

# 2013 Research Annual Report

## Center for Clinical and Translational Science and Training



### Division Details

#### Division Data Summary

##### RESEARCH AND TRAINING DETAILS

Number of Faculty	2
Number of Joint Appointment Faculty	17
Number of Support Personnel	85
Direct Annual Grant Support	\$1,506,532

##### CLINICAL ACTIVITIES AND TRAINING

Inpatient Encounters	32
Outpatient Encounters	11,706

#### 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

#### Integrating Research Design and Implementation Services for Investigators

We had broad usage of our Research Central service portal for more than 900 faculty and staff at UC and Cincinnati Children's, including 175 consultation requests for biostatistical study design support and 241 requests for Research Electronic Data Capture (REDCap) database/survey implementation. Our service integration meetings also have shown promise in early trials. In these meetings, CCTST methodologists and informaticians meet as a group with investigators to offer advice and strategies for developing and implementing specific projects.

#### Training Leaders to Develop and Improve Community Research Initiatives

The third class from the Community Leaders Institute (CLI) graduated 18 participants, with the first two classes obtaining more than \$3 million in grants thanks to the skills provided by the CCTST. The six-week CLI program enhances research and capacity-building competencies in community leaders, including directors, administrators, advocates and other persons who play a key role in organizational decision making and data usage. The long-term goal is to improve community research capabilities to address social, educational, environmental and physical health disparities in Greater Cincinnati.

#### Collaborating Statewide to Improve IRB Process for Multicenter Studies

A reciprocal agreement was developed between the three CTSA's in Ohio to accept reviews from any of their eight IRBs for multicenter studies. This collaborative effort will accelerate research by streamlining human

subject protection processes when participating institutions partner on research projects requiring IRB approvals. This is the first reciprocity agreement among multiple CTSA organizations in Ohio. Ultimately, it will foster collaborative efforts among investigators, increase efficiency and reduce the regulatory burden on researchers.

## Research Highlights

### CCTST Website Renovation

We completed renovation of the [CCTST website](#) with changes to accommodate requests by user focus groups, and demonstrated the site and its content to multiple Cincinnati Children's and UC Departments and Divisions. In addition to visual enhancements and streamlined navigation, improvements included the addition of a searchable database of intramural funding opportunities, a "find a collaborator" search feature based on research interest keywords, and a simplified process for entering/tracking service requests. A prominent homepage slideshow highlights recent CCTST accomplishments. Investigators may join the CCTST online, free of charge. Our membership roster now includes over 2,000 academic, community and scholar members.

### Biomedical Informatics

Our Dashboard is now accruing information about each core and its personnel on a quarterly basis. As a part of our continuous improvement process, we continue to refine *Research Central*, our portal for investigators to obtain services from CCTST, with enhanced tracking and integrated services. There has been robust usage of REDCap with 241 new projects, including surveys and database development. Under the direction of John Hutton, MD, UC Health and the COM have formed a Joint Center for Health Informatics to leverage the research capabilities of Epic, which has just been adopted by UC Health. A CTSA supplement grant was awarded with UC/Cincinnati Children's as a site working to support federated data sharing among multiple institutions, and a BEACON Quality Improvement Data Infrastructure grant was awarded to Cincinnati Children's/UC to support federated data sharing among Ohio hospitals to assess outcomes in newborns, children with asthma and adults with type 2 Diabetes. The search for a chair of the newly created Department of Biomedical Informatics has yielded multiple promising candidates.

### Biostatistics, Epidemiology, and Research Design (BERD)

We have seen increasing use of *Research Central*, our web portal of entry to CCTST resources, which has become a national model as an electronic research record. *Research Central* supported 175 consultation requests for BERD support and 241 for REDCap database/survey development. We are developing a strategy to make this successful program more responsive to the needs of trainees and young faculty, as well as more experienced faculty. We implemented a charge-back mechanism for services provided by *Research Central* during the 2<sup>nd</sup> quarter of 2012. During the last year, five pilot grants related to clinical research ethics and biostatistical or study design methodology were awarded. The medical devices collaborative c2c:MD, which meets monthly to foster cross-campus collaboration in medical device design, has been quite successful at catalyzing ideas to application by holding several studios.

### Research Education, Training and Career Development

The MS in Clinical and Translational Research now has 40 students, and there are 92 students enrolled in the Certificate in Clinical and Translational Research program with 39 graduates. We have launched our online curriculum for the Certificate program and implemented an online curriculum in Clinical Research Informatics.

We have helped develop and disseminate a Fellows Core Curriculum to Cincinnati Children's and UC residents and fellows. Currently, there are five KL2 and four Building Interdisciplinary Research Careers in Women's Health (BIRCWH) K12 Scholars in our programs supported by the CCTST. Since 2009, we have had five KL2 Scholar graduates: two received R01s, one was awarded a K23. Four BIRCWH Scholars have graduated: One was awarded a K23 and one has a fundable K23 score. The K Club of current and potential career development grant awardees meets monthly, addressing a wide range of topics and promoting peer-to-peer interactions; within the K Club, we have formed a small peer group comprising the KL2 and BIRCWH K12 Scholars. The CCTST is developing a more robust program to support new and competitive renewals of T32s and K12s at UC and Cincinnati Children's. The CCTST continues to support a number of pipeline programs for high school, undergraduate and graduate programs in medicine and pharmacy.

### Participant and Clinical Interactions Resources (PCIR)

The two sites for the Clinical Translational Research Center (CTRC) at Cincinnati Children's and the VAMC continue to have robust utilization, with increased complexity of visits at each site and increased diversity of users. The nursing staff has been reorganized in the CTRC at Cincinnati Children's, with potential enhanced quality and cost savings. A renewed focus on recruitment and retention is being addressed with efforts directed at coordinating activities across the AHC, taking advantage of a very mature recruitment program at Cincinnati Children's to expand to UC. 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 Accurant®, a commercial product designed to find research participants lost to follow-up. The CCTST leadership has been actively involved in the planning and design of the new Cincinnati Children's "Location T" (Clinical Research Services) building, with two floors to be dedicated to outpatient clinical and translational research, scheduled for completion in mid-2015.

### 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 Cincinnati Children's reside. 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 has made processes more seamless to investigators. Click Commerce® has been rolled out to the entire AHC and was installed in July 2012 at UC. With the other CTSA's in Ohio, we have developed a memorandum of understanding (MOU) for reliance on IRB review at any of our six affiliated IRBs. In addition, the Consortium of Greater Cincinnati IRBs, with representation from 17 hospitals in the Greater Cincinnati metropolitan area, has expressed interest in participating in this agreement. During the last year, the CCTST has sponsored cross-campus symposia for education and debate related to areas such as requirements for registering clinical trials with clinicaltrials.gov, challenges involving social networking and research, and participant compensation in research.

### Community Engagement and Research

The 36-member Community Partner Council, which has met quarterly, has provided input directed at ensuring bidirectional relationships between the community and AHC. The Community Health Grant Program awarded \$103,000 in grants, leading to at least five new community-AHC collaborations in medication adherence, diabetes, HIV/AIDS, mental health and Parkinson's disease. Within the practice-based research networks (PBRNs), 13 family medicine practices (total 30) have been added to the Cincinnati Lifespan Practice Research Consortium and three pediatric practices have been added (total >100) to the Cincinnati Pediatric Research Group. An AHRQ PBRN COIN grant was awarded to the three CTSA sites in Ohio, one of only eight such

grants in the country. The third 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). Trainees from the first two classes have obtained more than \$3 million in grants for their community-based organizations. Multiple CTAs are adopting the CLI model for training community members. The Community Engagement Speaker Series and Community Engagement Roundtables have featured prominent national leaders, and attract large, diverse audiences.

### Pilot and Collaborative Translational and Clinical Studies

The PCS core has had five broad-based, cross-campus pilot grant RFAs, which have attracted applicants from diverse sectors of the AHC and the other UC colleges. In grant year year, we made eleven T1 Pilot Awards, four T1 Jr. Pilot Awards, and two Core Awards. We have made 22 Just-in-Time Awards for \$5,000-7,500 to support core laboratory services for investigators needing additional data for grant submissions or resubmissions, and 11 retreat/workshop/symposium matching awards of up to \$3,000 each to foster interactions of clinical, translational and basic scientists. The CCTST provides technical and staff support for the COM's new Discovery Acceleration Initiative, a \$1 million effort that includes the Provost's Pilot Research Program, the expanded Just-in-Time program, and a new COM Study Section. The RFA for the 5<sup>th</sup> year of CCTST T1 Pilot Awards was released in August 2012; we received 83 LOIs for 52 T1 pilots, 21 T1 Junior pilots, and 10 cores. We invited 35 full proposals (24 T1 Pilots, seven T1 Jr. Pilots, and four Cores). We are exploring opportunities to support outcomes research and comparative effectiveness research pilot grants by extending efforts in place within Cincinnati Children's. The PCS supported the review and awarding of eleven Community Health grants and five Methods and Ethics grants; the Methods and Ethics grants were reviewed by the University of Rochester CTA, under a reciprocity agreement between our CTAs. We funded two Clinical Research Feasibility Fund (CReFF) awards for investigators doing research in the CTSC.

### Enabling Technologies (Translational Technologies and Resources)

The CCTST has provided 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 an example, the Molecular and Cell Therapy Matrix Program has expanded new technology to derive induced pluripotent stem cell (iPSC) lines to create cell lines such as enterocytes. In an overall strategy to support as many investigators as possible in the most cost-effective manner, we will be eliminating the Enabling Technologies Core in the 5<sup>th</sup> year of the grant; however, investigators may access these and other core services through our Just-in-Time grant program administered through the PCS Core.

### Evaluation

The Evaluation Core is an integral part of everyday CCTST functions. The project evaluator, Jack Kues, PhD, attends weekly project administrative staff meetings, monthly Steering Committee meetings, TnT (T1/T2 project review) and Integration meetings, and periodic meetings with the co-PIs. He is a member of the newly-created Executive Committee that is designed to formulate and implement changes in line with strategic initiatives. A dashboard has been implemented with data collected quarterly from the cores; it too is becoming a model for other CTAs. The dashboard allows the leadership to provide feedback to the cores and to provide the public an accounting of progress toward the goals of the CCTST. We have focused efforts on social networking and collaborative/team science. With the guidance of the Evaluation Core, the CCTST is also aggressively promoting use of an institution-wide Research Directory to create a research networking program similar to VIVO, SciVal and Harvard Profiles. The Evaluation Core is also spearheading efforts to form interdisciplinary

teams in the AHC on topics such as patient-centered outcomes research.

## 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 Aronow, PhD**, Professor (Biomedical Informatics)

**Research Interests** Translational & Molecular Disease Modeling Director

**Thomas DeWitt, MD**, Professor (General & Community Pediatrics)

**Research Interests** Research Education Co-Director

**Charles Dumoulin, PhD**, Professor (Radiology)

**Research Interests** Imaging Research Director

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

**Research Interests** K12 Training Program Co-Director

**John Hutton, PhD**, Professor (Biomedical Informatics)

**Research Interests** Informatics Director

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

**Research Interests** CTRC Bionutrition Core Director

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

**Research Interests** Biostatistics Director

**Punam Malik, MD, MS**, Professor (Hematology/Oncology)

**Research Interests** Stem Cell Matrix Director

**Frank McCormack, Jr., MD**, Professor (Int. Med.-Pulmonary Medicine)

**Research Interests** Pilot Funding Co-Director

**Monica Mitchell, PhD**, Professor (Behavioral Medicine & Clinical Psychology)

**Research Interests** Community Engagement Director

**Mark Mitsnefes, MD**, Professor (Nephrology)

**Research Interests** CTRC Director

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

**Research Interests** Research Subject Advocate

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

**Research Interests** CTRC Behavioral Core Co-Director

**Marc Rothenberg, MD, PhD**, Professor (Allergy & Immunology)

**Research Interests** K12 Training Program Co-Director

**Lori Stark, PhD**, Professor (Behavioral Medicine & Clinical Psychology)

**Research Interests** CTRC Behavioral Core Co-Director

**Bruce Trapnell, MD**, Professor (Pulmonary Medicine)

**Research Interests** Pilot Funding Co-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

HEUBI, J

### **Cincinnati Center for Clinical and Translational Sciences and Training**

National Institutes of Health(University of Cincinnati)

UL1 TR 000077

04/03/09-03/31/14

\$1,506,532

Trapnell, B	Pilot/Collaborative Studies	\$23,181
Hutton, J	Biomedical Informatics	\$96,491
Macaluso, M	Design, Biostatistics, Ethics	\$91,593
Mitsnefes, M	CTRC	\$1,168,884
Mitchell, M	Community Engagement	\$70,913
DeWit,T / Rothenberg, M	Research Education/K12 Program	\$50,834
Grupp-Phalen, J	K30 Program	\$4,636

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**Current Year Direct** **\$1,506,532**

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**Total** **\$1,506,532**