html), develops recruitment and outreach strategies at undergraduate institutions. For electronic outreach, our training programs' leadership and mentors have joined the AccessSTEM and AccessComputing Teams (http://www.washington.edu/doit/Stem) to open dialogues with disabled high school and college students about the great possibilities for performing interdisciplinary bio-science regardless of personal limitations.

UCCOM sponsors a Minority Graduate and Professional Visitation Program that attracts about 100 students from more than 20 historically minority colleges and universities. The students spend two days on campus visiting graduate departments and programs in which they are interested and attending programs and social events, including a banquet designed for this occasion. Visiting students have dedicated time to interact with faculty and current students to learn more about programs of interest. Prospective students are provided with information regarding admission policies and financial aid, and subsequent follow-up is done on a departmental basis, usually by telephone. This has resulted in underrepresented minorities reaching impressive levels

Commitment of UCCOM at the graduate student level

There are many sustained efforts by UCCOM in coordination with the university to encourage graduate student diversity. Three types of program announcements are used: 1) Advertisements in national scientific journals; 2) Brochures mailed to departmental and division heads of major universities and medical schools in the US; and 3) Letters from individual faculty to colleagues at UCCOM, and other universities. Letters are mailed especially to institutions that have a large minority population (e.g., Howard University, Morehouse College, andSpelman College). In 2015, UC celebrated 35 years of sponsorship of a Graduate Minority Fellows and ScholarsProgram, during which time, more than 1200 minority students have benefited from the Program. Graduate minority fellowships and scholarships are awarded to minority students entering graduate programs in the University on a competitive basis. Candidates are nominated from the various graduate departments and are awarded scholarships or fellowships based on demonstrated potential for academic success. In 2015, the UC College of Medicine awarded four Yates minority scholarships; a criterion for the award includes "Underrepresentation of nominee's ethnicity *within the program."* Groups that qualify include African Americans, Pacific Islanders, Latino/Hispanic, and Native Americans. In 2016, the Graduate School expanded the program to support 25 incoming masters and doctoral students.

UC has long-standing participation in a large number of outreach programs that are directed to provide research opportunities to underrepresented minorities and disadvantaged members within Ohio. In 2021, 13,7% (47) of the total UCCOM graduate students were URM (In US: 18.6% URM).

Efforts focused on residency programs

More specifically focused on residency training, the ODI created in 2017 a Minority House staff Association with a social median webpage aimed at connecting diverse residents across all programs to social, mentoring, and networking opportunities with other diverse residents, students, and faculty, creating opportunities for the advancement of under-represented house staff through mentorship, networking, professional development. This is an excellent forum to emphasize the option of a research-oriented academic career. In collaboration with ODI, a grant was recently funded by The Doctor's Foundation, a regional organization in partdedicated to increasing the number of minority healthcare providers to Cincinnati. It is anticipated this will contribute indirectly to the pool of minority residents eligible for R38/StARR training. The ODI started a minority4th year visiting clerkship in July 2017 to increase exposure to our residency programs and to increase the number of minorities in the Internal Medicine residency program. The statistics for the current 2020-21 PGY1 year are as follows: male/female -- 19 women, 12 men; diversity -- 7 underrepresented in medicine; board scores -- scores for the year were not used as deciding factor for entry into program. Finally, the ODI hosts a "2nd Look Diverse Resident" applicant visit to Cincinnati to introduce applicants to the city and its current diverse residents and faculty. This serves to showcase the city of Cincinnati and demonstrate health disparities in the city. In 2020, the event was held fromJanuary 17th - January 19th. This includes a broad discussion of health care disparities research and provides another potential increase in the pool of minority applicants to the R38. Finally, in 2020, the residency programstarted an Implicit Bias Improvement Group to reduce implicit bias that still occurs, often unintentionally, among healthcare providers, including residents.

There are many efforts to recruit and retain postdoctoral fellows and residents: this is spearheaded by Cincinnati Children's Hospital (CCHMC) Office of Postdoctoral Affairs in collaboration with the Office of Graduate Education at UCCOM. We believe that the best mechanism to stimulate retention is to make the Training Program experience rewarding to all of the Trainees, with an emphasis on both education and professional development. The URM Recruitment and Retention funds provided by Acting Dean Filak pay for timely tutoring for at-risk students.

The adoption of IDPs for Trainees provides a valuable mechanism for early identification and resolution of professional difficulties. In addition to Minority House staff Association mentioned above, strong social support networks are provided by the recently formed SACNAS Student Chapter initiated by Hispanic, Native American, and African American graduate students and postdocs at UCCOM (https://www.facebook.com/ucsacnasorganization/). The aim of the UC Cincy-SACNAS student chapter is to celebrate diversity and facilitate mentoring and networking of minority scientists in all phases of their career development with the support of the local P&G professional chapter. Dr. Cindy Bachurski, co-director of the Office of Graduate Education, is the faculty advisor for this new student group. Sonya Ruiz-Torres and Nicole Oatman, two of the 3 minority 5+year grad students in the Cancer and Cell Biology program are part of the inaugural executive board of Cincy SACNAS. One of our third-year MDB graduate students, who is working on a Cancer Biology research project, joined UCCOM specifically because of our SACNAS organization and now serves as the vice-president. The Office of Postdoctoral Affairs has been put in place to address issues directly related to the recruitment and retention of postdoctoral fellows. Still, it can also be utilized by the Internal Medicine residency program. It offers UCCOM postdoctoral fellows many resources, including mentoring, the Women's Faculty Association, the Annual Black Faculty Networking event, and yearly Postdoc Appreciation Week programming.

II. CCTST/CTSA

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 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, which in April 2009 received funding of \$22.8 million over 5 years. Following a one-year extension, the National Center for Advancing Translational Sciences (NCATS) granted the CCTST a 4 year, \$16.7 million renewal in August 2015. The CTSA grant is currently in a no-cost extension. The most recent revised competitive renewal application submitted on April 15, 2019 and was renewed through 2025. UC and its partner institutions CCHMC, UC Health, and Cincinnati VAMC comprise the 39th member of the CTSA Consortium, which now includes over 60 sites. Its offices are centrally located in the CCHMC "Location S" research building, directly across the street from the UC MSB.

Investigators request methodologist consultation services through the CCTST's online "**Research Central**" portal at <u>http://cctst.uc.edu</u> and may qualify for a renewable voucher for more intensive support, described in the Biostatistics, Epidemiology, and Research Design section below. The CCTST website also features service descriptions, a searchable database of intramural funding opportunities, events archive, 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 4,000 members have joined the CCTST, including over 400 community representatives. Over the next 3 years, the CCTST will continue its transformation into a highly functioning learning organization in which existing systems (including research) are enhanced by an open, investigator-centric system founded on the concept of a "Research Commons." Research Commons, building upon the CCTST's experience with Research Central, will serve as a "virtual mall" for investigators across the AHC and on the undergraduate campus to obtain help with the development and completion of clinical and translational research. The principle of a "commons" is one of open-access and bidirectional sharing of resources, expertise, and best practices. Investigators can come to the Commons to get resources (e.g., data, tools, consultations), and the products they generate from those resources are contributed to the Commons for others to use. The Commons Portal, currently under development, will allow investigators to access all resources and services in the Commons electronically. When completed, navigation on the Commons will be accomplished via a number of existing services (e.g., triage specialists, electronic faculty portfolio directory, and data warehouses).

The Center for Improvement Science (CIS). The CCTST's CIS has developed the infrastructure that will support an interprofessional team focused on learning and utilizing the principles of team science for translational research. It has taken steps to be a focal point in the institutions and started the implementation of a comprehensive, tiered education program on team science principles for everyone involved in research. In 2016, the CIS initiated a series of workshops, in collaboration with UC Office of Research to help investigators be more effective in teams. Plans have been developed to implement a course within the MS in Clinical and Translational Research related to the science of team science. When fully functional, the CIS will provide team science consultants to help teams form and function, and they are now working with academic units to integrate multi-disciplinary research and team science into the promotion and tenure criteria for faculty. The mission, structure, and model of operations were developed by an interprofessional and multi-institutional task force and are being fine-tuned by a Council representing multiple disciplines from multiple campuses, which has been meeting on a regular basis to help inform the leadership of the CIS in the right directions to realize its aims. Two other initiatives are being championed by CIS: 1) developing a more comprehensive database of internally-funded grant opportunities and encouraging groups to utilize CCAPS, the CCTST's grant management software program adapted from Northwestern University; and 2) creating an institution-wide research seminar calendar to foster collaborations between investigators.

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 75 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 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 CTSA funding renewal included support for 2 optional modules which will advance clinical and translational research across the AHC:

• The Acute Care Research Module has been developed to encourage and support research studies in the acute care setting. Potential subjects for these studies are eligible because of an acute illness, injury, or other traumatic event. These studies do not allow for elective planning of visits or admissions to research units, but rather require an on-site, boots on the groundwork force capable of rapid enrollments, research procedures and interventions, and data/specimen collection during a time of intense clinical interactions. While many acute phenomena can only be studied through this mechanism, these studies bring unique regulatory concerns and institutional obstacles that must be overcome. To direct the work of the Acute Care Research Module, the CCTST created an Acute Care

Research Council (ACRC) consisting of successful investigators conducting research in acute care settings across the AHC, including investigators from UC, CCHMC, VAMC, and the community. The ACRC has begun meeting monthly. Its current activities include conducting an environmental scan to catalog all ongoing acute care studies, including the number of clinical research coordinators (CRCs) involved, identifying barriers to acute care study success, and prioritization of the next steps for action to be taken by the Council. Because regulatory issues for acute care research were determined to be critical, the respective IRB Chairs from UC and CCHMC were added to the ACRC, and an Acute Care Regulatory Coordinator was hired to provide expertise and support specifically related to research in acute care settings.

 The Lifespan Data Integration Module has initiated maternal-infant data linkage among 3 health care systems to establish methods and protocols for the inclusion of additional regional systems. This initial linkage includes systems that span UCMC, CCHMC, and local home visitation program Every Child Succeeds (ECS). An IRB protocol for the Data Hub was approved at CCHMC, and reliance was granted by the UC IRB. Formalized data sharing agreements have been developed.

The Biostatistics, Epidemiology, and Research Design (BERD) program provides investigators with ready access to research methods support. As such, BERD provides free 1-hour consultative services to all CCTST investigators who desire methodologic guidance regarding their research projects. Information to be discussed during the consultation may include developing and refining study hypotheses, guidance regarding a statistical analysis plan, guidance regarding data management needs. BERD will refer investigators who require additional support beyond the 1 hour consultation (e.g., conducting a statistical analysis, building a research database) to the appropriate services.

For faculty members who are developing an extramural grant application, BERD provides a widerange of support services for the grant submission. These services include (but are not limited to) help refining hypotheses, study design, creating the statistical analysis plan (including power/sample size calculations), and assisting with preliminary data analysis. For faculty members who hold Kequivalent career development awards (e.g., KL2, K08, K25), BERD supports these services as well as provides statistical analysis and data management services. Vouchers are available to eligible faculty investigators for these services (see details below).

The **Biomedical Informatics (BMI)** core serves as the hub for research informatics throughout the AHC. Through close collaboration with the UC Department of Biomedical Informatics, which includes the Division of



Biomedical Informatics at CCHMC and the Center for Health Informatics (CHI) at UC, a robust infrastructure is being established to improve the conduct of clinical and translational science and training. Informatics services include analysis of genomics datasets; protein informatics services such as modeling,

virtual drug design, screening, and cheminformatics analysis; provision of complex datasets and data warehouse queries; and development of databases and surveys using REDCap (Research Electronic Data Capture), a software toolset and workflow methodology for small/medium research studies developed at Vanderbilt University and currently utilized across a consortium of 2,309 institutional partners in 108 countries, including over 516,000 active researchers and 404,000 projects in use or development (2017).

The **Regulatory Knowledge & Support (RKS)** program coordinates the resources of multiple initiatives centrally supported by the CCTST. The core provides institutional support and efficient and effective avenues for clinical researchers to facilitate regulatory compliance. Services include assistance with protocol development, data management, FDA filings, IRB applications, and consent formulation.

Major core accomplishments have included the implementation of ClickCommerce® for IRB protocol management at UC and VAMC, which is also in use at CCHMC. This single IRB portal allows researchers to move seamlessly across the AHC, evaluate success, and refine priorities. The core has also developed and implemented CITI research ethics refresher training that is utilized and accepted across the AHC and region.

UC Health's Clinical Trials Office (CTO) has begun to provide services for UC faculty, including the development of recruitment strategies and materials; study budget development; and improved contract processing. Importantly, this CTO shares leadership with that at CCHMC, building on the strengths of CCHMC's established program and ensuring continuity between institutions. With the Community Engagement core, RKS spearheaded the development of the Consortium of Greater Cincinnati IRBs (CGCI), a subgroup of the Greater Cincinnati Health Council focused on improving the quality of research and facilitating clinical research regionally. Together with CTSA sites in Cleveland and Columbus, the core has developed and implemented a memorandum of understanding for IRB review that allows all Ohio CTSA sites to rely on each other and is written to allow expansion to other sites.

The **Community Engagement** core is broadening and strengthening collaborations between the AHC and community. Over the last year, core efforts with a more traditional approach to community engagement (largely focusing on communities of Greater Cincinnati) have been expanded to include more direct interactions with the Anderson Center at CCHMC, including work related to Learning Health Networks and enfranchising efforts with the RPAC. The Anderson Center has a broader range of stakeholders, including patients, clinicians, healthcare systems, and federal agencies such as PCORI, NIH, and FDA. Other coredriven resources include the Community Partner Council, comprised of community members, neighborhood activists, and AHC members who facilitate connections through advice, education, and action.

The Community Engagement Core continues to provide consultations for investigators seeking advice regarding identification of partners in the community or academic side and implementation and completion of community-based studies. The Core has developed community engagement criteria for the Reappointment, Promotion, and Tenure (RPT) committee at CCHMC, with an RPT toolkit, with plans to expand to other departments in the UC COM.

The Community Leaders Institute (CLI) is a leadership development training program offered over five consecutive weeks from February–March. The goal is to build research and leadership skills that the individual can use to improve or develop a health program. Training sessions are designed to build leadership and research/program evaluation skills in the following areas: Grant Writing; Accessing Public Datasets; Program Evaluation; Quality Improvement; Survey Development & Assessing Community Health Needs; Design Thinking; and Research Ethics. Participants receive a small grant (\$1,500–\$2,000) and have the opportunity to apply the skills learned to a health-related project (to be completed over the next 12 months).

CIRTification provides research ethics training for community members in a way that is reliable and applicable to their role. The training focuses on establishing the confidence and skills of community partners to conduct human subject research effectively and safely in their communities.

The current training for academic and hospital researchers wishing to conduct research is called *'CITI (Collaborative Institutional Training Initiative) Training.'* CIRTification was introduced to provide a human research training alternative for individuals in community organizations, with limited understanding of conducting human research and protecting potential research participants.

The CCTST, under our community engagement initiative, has developed two (2) options for completing CIRTification Training for community members engaged in research; online and in-person (virtual during the COVID-19 crisis). The only difference between the online and in-person options is how they are administered. The content covered in both options is the same.

The Community Health Grant program offers grants of up to \$20,000 for translational research conducted by academic and community organizations/programs or physician practices that improve outcomes in children, adults, and/or the community.

The **Graduate Certificate in Community-Engaged Research for Health** is jointly offered by the University of Cincinnati College of Medicine, Department of Pediatrics, and the College of Arts & Sciences, Department of Psychology.

The Certificate program is geared towards graduate students, faculty members, and academic or community researchers interested in integrating community engagement into their research design. Topics include: an overview of community-engaged research for health equity, ethics, introductory research methods and dissemination, community psychology, racism in research, and communicating and translating scientific results to public audiences.

III. Training Programs:

Master of Science and Certificate in Clinical and Translational Research: Designed for clinical professionals with terminal degrees (MD, PhD, PharmD, etc.) seeking to become independent clinical or translational investigators, the MS in Clinical Research program was established in 2005 to provide training to translate scientific advances into applications for improved clinical practice and human health (<u>http://www.eh.uc.edu/Clinicalresearch/</u>). The program combines didactic course work, seminars, and individual mentoring to enable clinicians to develop the analytic and quantitative skills necessary to conduct research within their own specialty area. Students must complete 30 graduate credit hours and thesis research and select one of 5 concentrations: Clinical Epidemiology/Clinical Effectiveness; Molecular Epidemiology; Clinical Trials; Translational Research; or Biomedical Informatics. A 10-credit hour Certificate program was added in 2009, which may be taken online as of 2011. Faculty are drawn from several departments of the Colleges of Medicine and Pharmacy. All program faculty are actively engaged in clinical studies.

Master of Science in Clinical & Translational Research: There are two track offered.

Principal Investigator (PI) Track: The Principal Investigator track is designed to provide clinical professionals (physicians, nurses, and other terminal degree clinical professionals) with the necessary preparation for successful career development and independent investigator awards. The program emphasizes specific training in clinical epidemiology/clinical effectiveness, molecular epidemiology, clinical trials, and translational research that will enable clinicians to translate scientific advances into applications for improved clinical practice and human health. The disciplinary purpose and ultimate goal of the program are to move practitioners from the realm of personal clinical experience to objective evidence.

Clinical Research Professionals (CRP) Track: - The Clinical Research Professionals track is designed specifically for clinical research professionals who coordinate, manage, and lead collaborative research projects and clinical trials. The program provides a strong foundation in research methodology and program/project management, including training in research ethics and the Institutional Review Board (IRB) process. The disciplinary purpose and ultimate goal of the program are to provide clinical professionals with the necessary preparation for successful careers in clinical research.

Molecular Epidemiology in Children's Environmental Health:

This training program is an interdepartmental and interdisciplinary program in Molecular Epidemiology in Children's Environmental Health (MECEH). Participating faculty are from the departments of Environmental and Public Health Sciences, Pediatrics, and Molecular Genetics. The focus of MECEH program is to identify outstanding predoctoral, resident/fellow MDs and postdoctoral PhDs and equip each with the knowledge and skills to undertake epidemiological and clinical studies using molecular markers of exposure, effect, and susceptibility. The students' education includes laboratory experience learning state-of-the-art methodology in molecular methods. Health studies examine the impact of environmental exposures on complex diseases and disorders, including obesity, allergy, asthma, diabetes, cardiovascular disorders, neurological disorders, and juvenile rheumatoid arthritis. A variety of environmental exposures are examined, including lead, pesticides, diesel emissions, aeroallergens, and tobacco smoke, among others.

MS and PhD in Epidemiology: The Department of Environmental and Public Health Sciences is part of the College of Medicine and is housed in a state-of-the-art research facility equipped with the latest technologies in environmental chemistry, aerosol physics, genomics, and molecular genetics. The department offers graduate degrees and medical residencies. Its graduate programs are Environmental Genetics and Molecular Toxicology, environmental and Occupational Hygiene, environmental and occupational medicine, epidemiology, and biostatistics. Graduates find careers ranging from the practical, such as occupational medicine and environmental hygiene, to basic research into how genetic and environmental factors affect susceptibility to disease. Our graduates share a common goal: to improve the quality of life by understanding the causes of environmental damage and identifying the effective methods of prevention.

The MS requires 1 year of full-time graduate study or its equivalent and a minimum of 30 graduate credits in addition to a written thesis. The PhD requires 3 years of full-time graduate study or its equivalent and a minimum of 90 graduate credits, 60 of which must be from didactic course work in addition to the dissertation. Courses required for both degrees include Environmental Health Seminar, Epidemiology and Biostatistics Seminar, Ethics in Research, Introduction to Biostatistics, Introduction to Epidemiology, Introduction to SAS Programming, Design & Management of Field Studies in Epidemiology, and Molecular Epidemiology. Additional course requirements of the PhD include Advanced Physiology, Regression Analysis, Experimental Design, and Categorical Data Analysis (Rates & Proportions).

University of Cincinnati's Master of Pharmaceutical Science in Drug Development: Founded in 2004, the Master of Pharmaceutical Sciences in Drug Development (MSDD) program provides individuals a formal opportunity to further their knowledge in drug development. A collaboration between academia, industry, and government, the Master's in Drug Development provides cross-disciplinary training in drug development's scientific, regulatory, and business aspects. Graduates are uniquely prepared to participate in the multidisciplinary process of translating a therapeutic concept from the lab bench to the bedside. Along with our MSDD program, we offer two graduate certificate programs, including Clinical Trials Design & Research and Global Regulatory Affairs in Drug Development. These three options are all online, asynchronous and available to part-time and full-time students.

MS in Drug Development: A unique collaboration between academia, industry and government, the MS in Pharmaceutical Sciences with Specialization in Drug Development is offered through the Winkle College of Pharmacy and designed as a 2-year part-time curriculum primarily intended for full-time employees in the Cincinnati metropolitan region. Established in 2004, the program is open to individuals holding postbaccalaureate degrees in pharmacy, nursing, medicine, and other related biomedical sciences. Courses include Global Drug Development, Pre-clinical Product Development, Regulatory Affairs, Clinical Trials Design, Project Management, Drug Delivery Devices, Pharmacovigilance, and Pharmacoeconomics. A total of 30 credit hours are required for the degree. The program was developed through close collaborations between the College of Pharmacy and other units of the AHC, regional pharmaceutical companies, and clinical research organizations.

Master of Public Health: The UC MPH program was approved by the Ohio Board of Regents in December 2007 and began enrolling students in September 2008. Housed in the Department of Environmental Health, its mission is to prepare students for leadership in public health practice and research by generating, evaluating, and applying evidence to improve the public's health. This education will be provided from a multidisciplinary perspective, employing active-learning strategies and in collaboration with the full array of community institutions and organizations involved in the health of the public. The UC MPH program is one of the first public health training programs in the nation to emphasize an evidence-based approach to safeguarding and improving the public's health. In cooperation with the Health Promotion and Education. This is primarily a practitioner's degree for those desiring to work as public health educators in departments of public health, voluntary agencies, and other community health organizations. In cooperation with the Environmental Health faculty, concentrations in environmental public health and biostatistics were added in 2012. The UC MPH program became a founding member of the Association of Schools and Programs of Public Health (ASPPH) in 2013. There is a choice between seven concentration areas that can help you develop in-demand skills in real-world settings: Biostatistics, Environmental Public Health, Epidemiology, Global Health, Health Education &

Health Promotion, Health Services Management, and Occupational Public Health The U.S. News & World Report ranks the MPH program 89th out of 195 public health program and schools.

MD/MS in Nutrition Program: Offered jointly by the Colleges of Medicine and Allied Health Sciences, the MD/MS in Nutrition dual-degree program is completed over 5 years, with core courses and guided electives for the MS typically completed between the 3rd and 4th years of medical school. The required master's thesis is completed during the 4th year of medical school. The program provides medical students with: 1) a comprehensive knowledge of the biochemical and physiological aspects of human nutrition; 2) knowledge of methodologies used in nutrition research and nutrition intervention, and 3) skills in research design, implementation, evaluation, and interpretation. The combined knowledge of nutrition and medical principles encourages multidisciplinary approaches to investigative efforts of major public health problems such as diabetes, obesity, cardiovascular disease, and cancer and improves the ability of the practitioner to use behavioral strategies to enhance patient compliance with lifestyle recommendations.

MD/MBA Program: The University of Cincinnati College of Medicine and the nationally ranked Carl H. Lindner College of Business have developed a MD/MBA Dual Degree Program for those students who wish to expand their career opportunities. Offered jointly by the UC CoM and Carl H. Lindner College of Business, this dual degree program is designed for highly qualified students who desire to complement their standard medical education with a greater understanding of the economics, finance, marketing, and management of the health care system. Students apply during their second or third year of medical school. The program typically takes 5 years to complete via one of 3 curriculum pathways. Graduates have expanded career options, including management positions in major health care organizations.

Grant Title	Award Number	Project Period	PD/PI	Number of Pre- doctoral Positions	Number of Post- doctoral Positions	Number of Participa ting Faculty
Pulmonary Development and Disease Pathogenesis Training Program	T32HL007752	07/15/1994- 08/31/2024	Jeffrey A. Whitsett	3	5	36
Immunology/Aller gy Fellowship Training Grant	T32AI060515- 15	09/01/2004 -08/31/2019 (renewal submitted)	David I. Bernstein (now M. Rothenberg)	0	3	36
Molecular Epidemiology in Children's Environmental Health Training Program (MECEH)	2T32ES01095 7	08/15/2001 – 06/30/2021	Ranjan Deka	4	6	24
Medical Scientist Training Program	4T32GM0634 83	07/01/2013- 06/30/2023	Gurjit K. Khurana	8	0	125

Current T32 training grants that could provide opportunities include:

			Hershey			
Environmental Carcinogenesis and Mutagenesis	5T32ES00725 0	07/01/1988 - 06/30/2020 (renewal submitted)	William Miller	8	4	26
Cerebrovascular fellowship training program	2T32NS04799 6	7/1/2006– 06/30/2021	Daniel Woo	0	4	27
Training Program in Cancer Therapeutics	4T32CA11784 6	09/01/2006 - 08/31/2023	Susan E. Waltz	2	6	25
Cincinnati Pediatric Clinical Pharmacology Postdoctoral	T32HD06905 4	05/16/2011- 04/30/2021	Alexander Vinks	0	4	38
Pediatric Gastroenterology and Nutrition Training Grant	T32 DKo07727	01/01/1995- 06/30/2020	Lee Denson	0	6	25
Post-Graduate Hematology/Onco logy Translational (PG-HOT) Training Program	1T32CA23676 4	07/05/2019- 06/30/2024	Vladimir Bogdanov, Xiaoyang Qi	0	Year 1: 4 Year 2: 5 Years 3-5: 6	12
Host Response to Trauma Research Training Program	5T32GM0847 8	07/01/1993 06/30/2023	Alex Lentsch & Hector Wong	0	4	11
Enhancing Treatment Adherence and Health Outcomes	1T32HD0682 23	05/01/2012- 04/30/2022	Kevin A. Hommel	0	4	33
Research Training in Child Behavior and Nutrition	T32DK06392 9	07/01/2003 - 06/30/2023	Scott Powers & Margaret Zeller	0	4	27
Cincinnati Training Program in Pediatric Rheumatology	T32AR069512	04/01/2016- 03/31/2026	Alexei Grom	0	2	24
T32 Fellowship	T32HP10027	07/01/1998- 06/30/2021	Kristen Copeland	0	6	31
Understanding Cardiovascular Disease Mechanisms	T32HL125204	12/01/2014- 11/30/2020 (renewal submitted)	Jeffrey Molkentin & Evangelina Kranias	3	3	18
Pathogenesis and therapeutic targeting of immune disorders	T32AI118697	07/01/2016- 06/30/2021	David Hildeman	3	0	35

Predoctoral training program in the neurosciences	2T32NS00745 3	07/01/2016- 06/30/2021	James P. Herman	4	0	29
Research Training in Pediatric Nephrology	2T32DK007 695-21	7/01/2014- 6/30/2024	Prasad Devarajan	0	2	14

IV. Graduate Programs in Biomedical Sciences:

CoM programs included 351 graduate students in 2021.

Biomedical Informatics (PhD and Certificate): The UC Doctor of Philosophy in Biomedical Informatics program is an important cornerstone for a program of academic excellence in informatics at UC and its affiliate hospitals. Leveraging partnerships between the UC CoM, CCHMC, and the UC College of Engineering and Applied Sciences, the program provides an in-depth knowledge of key analytical concepts that underlie applications of informatics and biomedical data science, ranging from the study of molecules to individuals and populations. The inter-collegiate Biomedical Informatics Graduate Certificate Program offers graduate-level training in the field of biomedical informatics, complementing existing MS and PhD degree programs at the University of Cincinnati. The program is open to both graduate students and clinicians, and professionals with advanced degrees.

Cancer and Cell Biology: The Graduate Program in Cancer and Cell Biology is an interdepartmental graduate program with expertise in many critical areas of modern Cancer and Cell Biology research. The mission of the CCB Graduate Program is to train the next generation of scientists and educators in basic mechanisms of molecular and cellular function with an emphasis on understanding mechanisms of cancers. Its philosophy is that PhD training must be intellectually stimulating, scientifically rigorous, and geared toward developing the lifelong learning and critical thinking skills that will prepare graduates to be successful as research scientists, educators, and/or professionals in a variety of other fields. Program faculty are concentrated in the UC Department of Cancer Biology at CCHMC, with additional faculty drawn from more than 10 other departments/divisions at the UC CoM and CCHMC.

Environmental & Public Health Sciences: For decades, one of the top-funded academic units of its type in the country, the Department of Environmental & Public Health Sciences has the largest graduate program in the CoM, offering doctoral training in epidemiology, biostatistics, environmental genetics, and molecular toxicology, and environmental and industrial hygiene. Masters programs are offered in public health, biostatistics, environmental and industrial hygiene, epidemiology, and clinical and translational research. Research centers housed in the DEH include the NIEHS-funded Center for Environmental Genetics (CEG), whose mission is to promote integrative research among basic and applied scientists, epidemiologists, and clinicians to develop an understanding of the complex relationship between genetic predisposition factors and environmental Health, funded in part by an NIH T32 grant, which equips predoctoral students, resident/fellow MDs, and postdoctoral PhDs with the knowledge and skills to undertake epidemiological and clinical studies using molecular markers of exposure, effect, and susceptibility. The DEH also houses the MS and Certificate programs in Clinical and Translational Research described above, which require 30 and 10 semester credit hours, respectively, offered in multiple tracks.

Immunology: The Immunology Graduate Program at UC and CCHMC aims to provide unparalleled training for the next generation of forward-thinking and innovative immunologists. The program offers rigorous coursework and practical training in some of the world's most outstanding immunology laboratories. The top-

notch faculty's extensive experience in teaching and expertise in all areas of immunology provides the student with a well-rounded immunology training experience and preparedness for a future post-graduate career path in immunology. Students in the Immunology Graduate Program have access to outstanding core-facilities including state-of-the-art flow cytometry and cell sorting, 2-photon imaging, gene targeting, and transgenic mouse core, bioinformatics core, gene expression core, pluripotent stem cell facility, laser capture microdissection core, viral vector core, and many others.

Medical Physics: The UC CoM offers an exciting graduate program in medical physics with a strong clinical emphasis, awarding a Doctorate of Medical Physics (DMP) degree and preparing students for the American Board of Radiology Physics exam. Founded in 1959, UC's program is well established and ideally suited to those with a solid undergraduate background in physics and desire to serve others as part of a health care team. The 4-year program curriculum incorporates 3 components: didactic course and laboratory work, clinical practicum, and applied research project. The 4-year DMP program is accredited by the Commission for the Accreditation of Medical Physics Educational Programs (CAMPEP), and thus graduates of the program will qualify for entry into the American Board of Radiology (ABR) Board Examination. The program will offer students the opportunity to train in therapeutic radiation oncology physics, with plans to implement appropriate CAMPEP accredited training to qualify for certification in diagnostic and nuclear medical physics in the near future. As a medical physicist, graduates will contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). Graduates also contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery, and proton therapy) and collaborate with radiation oncologists to design treatment plans, monitoring equipment, and procedures to ensure that cancer patients receive the prescribed dose of radiation to the correct location.

Molecular and Developmental Biology: The Molecular & Developmental Biology Graduate Program at CCHMC offers a unique opportunity to participate in cutting-edge research while being embedded in one of the top 3 pediatric hospitals in the nation. The major emphasis of the over 60 laboratories at Cincinnati Children's is the study of human development and childhood diseases. Faculty represent some of the world's most respected pediatric researchers, and CCHMC has been the home of major breakthroughs in both pediatric and adult medicine . The program includes over 100 faculty representing 25 divisions at Cincinnati Children's. Students have the opportunity to conduct research across a broad spectrum of biomedical disciplines, ranging from basic studies of embryonic development to the development of diagnostics and therapeutics for a range of pediatric and adult diseases. Close links between clinicians and researchers allow constant reciprocity – bench-to-bedside translation of research findings into better treatments and bedside-to-bench transfer of novel clinical observations to the research laboratory.

Department of Pharmacology and Systems Physiology (PSP): The PhD Program is designed to provide training for the next generation of scientists, innovators, and leaders in pharmacology. The Department has a dual mission of research and education, each being fundamentally served by the other. According to our vision, educating future scientists and heath care professionals requires a dedicated effort to expose students to modern scientific methods and approaches, and true academic research depends on the training of highquality future scientists. One of our primary missions is in primary basic science, pre-clinical and translational research. Our research teams apply state-of-the art techniques to illuminate both normal and pathological physiology, as well as basic and applied pharmacology. Expertise is present in a broad range of disciplines ranging from traditional physiology/pharmacology to computational modeling of complex systems. Researchers benefit from our departmental cores dedicated to microscopy and transgenic animal models. The University of Cincinnati is noted for the first antihistamine drug discovery, for the Sabin polio vaccine, and for the discovery of the mechanism of action of dantrolene, which has largely ameliorated mortality due to malignant hyperthermia in the operating room. Other notable research from the University includes work on the biological mechanism of action of important cardiovascular drugs such as digitalis glycosides and calcium channel antagonists. Recent advances in cell signaling cytokines and genetic variance in drug responsiveness among asthma sufferers are further examples of the directions research within our program might lead you. Education

The PSP Department also maintains two stand-alone Master's programs. The <u>Special Master's Program in</u> <u>Physiology</u> is a one-year program leading to the M.S. degree. This program is an enrichment program designed for students seeking to bolster their credentials for medical school. The program accepts 32 students each year who participate in a rigorous curriculum designed to demonstrate their preparedness for medical school. The program boasts a greater than 90% success rate in getting its graduates accepted to medical school. The <u>Masters Program in Molecular, Cellular, and Biochemical Pharmacology</u> (or "Safety Pharmacology Program") is designed to train students as successful career professionals for research and laboratory management roles in the field of pharmacology, particularly pre-clinical drug discovery and development, or in fields in which pharmacology knowledge and skills are of significant value. The program also prepares students for advanced academic (e.g., PhD) or professional (e.g., MD, DVM) training in the life sciences.

Molecular Genetics, Biochemistry, and Microbiology: With the future of medicine and medical practice firmly rooted in recent advances in biochemical and genetic technologies, the graduate program in Molecular Genetics, Biochemistry, and Microbiology at the UC CoM is ideally placed to provide the challenge, intellectual excitement and high-level training necessary to jump-start a career in molecular biology and medicine. In addition to the traditional PhD program in Molecular Genetics, an exciting new PhD program in Human Genetics is now available to incoming students. The Human Genetics track will focus on quantitative genomics, cytogenetics, molecular genetics, and clinical genetics and genomics. The department's mission is to achieve excellence in training the next generation of scientists and physicians and to carry out research at the cutting edge of biomedical technology. The 18 full-time faculty have a variety of interests ranging from cancer biology to cardiovascular science to microbial pathogenesis. Faculty use a number of state-of-the-art approaches, including molecular genetics and structural biology, in their quest to answer today's most pertinent medical questions.

Neuroscience: The Neuroscience Graduate Program at UC was established in 1988 as an interdisciplinary program offering the PhD degree and now has more than 80 participating faculty members from 22 departments in the Colleges of Medicine, Pharmacy, and Arts & Sciences. The program encourages a focus on clinical translation and offers multiple areas of concentration: Stress & Neuropsychiatric Disorders, Developmental Neurobiology, Pain, Sensory Neuroscience, Stroke & Neural Trauma, Metabolism & Obesity, Epilepsy, Cognitive Development, and Motivation & Drugs of Abuse. In addition to scholarship and laboratory training in high-impact research within state-of-the-art facilities, the Neuroscience Graduate Program offers guidance and support for a wide range of professional careers.

Pathobiology and Molecular Medicine: The Graduate Program in Pathobiology & Molecular Medicine is administered by 2 clinical departments: Pathology and Internal Medicine. Doctoral students in the Program are exposed to each of these disciplines in a program of study that unites contemporary investigative research in biomedical sciences with an understanding of human disease and the challenges that face effective treatment. All students participate in a core curriculum of academic courses for the first year. This is comprised of a series of lectures and laboratories that encompass basic molecular and cellular biology and the molecular mechanisms of human disease. Additional elective coursework and 2-3 research laboratory rotations are tailored to the student's individual research interests. The student also has the option of participating in an industrial or government research entity. At the beginning of the 2nd year, students select a laboratory and begin work on their independent research project. A student may choose from approximately 40 participating laboratories directed by faculty members that conduct research in the following general focus areas: Cardiovascular & Lipid Disorders, Digestive & Kidney Disease, Endocrine, Metabolic, & Bone Disorders, Hematology/Oncology and Immunology & Infectious Diseases. Since an individual research project may span more than one focus area, the student's thesis committee will also recommend attendance at select clinical and research seminars in the focus area(s) which are likely to complement the student's research activities. The completion of all requirements for the Ph.D. degree generally takes 5 years.

Physician Scientist Training Program: The Physician Scientist Training Program (PSTP) is the combined MD/PhD program of the UC CoM. Students typically complete their first 2 years of medical school and then shift their study to graduate school training in one of the College's 8 graduate programs. Upon successful completion of a PhD thesis, students then return to medical school and complete their final 2 years of clinical training. During these 2 years, students complete 5 required core clinical clerkships: internal medicine, surgery, obstetrics and gynecology, psychiatry, and pediatrics; 2 acting internships; and several primary cares or specialty electives. During their final year, students are required to complete a senior research project that may be in the field of medicine that the student has chosen to pursue in the future or may be a continuation of the student's thesis work. PSTP students are recruited from a national pool of outstanding individuals at top undergraduate schools. About 120 applications are accepted annually for 6 positions. PSTP graduates typically go on to residency and fellowship training in major academic medical centers; many are now faculty members directing their own research programs in leading medical schools.

V. Affiliates:

University of Cincinnati Medical Center (UCMC) traces its origins to the Commercial Hospital and Lunatic Asylum founded in 1821, the first hospital built in the U.S. primarily for teaching purposes. The hospital was later renamed Cincinnati General Hospital. In 1969, a new facility was constructed on the AHC campus. The institution was renamed University Hospital in 1982, and in 2009 established a more collaborative partnership with the University of Cincinnati and UC Physicians known as UC Health. The hospital was renamed UC Medical Center in 2012. The hospital was recognized as one of "America's Best Regional Hospitals" by *U.S. News and World Report* for 2012-13 and noted in 2014 for 9 high-performing specialties, including cancer; cardiology and heart surgery; geriatrics; and pulmonology. In 2013, UCMC was certified by the Joint Commission as an Advanced Comprehensive Stroke Center, a new level of certification reserved for institutions. University of Cincinnati Medical Center, in conjunction with the University of Cincinnati Academic Health Center, claims many firsts, including Albert Sabin's development of the polio vaccine and the country's first training program for emergency medicine physicians. UC Medical Center is the only hospital in Greater Cincinnati to have a nationally ranked specialty. In 2018, for the fifth year in a row, our Ear, Nose & Throat (ENT) program was ranked in the top 50 in the country.

Cincinnati Children's Hospital Medical Center (CCHMC) was founded in 1883 and, in 1926, relocated to its present site across the street from the CoM. Subsequently, William Cooper Procter, a benefactor of the hospital, funded a building devoted to research in children's diseases (the Children's Hospital Research Foundation, opened in 1931) and a \$2.5 million endowment. Research breakthroughs have included the Sabin oral polio vaccine, rotavirus vaccine (Rotarix®), the first practical heart-lung machine, and the surfactant preparation used worldwide to prevent premature infant deaths.

Today, CCHMC is ranked in the top 3 of the nation by US News & world report. Statistics for July 1, 2020 to June 30, 2021:

Patient Care	
Admissions (includes short stay)	28,211
Emergency and Urgent Care Visits	125,114
Outpatient Visits	1,336,660
Total Patient Encounters	1,489,985
Surgical Procedures	
Inpatient	6,418
Outpatient	25,209
Total Surgical Hours	47,576

275				
231				
416				
1,011				
16,317				
Operating Revenues and Expenses (dollars in thousands)				
\$2,226,690				
\$202,492				
\$53,010				
\$2,745,891				
\$2,508,207				
\$57,425				
\$325,109				

In November 2021, CCHMC opened a new 249-bed critical care building, which added a new emergency department, operating rooms, and many spaces to support patients and families. The institution received \$140 million in external funding in 2021. Its 1.4 million gross sq. ft. of research space includes the new (2015), \$205 million Clinical Sciences Pavilion ("Location T"), a 15 story, 445,000 sq. ft. facility adjacent to and physically integrated with the 415,000 sq. ft., 11 story Location S which opened in 2007 directly across the street from the COM. Location T includes new laboratories, a research imaging facility, research-focused outpatient clinic, offices, and supporting infrastructure for over 1,500 physicians, scientists, and staff. CCHMC housed an NIH-funded General Clinical Research Center (GCRC) from 1963-89 and has co-sponsored a Center with UC since 1993 that is now part of the CCTST and known as the Clinical Translational Research Center (CTRC), based in Location T, which encompasses the Schubert Research Clinic. The new (2016) \$120 million proton therapy center on CCHMC's Liberty Township campus, jointly funded and operated with UC Health, is the only center in the nation to dedicate a gantry (bay) exclusively to research. Separate gantries are dedicated to adult and pediatric cancer treatment, with capacity for a combined 300 patients annually.

Established in 2010, the **James M. Anderson Center for Health Systems Excellence** serves as the catalyst for transformation across Cincinnati Children's and is leading efforts within the hospital to achieve the unprecedented performance in outcomes, experience, and value that the organization has made core to its mission. The Center works at the system level on strategic initiatives while also looking broadly across the organization to ensure that work within meso- and microsystems have maximum institutional impact. One of its key roles is to provide leadership, content expertise, and research and infrastructure support for strategic areas that are not only system-level priorities but which also serve as hubs for accelerating organizational transformation: safety, capacity management, chronic diseases, community/population health, learning networks, health policy, health services research, evidence-based decision making, and improvement science education.

In 2007, UC, CCHMC, and UC Health agreed to establish a Joint Cancer Center, together committing \$60 million to build and upgrade facilities and new clinical programs, attract world-class faculty and accelerate research findings. The development of shared clinical facilities allows continuous monitoring of pediatric cancer survivors into adulthood and beyond. Now known as the **Cincinnati Cancer Center (CCC)**, the collaboration's long-term goal is National Cancer Institute (NCI) designation as a Comprehensive Cancer Center. The Center's mission is to reduce the burden of cancer in the US, with a particular focus on southern Ohio and northern Kentucky, which will be attained through seamless integration of discovery science, translational research, clinical trials, and prevention strategies. More than 800 individuals, including faculty, research professionals, physicians, and staff, deliver leading-edge cancer research, clinical care, and effective cancer prevention and control measures to the region and across the nation through 3 programmatic areas:

Molecular and Cellular Basis of Cancer, Molecular Therapeutics and Diagnosis, and Cancer Etiology, Control and Prevention. The Center is also involved in an initiative to enhance research on the links between obesity and cancer, which involves faculty affiliated with the Cincinnati Diabetes and Obesity Center, UC Cancer Institute, and UC Metabolic Diseases Institute.

<u>CCHMC Schubert Research Clinic</u>: The Schubert clinic dedicated human subject studies opened in July 2015 at a cost of \$20 million. This state-of-the-art facility will be accessible to investigators across the AHC and incorporate the CTRC and other clinical research entities in the AHC into a physical and functional research clinic in the new Clinical Sciences (Location T) building (Figure). The unit will include 2 floors containing the outpatient clinic with 28 exam rooms (blue), a 3T MRI dedicated to research (orange), exercise physiology and body composition rooms containing DXA and pQCT (green) on the 1st floor, and an investigational pharmacy, metabolic kitchen with adjacent eating and food preparation areas, and a facility for sample shipment on the 2nd floor. The clinic infrastructure, support, and services available will provide the foundation and accommodation for different types of studies from all across the AHC in a broad range of populations serving all age ranges. Importantly, this new Research Clinic will be able to accommodate significant number of adult studies from UC investigators across the street studying adult diseases. Partnership with groups in the community will broaden the scope and provide much-needed services to study diverse populations.



Schubert Research Clinic

The **Cincinnati Veterans Affairs Medical Center (VAMC)**, located within the AHC complex, has 117 general medical and surgical beds and serves veterans within a 50-mile radius of Cincinnati and beyond, encompassing 15 counties in Ohio, Kentucky, and Indiana. It is accredited by the Joint Commission on Accreditation of Health Care Organizations (JCAHO). Its major clinical disciplines include Medicine, Neurology, Surgery, Psychiatry, Ambulatory Care, and Dentistry. Most of the University of Cincinnati house staff rotate through the VAMC. During FY 2016, the hospital provided 66,815 in-patient bed days of care and had 580,788 outpatient visits. The VAMC also supports 6 community-based outpatient clinics and 1 healthcare access site in Fort Thomas, Kentucky.

The Research Service supports a variety of research projects that are funded by the VA Central Office, Department of Defense (DOD), NIH, private foundations, and the pharmaceutical industry. In FY 2016, Cincinnati VAMC investigators received \$3,298,943 in VA funding and \$548,931 in extramural federal funding (\$241,118 from NIH), which supported 26 active investigators in 94 research projects. There are ongoing projects in infectious disease, immunology, oncology, psychiatry, psychology, substance abuse, cardiology, endocrinology, pulmonary medicine, nephrology, and neurology. Cincinnati VAMC faculty and staff are actively involved in clinical and basic science research. The Cincinnati Education and Research for Veterans (CERV) foundation, as well as a satellite location of the UC AHC's CTSA-funded Clinical Research Unit (CRU), are based at the VAMC. The CRU satellite consists of 3,000 sq. ft. of dedicated research space and contains both inpatient and outpatient rooms as well as a lab and an investigational drug pharmacy.

Hoxworth Blood Center, located on the Academic Health Center campus, is the only facility of its kind for the Greater Cincinnati region. Its mission is to enhance the well-being of patients in its service area by assuring a reliable and economical supply of the safest, most efficient possible blood, by combining effectiveness and providing innovative hematotherapy and cell therapy services, as well as by promoting research and education programs in transfusion and transplantation medicine.

Serving a 17-county area in Ohio, Kentucky, and Indiana, Hoxworth collects, tests, processes, and distributes over 140,000 blood components annually to 31 hospitals and medical centers. Hoxworth, a member of America's Blood Centers, is licensed and regulated by the U.S. Food and Drug Administration and accredited by the American Association of Blood Banks, American Society of Histocompatibility and Immunogenetics, and the Foundation for the Accreditation in Cellular Therapies. Founded by Dr. Paul I. Hoxworth in 1938, the Blood Center has grown to be an internationally recognized leader in transfusion medicine. The Center has 7 neighborhood donor centers, multiple mobile collecting units, more than 250 full- and part-time employees in 26 divisions (including therapeutic apheresis, transplantation immunology, cellular therapy/regenerative medicine, immunohematology reference laboratory and research), and a complement of over 300 volunteers. Since its inception, Hoxworth Blood Center has provided Transfusion Medicine Compatibility Laboratory Services to Cincinnati Children's Hospital Medical Center and medical oversight of the University Hospital Compatibility Laboratory.

Hoxworth's Research Laboratory is a leader in coordinating research projects in transfusion medicine and cell therapies, including clinical trials for transfusion medicine/cell therapy-related products. Its goal is to link basic research with clinical care, leading to improved methods that ensure the quality, safety, and efficacy of the blood and hematopoietic supply. In education, the Center offers an ACGME-accredited fellowship program in Blood Banking and Transfusion Medicine and provides Transfusion Medicine training to Adult and Pediatric Hematology/Oncology fellows, Anesthesiology fellows, and Pathology medical residents.

Jose Cancelas, MD, PhD, is Professor of Pediatrics at the University of Cincinnati College of Medicine, is Director of Hoxworth Blood Center, and holds the Beatrice C. Lampkin Chair for Stem Cell and Hematotherapy. He is also leader of the Stem Cell group of the Cancer & Blood Diseases Institute of Cincinnati Children's Hospital Medical Center (CCHMC).

Dr. Cancelas is a physician-scientist with a broad background in hematology, stem cell biology, hematopoietic malignancies, cell therapies, and transfusion medicine. His long-standing interest in hematopoiesis began during his doctoral and postdoctoral work at the Cancer Research Institute of Barcelona, the Erasmus University of Rotterdam, and CCHMC and Hoxworth Blood Center, University of Cincinnati. During his training and as an independent investigator, Jose developed methods and proof-of-concept for analysis of signaling pathways in hematopoietic/cancer stem cell activity in vivo.

He has published over 170 peer-reviewed manuscripts in the areas of hematopoiesis and transfusion/cell therapies. His laboratory is funded by the NIH, US DoD, and different private foundations and corporations. Sponsored research support was nearly \$2.0M in 2021.He has trained over 40 MD, MD PhD, and PhD professionals who are currently working in Hematology/ Oncology and Transfusion Medicine programs in USA, Europe and Asia. As Medical Director for both Cell Therapies at the Hoxworth Blood Center and the Cell Manipulation Laboratory of the Cancer & Blood Diseases of CCHMC, Dr.

Cancelas' work focuses on developing new blood and cell therapy products with augmented efficacy and/or safety profiles in the areas of transfusion, stem cell transplantation, and immunotherapy

UC Cancer Center: The UC Cancer Center was established in 2010 to encompass all cancer patient care. research, and education missions within the CoM and throughout patient care settings in UC Health, including the Barrett Cancer Center, which has a long-standing reputation for providing the most advanced and complete range of cancer services available in the region. Named a "high-performing site" by the National Cancer Institute's National Clinical Trials Network, the University of Cincinnati Cancer Center offers nearly 200 leading-edge clinical trial options for patients throughout their care for all stages of the disease. Our researchers are exploring and developing groundbreaking technologies — including programs, devices, and models of study, new diagnostic tools, and new targets for therapies — and work daily to make our world-class care even better. The UC Cancer Center has been awarded continuous accreditation by the Commission on Cancer since 1934, making it one of the nation's top five longestaccredited cancer programs. Our Comprehensive Breast Cancer Center is one of just 16 centers nationally to maintain triple accreditation from the National Quality Measures for Breast Centers (NQMBC), the American College of Radiology, and the National Accreditation Program for Breast Centers. UC Health is the region's only adult FACT accredited academic health system. As one of 50 participating sites in the Oncofertility Consortium, a nationwide program overseen by the National Institutes of Health, UC Cancer Center provides access to the latest clinical care initiatives and translational research in fertility preservation. UC Health's Lung Cancer Screening Program was the first lung cancer screening program in the region and the only one to have a multidisciplinary team of lung cancer experts who have expertise in lung cancer screening. UC Cancer Center is part of the Collaborative Ocular Oncology Group, a multicenter group of 12 ocular oncology centers in North America that is researching RNA characteristics of ocular melanoma to help predict the likelihood of it spreading to other body parts, which will help inform targeted therapy options. The Proton Therapy Center is a recent collaboration between UC, Cincinnati VA Medical Center, and CCHMC. This center first opened to patients in the spring of 2017. The center is most unusual in that it includes three treatment bays or gantries, with one devoted exclusively to research. The research specific bay is the only proton gantry in the world fully dedicated to clinical research. To ensure full utilization of the research gantry, researchers have met regularly for several years (under the auspices of the Radiation Biology/Particle Therapy group) to plan research projects and funding applications.

CCHMC HEART INSTITUTE offers team-oriented, interdisciplinary diagnosis and treatment for the full spectrum of pediatric cardiac problems. Our team members are among the best in their respective fields; Heart Institute clinicians are board certified in not just one but in as many as three and four areas related to pediatric heart care. Our staff includes acclaimed pioneers of procedures that have changed heart care across the nation, including catheter interventions and echocardiography in congenital heart disease. The Heart Institute team at Cincinnati Children's developed the Heart Institute Encyclopedia to provide easily accessible information on cardiac diseases, defects, disorders, and problems that may affect a child's heart.

TPSC Biospecimen Collection and Repository

The RLDC Biospecimen Collection and Repository operates under IRB-approved protocols to collect patient information, samples from minimally invasive procedures, or discarded samples from clinically indicated procedures. Data and samples are managed through the coordination of RLDC scientists and clinical staff, assuring that clinically collected samples will meet laboratory needs of researchers. All samples are tracked through FreezerWorks, an electronic sample management system with barcode labeling accessories that meets regulatory requirements, including 21 CFR Part 11, with a robust audit trail. The RLDC Biospecimen Repository includes two -80 freezers with alarm systems that report to a central security staff, with an on-site backup freezer for emergency storage of samples should a freezer failure occur. This system is already in place for sample management of the MILES and TRAIL LAM trials. RLDC Collection protocol samples from controls and patients with other rare lung diseases are also collected and stored in this repository and are available to support biomarker research.

TPSC Research Bronchoscopy Suite at the Cincinnati VAMC is under the direction of Dennis McGraw, MD.

The Research Bronchoscopy Suite is located in the Cincinnati VAMC Clinical Research Unit (CRU), one of 3 NCRR funded research centers based at VA hospitals. It was formed as a joint venture between the University of Cincinnati and the Cincinnati VAMC in 2003 and has supported more than 50 NIH, VA, foundation, and industry-sponsored protocols. The CRU consists of 3,000 square feet of dedicated research space on the 4th floor of the Cincinnati VAMC. The unit features (1) two monitored rooms, (2) a fully equipped cardio-pulmonary physiology laboratory with radiographic capability and equipment for noninvasive cardiopulmonary assessment, (3) an exercise laboratory with refrigerated centrifuge, (5) a nurses station staffed five days a week, with the capacity for 24-hour coverage, (6) five fully equipped outpatient examination rooms each with computers linked to CPRS and the internet, (7) an investigational drug pharmacy, and (8) additional space for temporary sample storage with -20° and -80° freezers. The CRU is staffed by 2 experienced research nurses and 2 research assistants certified as study coordinators. Beyond direct participation in specific research protocols, this group serves as a resource to investigators and staff at the Cincinnati VA for issues related to regulatory issues, study design and implementation, and compliance.

All study documents in hard copy, such as consent forms, are kept in a locked cabinet in the Clinical Research Unit (CRU) of the VAMC in Cincinnati, Ohio. Access to the files is limited to the Principal Investigator and designees only. Medical history and demographics data are stored electronically in the VAMC intranet. Participant data, excluding HIPAA identifiers, may be transferred to a REDCap database using the unique TPSC identifier. The REDCap database is a secure web application for managing online surveys and databases that have been developed as part of the Clinical and Translational Science Award consortium and is located at the University of Cincinnati. De-identified data will be transferred to REDCap by study personnel while at the Cincinnati VAMC, to reduce the risk of data loss or security breach. If there is a security breach, the VAMC Information Security Officer will be notified immediately, per the VA Handbook requirements. All research records will be maintained and controlled per the VHA Handbook 1200.12, RCS 10-1.

The **UC Gardner Neuroscience Institute**, a collaboration of the UC College of Medicine and UC Health, is a leading treatment, research and teaching center for complex neurological conditions that includes more than 100 faculty members from 15 clinical specialties. Through its centers of excellence and premier programs, the Institute advances compassionate, patient-centered neurologic and psychiatric care, life-changing research, and comprehensive education. Its physicians and researchers have created national models for evidence-based treatment and research of complex neurologic conditions, including ischemic and hemorrhagic stroke, brain aneurysms, brain, and spinal cord trauma, brain tumors, Parkinson's disease, epilepsy and seizure disorders, multiple sclerosis and trigeminal neuralgia. Institute physicians helped discover the only FDA-approved treatment for ischemic stroke and were also the first to receive FDA approval to use the YAG laser to vaporize inoperable brain tumors. The \$60 million Gardner Neuroscience Institute opened in 2019. The 114,000 sq. ft. building consolidates patient care and education and 215 faculty physicians, researchers, and staff in a single location.

UC Center for Integrative Health and Wellness. Integrative medicine combines conventional medicine with evidence-based complementary therapies such as mindfulness approaches, nutrition and health coaching, acupuncture, massage therapy, yoga therapy, and stress reduction techniques for optimal healing. The Center for Integrative Health and Wellness focuses on promoting integrative medicine principles at the UC Academic Health Center and throughout the community. The Center is working to engage members of all colleges and units across the university, along with its collaborative partners in the community, to develop robust integrative health and wellness initiatives and programs. Center faculty provide education to enrich and cultivate integrative medicine skills for medical students and promote the value of treating the whole person. Using evidence-based perspectives, graduates will be able to address and counsel patients in the use of integrative modalities, improving patient care and satisfaction. Likewise, Center researchers are involved in several federally funded research projects that focus on integrative care.

VI. Patient Resources Available for Research

With 714 registered beds and 1,086 medical staff, **University of Cincinnati Medical Center** (UCMC) is the largest hospital in the region and is the major referral center for many programs and therapeutic modalities not

available elsewhere in the metropolitan area. UCMC, West Chester Hospital, Drake Center for Post-Acute Care, Lindner Center of HOPE (behavioral care), numerous outpatient care facilities throughout the region, and UC Physicians (UCP), the practice group for over 750 clinical faculty members at the UC College of Medicine, together comprise UC Health. UCP was integrated into UC Health in 2011. Clinical services are provided in an array of different specialties, including family medicine, surgery, internal medicine, emergency medicine, oncology, urology, cardiology, neurology, neurosurgery, otolaryngology, dermatology, rehabilitation, pain management, anesthesiology, orthopedics, obstetrics-gynecology, ophthalmology, radiology, radiation oncology, pathology, and psychiatry. A Level 1 trauma center, UCMC, logged 83,279 emergency department visits in 2016.

CCHMC has 16 patient care locations and 673 registered beds in the Cincinnati metropolitan area, including 102 inpatient psychiatry beds and 30 residential psychiatry beds. In FY2016, CCHMC had 1,304,776 total patient encounters (+5.4%), 19,684 admissions, 92,528 emergency department visits, and 33,903 surgical procedures, serving patients from all 50 states and 61 countries. A total of 197 transplants were performed, including 26 kidney, 28 liver, 125 stem cell, 12 heart, 5 lung, and 1 multi-visceral procedure. Employment increased 1.1% to 15,429, including 1,891 active medical staff. A new, 600,000 sq. ft. building housing 276 critical care beds and related support functions, including a roof-top heliport for emergency care and an emergency department are planned for completion in 2021.

Institutional Assets for Research Training

The Academic Health Center is the region's center of medical education. The CoM trains 678 medical students, 575 graduate students (including 55 MD/PhD), 664 residents and clinical fellows, and 234 postdoctoral fellows annually. CCHMC has 502 medical residents, 254 clinical fellows and 181 research postdoctoral fellows; postdoctoral fellow training is funded largely by institutional funds of the Cincinnati Children's Research Foundation and by federal training grants. The James L. Winkle College of Pharmacy has 533 students, including the PharmD and MS/PhD programs. The College of Nursing has 2,653 undergraduate and graduate students. The College of Allied Health Sciences has 2,993 undergraduate and graduate students.

VII. Informatics Infrastructure

CCHMC Division of Biomedical Informatics: The Division of Biomedical Informatics provides a variety of computational resources, services, and support to investigators at Cincinnati Children's and across the AHC. Available computational resources include the i2b2 research data warehouse for cohort identification, a cluster with more than 300 processing cores for executing computationally intensive jobs, network filers and relational database systems for secure and regulatory compliant data storage, and an array of licensed and open-source scientific software applications including statistical analysis packages. Support services for both basic and clinical research are offered. Service staff can help with the selection, purchase and installation/configuration of basic research tools (e.g., electronic lab notebook software, cluster computing applications), and can provide both formal (grant-funded) and informal assistance in areas such as sequence analysis and microarray data analysis. Staff also specialize in the development of electronic data capture systems using tools such as Microsoft SharePoint Services with InfoPath, in addition to designing/developing informational and collaborative portals, research patient registries and other custom software, including multimedia applications.

UC Department of Biomedical Informatics: The Department of Biomedical Informatics was established within the College of Medicine in 2014. Its mission is to use data to effectively create and apply knowledge to improve the understanding, diagnosis, treatment and prevention of health care problems. The department is the academic home for informatics faculty and assists with collaborations and data sharing among UC, CCHMC and UC Health. UC began offering a PhD program in Biomedical Informatics in 2016, which has engaged 29 faculty and enrolled 5 students to date. A Graduate Certificate in Biomedical Informatics is also offered. The department houses the **Center for Health Informatics (CHI)**, established in 2006, in which experts from the AHC and community organizations address issues in clinical practice, clinical research, and public health to improve the quality and safety of patient care and advance medical science. The Center is affiliated with hospitals and healthcare organizations throughout the region, which provide access to real-world settings for gathering data and testing informatics innovations. While the CHI's primary focus is on the sub-

domains of health informatics concerned with clinical care, clinical research and public health, its faculty also collaborate closely with departments and divisions of UC and partner institutions that focus on other subdomains such as bioinformatics and computational biology.

Donald C. Harrison Health Sciences Library: Reopened in 2008 following extensive renovation and expansion, the former Academic Information Technology & Libraries was renamed for benefactor Donald C. Harrison, MD, who served as AHC provost and senior vice president for health affairs from 1986-2002. The Library encompasses nearly 45,000 sq.ft., bridging the existing Medical Sciences Building (MSB) and light-filled atrium of the new CARE/Crawley building. Featuring a 90-seat computer lab, numerous meeting spaces, and over 200,000 print volumes on site, it also provides a full calendar of computing classes and access to over 800 online databases, 110,000 electronic journals, and 149,000 e-books. The Health Sciences Library serves the research needs of students, faculty, and staff of all AHC Colleges, affiliates including UCMC, CCHMC and VAMC, the Greater Cincinnati community, and investigators/scholars across the country and globe. In 2014, the Library was ranked 14th among "the 25 most impressive university medical school libraries in the world" according to the website Best Master's Degrees Reviews and Rankings.

NetWellness: Established in 1995 as one of the first health sites on the internet, NetWellness (<u>www.netwellness.org</u>) is a non-profit service providing health and medical information directly to the public from 3 academic health centers (UC, The Ohio State University, and Case Western Reserve University). NetWellness covers a full range of health topics in an easy to understand format with information for all age groups and diverse populations, including minorities and the underserved. NetWellness provides the knowledge needed to increase prevention, enhance provider/patient communication, and reduce health care costs. In NetWellness, these Ohio universities have created the largest expert network of its kind, providing health information and education to consumers directly from experts who are specialists in their field. NetWellness is non-profit and without commercial advertising, serving the public as an unbiased resource. In its 22 years of operation, its reputation has grown as a leader in free, accurate health information, garnering numerous national awards for the site. Over 360 expert faculty members have volunteered their time to provide state-of-the-art health content, including over 600 articles and an "Ask an Expert" feature that has answered nearly 68,000 questions to date.

The Health Collaborative. In April 2015, the Health Collaborative, Greater Cincinnati Health Council, and HealthBridge merged into a single organization called The Health Collaborative. These 3 long-standing nonprofit health and health care improvement organizations now work together under a single management structure which more efficiently aligns services and more effectively meets the needs of the communities, stakeholders, and members they serve. Its members are health systems and hospitals (including UC Health, CCHMC, and Cincinnati VAMC), as well as care partners (post-acute and non-acute care providers), and business partners. The Collaborative provides insight into regional health issues, helping catalyze community will around solutions, and measuring progress on shared community aims; expertly manages large-scale improvement initiatives involving multiple stakeholders working together toward a defined common goal; and provides data and value-added solutions to help stakeholders succeed and accelerate innovation to make health and healthcare a competitive advantage for the region. Among its many services is the Health Information Exchange, the secure electronic movement of health-related information among organizations utilizing nationally recognized standards and policies. As patients move from one healthcare setting to another, HIE ensures patient information is available at the point of care where and when it is needed.

VIII. Core facilities

List of Core Facilities at the Academic Health Center

- 1. Animal Behavioral Core (CCHMC)
- 2. BSL 3 Facility (UC)
- 3. Cardiovascular Imaging Core (CCHMC)
- 4. Cell Manipulations Laboratory (CCHMC)
- 5. Center for Autoimmune Genomics and Etiology (CAGE, CCHMC)
- 6. Center for Imaging Research (UC)
- 7. Confocal Imaging Core (CCHMC)

- 8. Diagnostic Immunology Lab (CCHMC)
- 9. DNA Sequencing and Genotyping Core- Computational Medicine Center (CCHMC)
- 10. Facscalibur/Flow Cytometry Core (UC)
- 11. Gene Expression Core (CCHMC)
- 12. Genomics, Epigenomics and Sequencing Core (UC)
- 13. Heart Phenotype Lab (UC)
- 14. Human Genetics Core (CCHMC)
- 15. Imaging Research Center (CCHMC)
- 16. Laboratory Animal Medical Services (LAMS, UC)
- 17. Live Microscopy Core (UC)
- 18. Mass Spectrometry (UC)
- 19. Mass Spectrometry Facility (Clinical and Biomedical) (CCHMC)
- 20. NMR-based Metabolomics Core (CCHMC)
- 21. Pathology Research Core (CCHMC)
- 22. Pharmacometrics Core (UC/CCHMC)
- 23. Pluripotent Stem Cell Facility (CCHMC)
- 24. Protein Informatics Core (UC/CCHMC)
- 25. Proteomics Laboratory (UC)
- 26. Pyrosequencing Lab for Genomic and Epigenomic Research (CCHMC)
- 27. Research Flow Cytometry Core (CCHMC)
- 28. Structural Biology and Protein Expression/Purification Facility (UC)
- 29. Transgenic Animal and Genome Editing Core Facility (CCHMC)
- 30. Translational Trials Development and Support Laboratory (CCHMC)
- 31. Tumor Bank and Biobank (UC/CCHMC)
- 32. Vector Production Facility (CCHMC)
- 33. Viral Vector Core (CCHMC)
- 34. Vontz Core Imaging Laboratory (UC)

UC institutional Research Core Administration—The UCCOM maintains <u>15 research core facilities</u> designated as core service centers following full government cost compliance standards. These facilities exist within multiple departments, but are collectively managed by the COM, Office of Research, through the Associate Dean for Research Core Facilities, Ken Greis, PhD. (ken.greis@uc.edu; Tel: 515-558-7012; <u>see the letter of support</u>). The Associate Dean is charged with incorporating best practices to improve the efficiency and impact of the existing core infrastructure and set the strategic direction for the core resources. The core is governed by the Core Management, Planning and Sustainability (CoMPaS) Committee, chaired by the Associate Dean, but with members, including core users, directors, technologists and administrative stakeholders (see current roster below). The CoMPaS team meets monthly to address all core-related activities. The **mission** of the COM core facilities to ensure the greatest benefit to our research enterprise. The **vision** of the CoMPaS Committee is to provide a partnership with faculty, core leaders, and institutional leadership to ensure the highest quality of shared research technologies, capabilities, and infrastructure that will deliver consistent growth in our research standing by facilitating quality research that leads to publications and research funding.

CoMPaS Members	Title	Committee Stakeholder
Ken Greis, PhD	Prof and Associate Dean for Research Core Facilities	Chair
Sean Davidson, PhD	Prof and Vice Chair for Research in Pathology and Lab Med	Research leader; Core User
Gary Shull, PhD	Prof of Molecular Genetics	Former Core Director
Rhett Kovall, PhD	Prof of Molecular Genetics	Research Leader; Core User
Nicole White, MPH	Adminstrative Director for Cincinnati Children's Share Resources	Core Administration
Sakthi Sadayappan, PhD	Prof of Cardiology, Director of HL&Vascular Institute	Research Leader; Core User
Kelsey Dillehay McKillip, PhD	Asst Prof & Director UC Biorepository and UC Histopathology	Core Director
Sherry Thornton, PhD	Assoc Prof & Director of Cincinnati Children's Res Flow Cytometry	Children's Core Director
Mario Medvedovic, PhD	Prof of Environ. Health, Director of Division of Biostat & Bioinfor	Research leader; Core Director
Phil Taylor, PhD	Asst Vice President for Strategic Initiatives	VP for Research liaison

Administratively, the CoMPaS Committee is responsible for evaluating each core on an annual basis with an emphasis on core utilization and recovery, technology enhancements and research impact. This evaluation is facilitated through the interaction with the advisory committee established for each core facility. The CoMPaS Committee then makes recommendations to the Dean's office regarding the annual budget, core enhancements and/or subsidy investments for each core facility. The overall financial expenditures for the COM core facilities is about \$2.2 million in per year of which about 55% (\$1.2 million) is supported by sustained COM investments. This includes service contract support, annual core enhancement funding and subsidies to address any shortfall of overall recovery across the cores.

UC institutional investments in core infrastructure—To further enhance core recoveries and boost efficiency, the CoMPaS Committee is actively evaluating core management and billing systems to incorporate into the cores beginning in 2020. Other recent institutional core investments have included expanding capabilities in metabolomics (lipid profiling and metabolic flux), integrating targeted X-ray irradiation (XStrahl, XenX system) and imaging analysis to preclinical animal studies, upgrades to the microscopy cores with new systems (Leica, DMi8 Widefield Fluorescence microscope and a Nikon SIMe super-resolution microscope) and a new imaging processing workstation and software license (Imaris 9.2 for Cell Biologists CL). Finally, institutional support for the necessary operational components (uninterrupted power supply and nitrogen generation) and computational hardware and software to support the integration of a Thermo Orbitrap Eclipse mass spectrometry was critical for the successful award of over \$800,000 to upgrade and advance the proteomics core with a NIH shared instrumentation grant (<u>1S10OD026717-01</u>). Thus, collectively, the UCCOM actively supports and manages core facilities and equipment as the necessary infrastructure for a successful research enterprise. Additional details for each research core facility with updated service fees are available online.

<u>https://med.uc.edu/research/core-facilities :</u> The UCCOM houses a number of research core facilities designated as core service centers. Dr. Sadayappan is a member of the Core Service Committee at UCCOM.

<u>https://www.cincinnatichildrens.org/research/cores :</u> CCHMC is dedicated to advancing basic, translational, clinical, and outcomes-based research. The core provides cutting-edge, cost-effective technology and data analysis that would be unattainable on an individual research basis. The fee-for-service program also offers unique studies that can't be found anywhere else. Dr. Sadayappan has a joint appointment at CCHMC to utilize all the core facilities.

Investigators at the UC and CCHMC have access to more than 35 shared core research facilities. The research core facilities include typical centers, such as microscopy and live animal imaging, genomics (including single-cell sequencing), proteomics and metabolomics, as well as research flow cytometry, biostatistics and bioinformatics, and a transgenic animal and genome editing core. In addition, some more unique or advanced cores include a pluripotent stem cell and organoid development facility, clinical informatics, viral vector production, and a Biosafety Level 3 laboratory. Importantly, each of the cores is managed and staffed by experts in their respective areas, thus allowing the research community access to the technology that best meets the needs of their research programs. Finally, the cores are subsidized by the institutions to provide affordable options to all investigators. Through a reciprocal collaborative agreement between both organizations, the preferred (lowest) rate is available to all UC and CCHMC investigators for use in any of the collective core facilities.

Live Microscopy Core: The microscopy core supplies equipment and expertise, which allow trainees to image living tissues, either isolated or in anesthetized animals, with high-resolution light microscopy. The facility supplies chambers for mounting isolated living tissues, procedures and training on animal anesthesia and

surgery to expose intact organs for imaging over extended intervals, as well as equipment for imaging living (or fixed) tissues with high resolution. The core contains an integrated 100 ft² room for animal surgery in preparation for imaging, and it secures IACUC approval for importing animals from other investigators into the facility for non-survival experiments. The core contains >\$2.5 million in equipment purchased since 2004, including a Zeiss LSM510 NLO confocal and two-photon microscope, a Zeiss LSM510 META confocal microscope, a Zeiss LSM710/Duo fast-scan confocal microscope, digital imaging low-light fluorescence microscope (Leica) and Laser Capture Microdissection microscope (Arcturus Veritas). The facility also provides access to, training, and use of Metamorph software for image analysis.

Biostatistics Core: The Center for Biostatistical Services is housed within the Department of Environmental Health of the COM. Its mission is to leverage grant funding by providing first-rate biostatistical assistance with proposals during their pre-award and post-award phases. The Center is staffed by 7 biostatisticians, plus several Master's level biostatisticians and graduate students. One of the biostatisticians, Dr. Roman Jandarov, is a Co-I for the R35 proposal, has contributed to the design of the clinical aspects of the application, and will be intimately involved in data analysis. This core provides consultation and/or ongoing support to researchers at UCCOM, such as development of clinical research plans, regulatory compliance, preparation of Institutional Review Board (IRB) applications, consent forms, documentation, application filling and approval process guidance, and assistance in the development of grant proposals, data entry and management services using the Teleform and Complion database (https://complion.com), RedCap, Epic and data analysis (see the letter of support from Mrs. Yolanda Wess, Academic Research Services). The PI and his lab have access to technical and clerical support essential to biostatistics collaboration; appropriate books, journals, and technical manuals; statistical software tools, such as SAS, S-Plus, STATA, SUDAAN, StatXact, and LogXact; and data management tools such as Teleform.

Division of Epidemiology (DBE): Services of the DBE at CCHMC include guidance and assistance in developing study designs and protocols, creating data collection instruments and databases, developing data management protocols, and crafting analysis plans. The DBE also provides input on grant applications and complete data analysis services. In addition to these core services, DBE faculty conduct their own research, focusing on research methodologies and population-based investigation of disease etiology and prevention strategies.

Pathology and Histology Resources: This core includes technical support, cryostat, microtomes, embedding table, histochemical and immunohistochemical, and radiographic supplies to perform routine staining, *in situ* autoradiography, and electron microscopy. They maintain 3 computer-based digital image analysis systems and software for morphometric analysis of tissue histology. A full electron microscopy core is also part of the morphology core to perform the proposed R35 research program.

Mass Spectrometry Facility: Recently, the State of Ohio Mass Spectrometry Consortium was formed through a partnership with 10 Ohio universities. The University of Cincinnati Mass Spectrometry Facility is one of the two primary centers in the Consortium. The Facility has recently acquired several state-of-the-art instruments that enable rapid screening of samples, trace metal analysis, and detailed structural analysis and characterization of biological molecules and organic and inorganic materials. In addition, a system has been established for rapid data transmission among all members of the Consortium. The Facility functions on a fee-for-service basis and serves the whole University of Cincinnati community. Three mass-spec instruments are also held within the proteomics facility at UCCOM under the direction **of Dr. Ken Greis, PhD** (see the letter of support).

Confocal Imaging: The PI and his lab members have access to shared state-of-the-art imaging equipment in the Department of Internal Medicine, including Leica Fluorescence stereomicroscopes. These instruments are equipped with several optimized filters for viewing commonly used fluorescent compounds, and they are located close to the PI's lab in a dedicated imaging facility with a wet bench and tissue culture incubator. In addition, the PI has an Olympus IX73 Inverted Research Microscope & Camera System in his lab for histology and cell imaging.

Research Flow Cytometry Core: Both UCCOM and CCHMC have core facilities to perform flow cytometry analysis which is the key experiment in the entire proposed studies. CCHMC maintains six analytical cytometers (BD FACSCanto, BD FACSCanto II, BD LSR II, and BD LSRFortessa models) and four cell sorting cytometers (BD FACSAria II, Beckman Coulter MoFlo XDP, and Sony SH800S). Online scheduling and onsite

training are always available. In addition, ImageStreamX is available to combine the visual power of microscopy with the speed and sensitivity of flow cytometry by digitally imaging cells directly in flow for measuring fluorescence in cellular applications, including immunofluorescence, cell cycle analysis, proliferation and phospho-flow. Luminex, a high-throughput multiplexing suspension array system, which enables the simultaneous quantitation of a wide array of cytokines and mediators (up to 100) in a single human, mouse or rat sample (i.e., serum, lavage, sputum, or cell culture supernatants), is available at the core facility. This assay is particularly useful for measurement of mediators/cytokines in small samples. In separate rooms, computers and software, such as FACSDiva, FCS Express, FlowJo, ModFit, FCAP Array CellQuest Pro and DEAS, are available to users for data analysis.

Center for Stem Cell & Organoid Medicine: The organoid facility at Cincinnati Children's is an extraordinary, world-class operation. It is a multi-disciplinary team of scientists, clinicians and entrepreneurs using advancements in developmental biology and stem cell technologies to revolutionize personalized medicine and improve patient care. Dr. Sadayappan's basic studies using human blood samples has been designed to take advantage of this state-of-the-art resource and collaborations with its investigators. The scientists in this forum have developed a way of using stem cells from patients to generate miniature organs known as organoids; This forum is available to Dr. Sadayappan to get access, support and perform assays. https://www.cincinnatichildrens.org/research/divisions/c/CuSTOM

Transmission Electron Microscopy and Image Analysis: The PI, postdoctoral fellow and research assistants have direct access to the transmission (Hitachi H-600, TEM) and scanning (Jeol 840 A, SEM) electron microscopes at Cincinnati Children's Hospital <u>where the PI has a joint appointment</u>. The facility has ultramicrotomes, knife breakers and a dark room for sample preparation. Two workstations are available for video input from SEM or fluorescence light microscopes for computer-based image processing and analysis. Images are recorded digitally with a Kodak 1.6 Megaplus camera system operated with AMT software (Advanced Microscopy Techniques, Danvers, MA) and processed with Adobe Photoshop CS4. The service includes sample processing and imaging of the sarcomere. The micrographs will then be analyzed by the postdoctoral fellow, using the MetaMorph Imaging Software (version 7.6).

IX. Department of Internal Medicine

FACILITIES AND RESOURCES: University of Cincinnati College of Medicine Department of Internal Medicine (DOIM)

Starting in 2011-2012, the DOIM initiated targeted internal investments and programs to support promising MD, MD/PhD and PhD investigators at every level of their career. The overall objective was to support faculty based on a tripartite missions of patient care, teaching, and research. First, to establish a critical mass of investigators, the DOIM increased from 191 faculty in 2011 to 320 faculty in December 2021. The DOIM is currently home to 9 divisions, 112 residents, 80 fellows and 373 staff. Second, a Research Governance Committee (RGC) was put in place that consisted of 2-3 researchers from each Division; the RGC was charged with improving the research culture and disseminating information. The RGC defined specific goals and monitored progress with reports provided at monthly DOIM Staff and Leadership meetings. Third, the DOIM created internal funding for "unsponsored research" and made a concerted effort to identify and nominate faculty for recognition and awards, both internal and external. Discrete and targeted mechanisms to dispense bridge funding and pilot internal grant funding programs were established to support junior and senior faculty while promoting collaboration between divisions and departments. Fourth, a program was developed for mentorship, training and faculty development at all levels. Specifically, the DOIM created a junior faculty club (J-club) involving 10-12 of the research-oriented junior faculty (Jclub. As a part of participating in the club, an individual development plan was required, and members were encouraged to apply for internal and NIH developmental awards.

Administratively, it is divided into 4 areas: educational, clinical, research and veterans affairs. Physicians within the Department are part of the UC Health University of Cincinnati Physicians group practice, providing comprehensive clinical services in primary care and all medical subspecialties. New clinical practice programs include a diabetes center, sleep center and heart and vascular center. The Department is deeply committed to its research mission and to the training of future clinical investigators and researchers in foundational, clinical, translational, outcomes and other health care-associated research areas. Faculty research is often interdisciplinary and collaborative between clinical and basic scientists, including projects with investigators at Cincinnati Children's Hospital Medical Center, the Cincinnati VA Medical Center, the James L. Winkle College of Pharmacy, and the College of Education, Criminal Justice, and Human Services. The Department has particular research strengths in: cancer, with numerous collaborators across the Academic Health Center, including the CCHMC Hematology Oncology Unit; cardiovascular health, including a Cardiovascular Center of Excellence; digestive diseases, including the Hepatology Research Group, one of the premier research groups involved in the study of HCV and HBV co-infections in the context of HIV; diabetes and obesity; infectious diseases, including the AIDS Clinical Trial Unit; outcomes research; rare lung diseases including LAM and pulmonary alveolar proteinosis; and sickle cell disease, including participation in national clinical trials of the Sickle Cell Research Network.

In 2016, to assist in the implementation of the research mission of the DOIM, an "Academic Research Service" (ARS) administrative unit was created consisting of a senior business administrator, research manager, administrative assistant, grant writer/educator, grant matcher/web designer and a 25% FTE biostatistician from the Division of Bioinformatics. The goal was to provide comprehensive services related to the preparation and submission of all types of grants and manuscripts for investigators within the DOIM without being redundant to other services already offered by the College of Medicine. Best practices were identified by coordinating with existing efforts within the Pulmonary Division and partnering with existing initiatives within Divisions and the Academic Health Center. Representative activities included weekly Grand Rounds, annual departmental research retreats, individual division-sponsored talks, monthly faculty-staff meetings, and educational opportunities offered by affiliated organizations such as the UC Heart, Lung, and Vascular Institute housed largely within the DOIM.

In 2015 the department chair convened a faculty development cabinet to create a departmental IDP template for research-active faculty and to outline the expectations of mentoring for junior faculty. All junior faculty were expected, with the assistance of their division director and the associates chairs for research, clinical affairs, and education, to identify a mentoring committee composed of 2-3 senior faculty. To further support mentoring, in the spring of 2017 a junior-faculty peer-mentoring group (J-club) was established. For the time span of Spring 2017 to Spring 2021, 12 of 23 participants received major grant funding (~\$100k). In 2019, a research regulatory service component was formed to provide support services to clinical researchers in the areas of regulatory training, monitoring visits and audits, IRB submissions, and maintenance of required regulatory documentation. A research financial services component of ARS was initiated in the same year and was charged with assisting in the financial management of clinical trials, including budgeting projections, set up of trial accounts, invoicing of sponsors, effort allocations, and contracting with sponsors. Regulatory services, laboratory services, and financial services were all provided for a fee such that they did not require a departmental cost beyond their establishment. As of 2019, approximately 46% of research-oriented faculty (51 of 112) have used some feature of ARS services and a program involving ten training sessions devoted to the full scope of how to maximize the probability of obtaining funding. Laboratory processing service was established and managed by the ARS. Eventually, five of six divisions conducting clinical research have been utilizing this service. Finally, major responsibilities were to organize a yearly research symposium and publish an Annual Report highlighting the research accomplishments of the DOIM and offering a means to foster collaborations.

As of FY21, total grants, ~ held by primary R01 awards. The amount is \$119 Investigators with intramural distinguished





achievement awards, junior and senior pilot awards, challenge awards, bridge funding, submission incentive awards, and others. This investment of \$2.7 million has seen a return of \$22 million in external awards, and one of the goals is to foster the awarding of external K awards from the NIH. During FY19 through 22, 5 NIH-sponsored K career development and three CCTST-sponsored KL2/CT2 grants were awarded to junior investigators in the Department of Internal Medicine. **Figure 1** demonstrates the increase in funding from FY15 to FY21; of note, the submission success rate increased from less than 20% to over 40%.