Center for Clinical and Translational Science and Training

Cincinnati Children's

Center Summary

RESEARCH AND TRAINING DETAILS

Number of Faculty	2
Number of Joint Appointment Faculty	14
Number of Support Personnel	79
Peer Reviewed Publications	2

CLINICAL ACTIVITIES AND TRAINING

Inpatient Encounters	128
Outpatient Encounters	11,934

Center Photo

Row 1: J Heubi, M Macaluso, B Harnett, J Strasser, J Tsevat, M Eckman
Row 2: J Hutton, A Hartkemeyer, E Haynes, P White, J Kues, J Grupp-Phelan, C Lindsell

Significant Accomplishments

Ohio Clinical Trials Collaborative Formed

The CCTST played an integral role in forming the Ohio Clinical Trials Collaborative, a statewide network of Clinical and Translational Science Award sites in Cincinnati, Columbus and Cleveland and six partnering institutions, including Cincinnati Children's. The Collaborative is establishing a clinical trials structure across Ohio to facilitate trials available through commercial clinical research organizations, the pharmaceutical industry, and government agencies.

Landmark Collaborative IRB Agreement Reached

Hospitals and research institutions across Cincinnati and Northern Kentucky have formed a collaborative Institutional Review Board (IRB) agreement that will allow any of the six participating sites, including Cincinnati Children's, to serve as the IRB-of-record for human subject research that involves multiple participating study sites. All participants are members of the Consortium of Greater Cincinnati IRBs.

Design Thinking Research Awards Established

Design thinking has been defined as "devising courses of action aimed at changing existing situations into preferred ones." Toward that end, the CCTST and the Live Well Collaborative established the Design Thinking Research Awards to support novel approaches to health care challenges by Cincinnati Children's faculty. Funds partially support studio projects utilizing design teams led by UC faculty and students who work with investigators and stakeholders to develop innovative solutions, tools and prototypes that can be readily evaluated. Leaders plan three funding rounds per year.

Research Highlights

Biomedical Informatics

The University of Cincinnati (UC) and Cincinnati Children's Hospital Medical Center have jointly recruited Peter White to Chair the new Department of Biomedical Informatics. He is actively integrating programs at UC and Cincinnati Children's, implementing a PhD graduate program in biomedical informatics, recruiting additional faculty, and expanding informatics services that support Center for Clinical and Translational Science and Training (CCTST) programs.

UCHealth, the health care delivery system for adults affiliated with the University, has implemented the Epic electronic health record and is working closely with the Center for Health Informatics to expand a research patient data warehouse to support translational research, under the direction of the new Department. This warehouse is closely modeled after, and will complement, the research patient data warehouse at Cincinnati Children's, so our CCTST will now provide translational researchers with integrated information derived from both the adult and pediatric populations. We also have developed a UC I2B2 interface tool that allows researchers to access de-identified data for research planning purposes and dovetails with the existing Cincinnati Children's reporting capacity. 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 at both UC and Cincinnati Children's, including surveys and database development.

Biostatistics, Epidemiology & Research Design (BERD)

Research Central, our web portal of entry to CCTST resources, has become a national model as an electronic research record. Its use at UC and Cincinnati Children's has continued to increase. During FY14, Research Central supported 457 projects, including 181 requests for BERD methodological support and 212 for REDCap database/survey development. About 50% of this activity was in support of research at Cincinnati Children's. We are developing a strategy to make this successful program more responsive to the needs of trainees and faculty with varying experience. We are also supporting the growth of a community of methodologists that includes colleagues across the Academic Health Center (AHC), UC and beyond. During FY14, BERD held a series of 14 methodological seminars highlighting work done by local scholars as well as by national experts in biostatistics and epidemiology. In addition, we awarded six pilot grants related to clinical research ethics and biostatistical or study design methodology. BERD has maintained an active role in the network of BERD units affiliated with academic health centers that receive Clinical and Translational Science Awards (CTSAs) from the NIH, and in FY14 we provided logistical and analytic support for the national survey of BERD units, a unique resource of information about the growing number of groups of methodologists who support clinical and translational research. The CCTST Integration Committee of core directors, methodologists and informaticians continues to meet regularly with investigators to recommend strategic direction, identify barriers and help form multidisciplinary teams, while providing ongoing follow-up and support.

Research Education, Training and Career Development

Since its inception, the MS in Clinical and Translational Research Program has experienced a 10-fold increase in enrollment. The MS in Clinical and Translational Research now has 49 students and 112 alumni, and there are 72 students enrolled in the Certificate in Clinical and Translational Research program with 54 graduates. We have implemented an online curriculum for the Certificate program. We have helped develop and disseminate a Fellows Core Curriculum to Cincinnati Children's and UC residents and fellows. The CCTST runs several career development programs currently, there are three KL2, two CT2, three Building Interdisciplinary Research Careers in Women's Health (BIRCWH) K12 Scholars, and two WH2 Women's

Health Scholars in programs administered by the CCTST. 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, BIRCWH K12, CT2, WH2, and Cincinnati Children's PS2 Scholars. The CCTST continues to support a number of pipeline programs for high school, undergraduate and graduate programs in medicine and pharmacy. The CCTST also conducts mentor training workshops.

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 Accurint®, a commercial product designed to find research participants lost to follow-up. The CTRC has transitioned to using the WebCAMP program developed originally for the GCRCs and now used by CTSA organizations to collect study information, census and grant data for the NIH annual reports. 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
Regulatory Knowledge and Support is coordinated across the institutions that comprise the AHC through regular meetings and communication. Outreach is a primary focus. In May 2014 we co-sponsored an Office of Human Research Protections (OHRP) regional community forum "Clinical Research and All that Regulatory Jazz" that brought in 450 attendees from the local area and across the country. The annual regional Human Subjects Protection Conference continues to grow and will take place in September. During the last year, the CCTST sponsored other cross-campus symposia for education and debate related to research integrity including the suppression of negative results and pressures to obtain funding, promotions, etc. Online training has been updated and is coordinated across the AHC and local hospitals to facilitate multi-center research. We have also developed and provided templates to facilitate IRB submission and review (e.g. template protocol for medical chart reviews). We have also developed agreements between all but one community hospitals to accept reliance for protocol review for a single IRB. With the other CTSAs in Ohio we continue to build the infrastructure to support a clinical and translational corridor across the state that supports a program called Ohio Clinical Trials Consortium (OCTC).

Community Engagement and Research
The Community Health Grant Program (CHG) awarded more than $105,000 in grants, leading to at least nine new community-AHC collaborations in diabetes management, childhood asthma, obesity and asthma disparities, obesity prevention and intervention, physical activity in vulnerable populations, access to sexual healthcare for African American women, substance abuse recovery, bilingual wellness, and tobacco treatment for vulnerable populations. CHG awardees have leveraged more than $5 million in state and federal funding in the last five years. Within the practice-based research networks (PBRNs), 32 practices have collaborated with the Cincinnati Lifespan Practice Research Consortium to conduct research related to ADHD, asthma, influenza, and community-acquired pneumonia. An AHRQ PBRN COIN grant was awarded to the three CTSA sites in Ohio, one of only eight such grants in the country. The fifth class of 23 graduated from our Community

Leaders Institute (CLI), a six-week course to develop leaders in community research and community-based participatory research (CBPR). Trainees from the first four classes have obtained more than $3 million in grants for their community-based organizations. The CLI has become a national model for training community members and has been replicated at four CTSA sites. The Community Engagement Speaker Series continues to feature prominent national leaders and attract large, diverse audiences, and has also become a national model for promoting bidirectional training. This past year's Speaker Series featured experts on poverty and health and maternal and child health, with the spring series having the highest attendance (N= 323) and satisfaction rating (100% rated very good/excellent) to date. Core training initiatives have resulted in three published manuscripts. Critical to the core's success is the 45-member Community Partner Council (CPC), which meets quarterly and provides input directed at ensuring bidirectional relationships between the community and AHC.

Pilot and Collaborative Translational and Clinical Studies
The PCS core has had six broad-based, campus-wide pilot grant funding cycles. Each cycle attracted applicants from diverse sectors of the AHC and other UC colleges and has supported translational bench-to-bedside (T1) pilot research through Pilot T1 Research Grants, Junior Investigator, and Innovative Core grant awards. In 2013-4, ten Pilot T1 Research Grants, three Junior Investigator Grants, and three Innovative Core Grants were awarded to investigators located at UC or Cincinnati Children's. Similar numbers of awards in each grant category were made in 2014-5. In addition, the PCS Core has continued to provide Just-in-Time (JIT) grant funding of up to $7,500 to support the use of core laboratory services to help investigators gather additional data for external grant resubmissions or submissions. Twenty-two JIT grants were awarded in 2013-4 and ten have been awarded to date in 2014-5. The PCS Core also continues to provide matching funds (up to $3,000 per event) to support retreats, workshops, and symposia to foster interactions between clinical, basic, and translational researchers. New in the next year is the Study Section Apprenticeship Program, which is intended to help researchers get a better understanding of the peer-review process and study section dynamics, improve their competitiveness for future grant submissions, and prepare them for active participation in the peer-review process.

Evaluation
The Evaluation Core is a key function area for the CCTST. Core staff attend weekly CCTST staff meetings, participate in all major CCTST functions, and work with other core directors and key CCTST staff to design mechanisms to gather qualitative and quantitative data related to the functioning of CCTST resources and the impact of these services on investigators and institutions. The Evaluation Core maintains the online CCTST Dashboard which includes data on key outcome metrics for each of the CCTST core services. The Core has developed, and maintains, an up-to-date database on publications by CCTST members and member use of various CCTST services. The Evaluation Core also provides consultative services to CCTST cores and members for the development of surveys and other evaluation tools. The Evaluation Core reports provide insight into the impact of the CCTST on research across the partner institutions and are used to develop innovations such as the Integration Committee and Team Science. Many of the resources and strategies developed by the Evaluation Core have become models for other CTSA sites.

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.

Division Publications

1. Lori E Crosby TSWDP, Monica JM. **The Community Engagement and Translational Research Speaker Series: An Innovative Model of Health Education**. *Journal of Community Medicine & Health Education*. 2013; 3:227.
2. Tsevat J, Lindsell CJ, Parr WD, Kues JR, Kissela BM, Heubi EC, Flessa JW, Heubi JE. **Beyond project-focused consultation to investigator-focused consultation: the CCTST Integration Committee model**. *Clin Transl Sci*. 2014; 7:3-5.

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

Lara Danziger-Isakov, MD, MPH, Associate Professor (Infectious Diseases)
Research Interests Research Subject Advocate

Thomas DeWitt, MD, Professor (General & Community Pediatrics)
Research Interests Research Education Co-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

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

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

Peter White, PhD, Professor (Biomedical Informatics)
  Research Interests Informatics 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	04/03/2009-03/31/2015	$1,621,005
McCormack, F/Trapnell B	Pilot/Collaborative Studies	$23,051
White, P/Hutton J	Biomedical Informatics	$145,054
Macaluso, M	Design, Biostatistics & Ethics	$80,219
Mitsnefes, M	CTRC	$1,247,115
Mitchell, M	Community Engagement	$69,767
DeWitt, T/Rothenberg, M	Research Education/KL2 Program	$51,189
Grupp-Phalen, J	K30 Program	$4,610
	Current Year Direct	**$1,621,005**
	Total	**$1,621,005**