

Division Data Summary

Research and Training Details

Number of Faculty	2
Number of Joint Appointment Faculty	11
Number of Support Personnel	85
Direct Annual Grant Support	\$2,203,344

Clinical Activities and Training

Inpatient Encounters	27
Outpatient Encounters	3,918

Division Photo



Row 1: C Lindsell, J Strasser, M Mitchell, J Tsevat, T Cripe
 Row 2: J Heubi, S Powers C McGraw, M Wess, A Morrow, J Kues, J Lynch, J Corsmo

Significant Publications

All publications resulting from projects utilizing the CCTST or Clinical Translational Research Center (CTRC) are listed in the divisional sections of this annual report. A complete listing of these publications is available in the CCTST bibliography, along with a copy of each journal article.

Division Highlights

Biomedical Informatics

John Hutton now serves as the Director and Mark Wess as Co-Director. During the last year, we have revamped and expanded the CCTST website, which has served as a focus area for clinical and translational research across the AHC. There has been a concerted effort to expand biomedical informatics support of each of the core areas with strong emphasis on expanding the Community Engagement site to support both investigators and community members. A revised version of our extensively used portal for investigators, *Research Central*, has been developed and there has been robust usage of REDCap. Progress has been made toward developing a data warehouse at both UC and CCHMC with enhanced functionality via work on the i2b2 software/framework and work has commenced on establishing a centralized biospecimen banking program. Work has continued on full implementation of federated identity management across CCHMC and UC thereby allowing UC investigators less cumbersome access to resources at CCHMC. A new track in the MS in Clinical and Translational Research has been implemented in Clinical Research Informatics. Biomedical Informatics has served as a collaborator for 2 large grants to support the pediatric chronic disease registry and enhancement of a community clinical repository and disease registry.

Biostatistics, Methods and Ethics in Translational and Clinical Studies (BioMETrCs)

Work has continued to develop a unified federated core within the CCTST to provide comprehensive services to investigators at any stage in their careers. During the last year, we have revised our processes for supporting investigators via *Research Central*, our virtual portal of entry to CCTST resources. We now have triage personnel (RNs with clinical research experience) who define the investigator's problem and then triage

them to the needed service. If there is need for study design services, experienced researchers meet with investigators. If needs are related to biostatistics or data management, faculty and staff from BioMETrCs or staff and faculty from the Biomedical Informatics core respond to provide services including biostatistics or REDCap or other data management solutions. In 2010, Research Central supported over 400 consultation requests. We continue to provide free service for up to 10 hours of PhD time or 20 hours of MS staff time and if it appears that the investigator needs more time, we identify faculty who can charge for additional time on a fee-for-service of percent effort basis through their academic unit. During the last year, 10 pilot grants related to clinical research ethics and biostatistical or study design methodology were awarded. A formalized plan was implemented to encourage interaction among research methodologists with continuing education and professional development activities related to their disciplines.

Participant Clinical Interactions Resources (PCIR)

The two sites for the Clinical and Translational Research Center (CTRC) at CCHMC and the VA Medical Center continue to have robust utilization with increased complexity of visits at each site. We continue to support modest inpatient usage, outpatient, and scatter-bed usage and robust outpatient usage with nursing services and support ancillary costs and core services. Despite some budgetary adjustments, investigators likely do not recognize any differences in support between resources provided under the GCRC grant vs. the CTSA. The Scientific Advisory Committee (SAC) remains in place because the resources expended need to be closely scrutinized. To minimize obstacles for use, we have eliminated the requirement for SAC review of all projects – projects with PHS funding are now exempted from review and only undergo executive review by the director. During the last year, the UC Clinical Trials Office has been reorganized under UC Physicians with current direction shared with the CCHMC Clinical Trials Office and a direct relationship for both with the CCTST. Considerable efforts have been directed toward recruitment and retention of research subjects at UC and CCHMC. A CCTST-supported recruitment specialist has begun efforts to expand services to UC with some early success. We have actively participated in ResearchMatch and we have staff supporting retention efforts for studies by using Accurint®, a commercial product designed to find “lost” research participants.

Pilot and Collaborative Translational and Clinical Studies (PCS)

Since the CTSA award was made (April, 2009), the PCS has had three broad-based, cross-campus pilot grant solicitations that attracted applicants from diverse sectors of the AHC and the other UC colleges. With the second cycle, we received 92 applications and 4 core requests for \$1.2 million in funding. After letters of intent were reviewed, the initial pool was pared to 29 regular and 3 core applications. Each application was evaluated by 3 reviewers and, using an NIH Study Section format, final scores were determined and funding decisions reviewed by the CCTST leadership. For the second cycle, 12 awards were made to PIs at CCHMC (N=9) and UC (n=3) with considerable collaboration between investigators across UC and CCHMC. The RFA for the 3rd year was released on August 27, 2010 with 102 letters of intent received for 98 pilots and 4 cores. The Letters of Intent are now being reviewed prior to requesting full applications for consideration of funding. This year, we provided infrastructure support to other pilot funding programs on campus having clinical and translational themes, including those for atherosclerosis research and neuroscience research. We also initiated a “Just-in-Time” small grant program to support small projects designed to obtain data needed to submit competitive extramural grant applications.

Translational Technologies and Resources

The CCTST through the CTSA and institutional support provides limited resources for programs that may be integrated into T1 research efforts. During the last year, programs such as drug discovery, proteomics,

imaging, cell and molecular therapy and translational and molecular disease modeling have assisted a limited number of investigators with specific needs. As examples, the Molecular and Cell Therapy Matrix Program has developed new technology to derive induced pluripotent stem cell (iPSC) lines from humans by using a multicistronic vector that can be removed from the genome after reprogramming. They have now generated 40 human iPSC cell lines and have obtained several additional grants for this technology. The Drug Discovery Core has expanded the number of investigators and institutions that utilize their services. Notably, a 3-year inter-institutional drug discovery consortium has been developed between Case Western University and UC and 3 additional companies have contracted to use the Compound Library. The Proteomics Core has assisted investigators in biomarker profiling in new studies of mild traumatic brain injury, idiopathic pulmonary fibrosis and bloodstream infections with *Candida* species. Translational and molecular disease modeling has developed a program called "ToppCluster," which allows researchers to build state-of-the-art graph networks and models of normal and abnormal biological systems.

Evaluation

The Evaluation Team has become well integrated into most of the core groups and has engaged in examining, revising, and developing new evaluation tools and data by these groups. The Evaluation Core is now seen as an integral part of the CCTST and Evaluation Core members interact with members of each of the cores. The project evaluator, Jack Kues, Ph.D., attends weekly project administrative staff meetings, bi-weekly steering committee meetings and bi-weekly TnT meetings. Three major initiatives have been undertaken by the Evaluation Core with support from all the cores: (1) Despite some delays, the Evaluation Team is developing a comprehensive Dashboard both to collect data centrally from the various cores and to provide feedback to the cores and the public regarding progress toward the goals of the CTSA. (2) There has been considerable concern about the visibility of the CCTST within UC and in the community, so the Evaluation Core is directing efforts to enhance our visibility and use of our resources by UC faculty and community members through better branding and marketing methods. (3) There is a real interest in developing better collaborative efforts among faculty and trainees in the AHC, the undergraduate campus, and the community. Efforts are being directed toward integrating social network analysis into the evaluation strategy.

Faculty Members

James E. Heubi, MD, Professor

Co-Director, Associate Chair, Clinical Research; Associate Dean, Clinical Research; Program Director, CTRC

Research Interests

Joel Tsevat, MD, PhD, Professor

Co-Director, Associate Dean for Clinical and Translational Research, UC College of Medicine

Research Interests

Joint Appointment Faculty Members

Timothy Cripe, MD, PhD, Professor

Hematology/Oncology

Research Interests Pilot Funding Director

John Hutton, PhD, Professor

Biomedical Informatics

Research Interests Informatics Director

Ardythe Morrow, PhD, Professor

Neonatology & Pulmonary Biology

Research Interests Biostatistics Director

Frederick Barr, MD, Professor

Critical Care Medicine

Research Interests CTSC Director

Monica Mitchell, PhD, Professor

Behavioral Medicine & Clinical Psychology

Research Interests Community Engagement Director

Thomas DeWitt, MD, Professor

General & Community Pediatrics

Research Interests Research Education Co-Director

Marc Rothenberg, MD, PhD, Professor

Allergy & Immunology

Research Interests K12 Training Program Director

Charles Dumoulin, PhD, Professor

Radiology

Research Interests Imaging Research Director

Bruce Aronow, PhD, Professor

Biomedical Informatics

Research Interests Translational & Molecular Disease Modeling

Punam Malik, MD, MS, Professor

Hematology/Oncology

Research Interests Stem Cell Matrix Director

James Wells, PhD, Associate Professor

Developmental Biology

Research Interests Stem Cell SCCTF Director

Significant Accomplishments

Improving Research through the Community Leaders Institute

In 2010, the University of Cincinnati's Center for Clinical and Translational Science and Training (CCTST), the effector arm of the Clinical and Translational Science Awards program, graduated its first class from the Community Leaders Institute. The goals of the six-week leadership institute are : to train community participants in critical aspects of community and translational research; to increase participants' use of data to improve services, programs and evidence-based practice; and to increase the potential for academic-community collaboration and translational health research. Participants are trained in grant writing, accessing public datasets, creating databases using REDCap and other software, ensuring evidence-based practice and survey development and assessing. As a result of the institute, 100 grant proposals were submitted, and eight of 11 participants received grants totaling \$1.8 million. In addition, participants developed surveys, created databases/analyzed data, implemented quality-improvement approaches or strengthened evidence-based practices and accessed public databases to obtain data for grants or training. The 2011 institute was expanded to 15 participants, including a range of providers who work with children, adults and seniors.

Developing a Robust Environment to Train Scientists

The master's program in clinical and translational research now has 57 students. A certificate program in clinical and translational research, launched in 2009, is a 14-credit-hour program to train fellows and junior faculty interested in serving as collaborators on clinical and translational research projects. A total of 44 students have enrolled, and 12 have graduated. With support from an American Recovery and Reinvestment Act (ARRA) supplement, work has continued on developing an on-line version of the certificate program, which may appeal to an even larger audience. Work continues on a second ARRA supplement to create an on-line curriculum in clinical research informatics. A second KL2 RFA attracted 18 applications for two slots, which were awarded to faculty in pediatrics and neurology. During the last year, we renewed the BIRCWH K12, which we now administer through the Center for Clinical and Translational Science and Training. The CCTST has supported new and competitive renewal applications for T32s and K12s and is developing a K-Club to support career development for young investigators with KL2, K12, K23, K01 and K08 awards.

Harmonizing, Streamlining Regulatory Elements

With support from the Center for Clinical and Translational Science and Training (CCTST), there has been increasing integration of the Offices of Research Compliance and Regulatory Affairs (ORCRA) at Cincinnati Children's, the University of Cincinnati and UC Health. The Academic Health Center (AHC) and ultimately the entire UC campus will be aligned in requiring scientific review prior to Institutional Review Board submission, with the CCTST providing support for investigators whose protocols undergoing pre-review are identified for additional methodological, biostatistical or other assistance. To better harmonize IRB activities across the AHC, UC, with the assistance of the CCTST, has purchased the software program Click Commerce, already in use at Cincinnati Children's. Work is continuing to develop a community-wide harmonization of the review processes at IRBs for the 17 hospitals in Greater Cincinnati, with much of the preliminary groundwork completed during 2010. During the last year, the CCTST has sponsored cross-campus town hall meetings for education and debate on industry-academic relationships and intellectual property and is planning meetings on biobanking and responsible authorship.

Grants, Contracts, and Industry Agreements

Grant and Contract Awards

Annual Direct / Project Period Direct

Grant and Contract Awards		Annual Direct / Project Period Direct
HEUBI J		
Cincinnati Center for Clinical and Translational Sciences and Training		
National Institutes of Health(University of Cincinnati)		
UL1 RR 026314	04/03/09-03/31/14	\$2,101,990
Cripe, T	Pilot/Collaborative Studies	\$25,761
Hutton, J	Biomedical Informatics	\$84,880
Morrow, A	Design, Biostatistics & Ethics	\$87,392
Barr, F	CTRC	\$1,682,751
Mitchell, M	Community Engagement	\$52,339
DeWitt/Rothenberg	Research/Education/K12 Training Program	\$39,647
Grupp-Phelan, J	K30 Training Program	\$28,982
Dumoulin, C	Imaging Research	\$25,761

Aronow, B	Translational & Molecular Disease Modeling	\$31,761
Malik, P	Stem Cell Research	\$42,716
Cincinnati Center for Clinical and Translational Sciences & Training ARRA Supplement: Research Workforce Development & Dissemination		
National Institutes of Health(University of Cincinnati)		
UL1 RR 023614-01S2	07/01/10-09/23/11	\$79,325

GAVIN, M

CALERIE Phase II

National Institutes of Health(Duke University)

U01 AG 022132	06/13/11-08/31/13	\$22,029
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Current Year Direct \$2,203,344