

Division Details

Division Data Summary

Research and Training Details

Number of Faculty	2
Number of Joint Appointment Faculty	15
Number of Support Personnel	98
Direct Annual Grant Support	\$1,986,540

Clinical Activities and Training

Number of Clinical Staff	0
Inpatient Encounters	3
Outpatient Encounters	10,677

Division Photo



Row 1: M Eckman, M Macaluso, J Strasser, S. Powers, J Tsevat, J Heubi, J Kues
Row 2: B Harnett, E Haynes, J Lynch, J Hutton, B Trapnell, B Kissela, C Lindsell

Significant Accomplishments

Facilitating Inter-Institutional Access for Researchers

During the last year, we have continued working toward a total renovation of the CCTST website, which has served as a focus area for clinical and translational research across the Academic Health Center. We have produced a series of video clips for each of the core areas on the website. As a part of our continuous improvement process, we continue to revise Research Central, our portal for investigators to obtain services from CCTST. There has been robust usage of REDCap with 207 new projects, including surveys and database development. Progress has been made toward developing a data warehouse at UC and Cincinnati Children's with enhanced functionality via work on the i2b2 software/framework. Work has continued toward the full implementation of a centralized biospecimen banking program, which has started accruing samples. Full implementation of federated identity management across Cincinnati Children's and UC has been accomplished, thereby allowing UC investigators easier access to resources at Cincinnati Children's and vice versa. A new Clinical Research Informatics track in the MS in Clinical and Translational Research program was initiated.

Providing Research Methods Support and Collaboration

During the past year, Maurizio Macaluso, MD, DrPH, (the new director of the Division of Biostatistics and Epidemiology) has replaced Ardythe Morrow, PhD, as co-director of BERD. During the last year, we have revised our processes for supporting investigators via Research Central, our web portal of entry to CCTST resources. We utilize triage personnel (two RNs with clinical research experience) who define the investigators' needs, such as biostatistical support, a REDCap database, mentorship, etc., and then connect them with the needed service. Research Central supported 319 consultation requests and has become a model for several other CTSA's. We have made substantial progress in developing a charge-back mechanism for services provided by Research Central, with anticipated implementation in the first quarter of 2012. During the last

year, five pilot grants related to clinical research ethics and biostatistical or study design methodology were awarded. Finally, working with Biomedical Engineering and several other departments, BERD has formed a medical devices collaborative that meets monthly to foster collaboration in medical device design.

Expanding Funding Opportunities for Pilot and Collaborative Studies

The Pilot and Collaborative Translational and Clinical Studies program has had three broad-based, cross-campus pilot grant RFAs, which attracted applicants from diverse sectors of the Academic Health Center. In the third cycle, we received 102 pilot grant applications and core requests for 14 grants totaling \$1.2 million. In response to concerns by the External Advisory Committee last year, we implemented a Junior Pilot T1 program directed toward instructors and assistant professors, making seven awards of \$25,000 each. The RFA for the fourth year was released in August 2011 with 76 letters of intent received for 72 pilots, two renewals, and two cores. We have reviewed 41 full applications, with funding decisions imminent. We have also explored opportunities to support outcomes research and comparative effectiveness research pilot grants through efforts in place within Cincinnati Children's. During the last year, there were five "Just-in-Time" awards, designed to support collecting data needed to submit competitive extramural grant applications, seven retreat/symposium awards designed to foster transdisciplinary research, and two Clinical Research Feasibility Fund awards for investigators performing research in the Clinical Translational Research Center.

Division Highlights

Research Education, Training and Career Development

The MS in Clinical and Translational Research now has 54 students. A Certificate in Clinical and Translational Research program, launched in 2009, is a 14-credit hour program to train fellows and junior faculty primarily interested in serving as collaborators rather than as principal investigators on clinical and translational research projects. Fifty-five students have enrolled and 17 have graduated. With an ARRA supplement, we implemented an on-line version of the Certificate program. A second ARRA supplement is creating an online curriculum in Clinical Research Informatics. Our third KL2 RFA attracted 15 applications for 2 slots. Four Building Interdisciplinary Research Careers in Women's Health (BIRCWH) K12 Scholars appointed in 2010 completed their first year. The CCTST has supported new and competitive renewal applications for T32s and K12s and has developed a K Club designed to support career development for young investigators. The K Club has held monthly meetings covering topics requested by its members. The CCTST Grand Rounds series has been quite successful with now monthly (formerly quarterly) presentations by outstanding local and national experts in topics relevant to clinical and translational research.

Participant and Clinical Interactions Resources (PCIR)

The two sites for the Clinical Translational Research Center (CTRC) at CCHMC and the VA Medical Center continue to have robust utilization with increased complexity of visits at each site. 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 been expanding services to UC with considerable success. We have actively participated in ResearchMatch and have staff supporting retention efforts for studies by using Accurint®, a commercial product designed to find "lost" research participants.

Regulatory Knowledge and Support

UC and its AHC have two separate Offices of Research Compliance and Regulatory Affairs (ORCRA) in which the IRBs for UC and CCHMC reside. There has been increasing integration of these programs through an AHC IRB Advisory Committee, a Research Cabinet formed by the Senior Associate Dean for Research, and an AHC ORCRA Advisory Committee. To better harmonize IRB activities across the AHC, Click Commerce®, which is already in use at CCHMC, will be installed at UC during the first quarter of 2012. Work is continuing with the 17 hospitals in the Greater Cincinnati metropolitan area to identify and remediate obstacles to multisite research within our community. Much of the preliminary ground work has been completed during 2010-11, beginning with an agreement to develop uniform informed consent forms. During the last year, the CCTST has sponsored cross-campus town hall meetings for education and debate related to biobanking, responsible authorship, and ethical exceptions and expectations related to informed consent.

Community Engagement and Research

The 32-member Community Partner Council, which has met quarterly, has provided input directed at ensuring bidirectional relationships between the community and the AHC, including a community perspective regarding consent for specimen collection in the biobanking initiative developed at CCHMC. Within the practice-based research networks, 17 family medicine practices have been added to the Cincinnati Lifespan Practice Research Consortium and 18 pediatric practices have been added to the Cincinnati Pediatric Research Group. We awarded 7 Community Health Grants totaling \$93,000 in areas of obesity; infant mortality, including prevention and prenatal care; and mental health. The second class of 15 graduated from our Community Leaders Institute (CLI), a 6-week course to develop leaders in community research and community-based participatory research (CBPR). The first 2 classes have succeeded in obtaining \$2.5 million in grants for their community-based organizations utilizing skills obtained from the CLI. The CLI is becoming a national model; the UCLA and UK CTSA's are planning to develop them. The Community Engagement Speaker Series featuring a number of prominent national leaders, and Community Engagement Roundtables have been quite successful.

Translational Technologies and Resources

The CCTST through the CTSA grant 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 expanded 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 more than 40 human iPSC cell lines and have obtained several additional grants for this technology. The Drug Discovery Center has increased the number of investigators and institutions that utilize its services. Concerted efforts have begun to foster interaction among the three Ohio CTSA's to leverage expertise in drug discovery at each of the institutions. The Proteomics Core has assisted investigators in biomarker profiling in new studies of idiopathic pulmonary fibrosis and *Candida* bloodstream infections. 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 Core has become an integral part of everyday CCTST functions. The project evaluator, Jack Kues, PhD, attends weekly project administrative staff meetings, bi-weekly Steering Committee and TnT (T1/T2) meetings, and weekly meetings with the co-PIs. Two major Evaluation Core initiatives have continued into Year 3: 1) With support from the Biomedical Informatics Core, the Evaluation team is developing a

comprehensive dashboard 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 CCTST, and 2) there is a real interest in developing better collaborative efforts among faculty and trainees in the AHC, the West Campus, and the community. As such, efforts are being directed toward social networking. The CCTST has created a membership program that now numbers over 800 faculty and community members, and members will be able to search easily for collaborators with similar or complementary research interests. With the guidance of the Evaluation Core, the CCTST is also aggressively promoting use of eProfessional, a research networking program similar to VIVO and Harvard Profiles developed and implemented at UC several years ago but not yet realizing its full potential.

Significant Publications

All publications resulting from projects utilizing the CCTST or Clinical Translational Research Center (CTRC) are listed in the other divisions' sections of this annual report.

A complete listing of these publications is available in the CCTST bibliography, along with a copy of the journal article.

Faculty, Staff, and Trainees

Faculty Members

James E. Heubi, MD, Professor

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

Joel Tsevat, MD, PhD, Professor

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

Joint Appointment Faculty Members

Bruce Trapnell, MD, Professor (Pulmonary Medicine)

Research Interests Pilot Funding Director

John Hutton, PhD, Professor (Biomedical Informatics)

Research Interests Informatics Director

Maurizio Macaluso, MD, DPH, Professor (Biostatistics & Epidemiology)

Research Interests Biostatistics Director

Mark Mitsnefes, MD, Professor (Nephrology)

Research Interests CTRC Director

Heidi Kalkwarf, PhD, Professor (General & Community Pediatrics)

Research Interests CTRC Bionutrition Core Director

Powers Scott, PhD, Professor (Behavioral Medicine & Clinical Psychology)

Research Interests CTRC Behavioral Core Director

Noll Jennie, PhD, Professor (Behavioral Medicine & Clinical Psychology)

Research Interests Research Subject Advocate

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 Co-Director

Jacqueline Grupp-Phalen, MD, MPH, Assistant Professor (Emergency Medicine)

Research Interests K12 Training Program Co-Director

Charles Dumoulin, PhD, Professor (Radiology)

Research Interests Imaging Research Director

Bruce Aronow, PhD, Professor (Biomedical Informatics)

Research Interests Translational & Molecular Disease Modeling Director

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

Grants, Contracts, and Industry Agreements

Grant and Contract Awards

Annual Direct

GAVIN, M

CALERIE Phase II

Duke University(National Institute on Aging)

U01 AG 022132

09/01/10-08/31/13

\$22,119

HEUBI, J

Cincinnati Center for Clinical and Translational Sciences and Training

National Institutes of Health(University of Cincinnati)

UL1 RR 026314

07/01/10-09/23/11

\$79,324

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

\$1,885,097

Trapnell	Pilot/Collaborative Studies	\$23,181
Kouril/Wagner	Biomedical Informatics	\$92,397
Mitsnefes	CTRC	\$1,463,314
Mitchell	Community Engagement	\$68,331
Macaluso	Design, Biostats, Ethics	\$90,282
Grupp-Phelan	K30 Training Program	\$49,344
DeWitt/Rothenberg	Research/Education, K12 Program	\$39,647
Dumoulin	Imaging Research	\$23,181
Aronow	Translational/Molecular Disease Modeling	\$23,181
Malik	Stem Cell Research	\$40,294

Current Year Direct **\$1,986,540**

Total **\$1,986,540**

