What the Center for Clinical and Translational Science and Training (CCTST) offers investigators across the Academic Health Center, UC and the Community

James E. Heubi, M.D.
Director, CCTST
November 5, 2015
Operational Phases of Translational Research

Selected Accomplishments

• Created a federated core within the CCTST, Research Central, to provide comprehensive services with > 4,200 unique encounters since 2009

• Created CCTST Integration Committee to help investigators with strategic direction, identify and overcome barriers, help form multidisciplinary teams, and provide ongoing support.

• Created Community Leaders Institute, a 6-week training program that create leaders with competence in community-based research with 83 graduates obtaining >$5 M in grants

• Developed collaborations with CTSAs at OSU and UK as a member of the Appalachian Translational Research Network

• Created the Ohio Clinical Trials Consortium (OCTC) with CTSAs at CWRU and OSU, to provide support for NIH, industry sponsored or investigator initiated trials across the State
Selected Accomplishments

- Created online 10-credit hour Certificate in Clinical and Translational Research
- Graduated over 200 students from the CCTST-supported MS in Clinical and Translational Research and Certificate in Clinical and Translational Research programs
- MS and Certificate students have published over 1,500 papers and obtained over $140M in research grants
- Fostered closer relationships between Greater Cincinnati community hospital IRBs with common training in ethics, templates for informed consent, and an IRB reliance agreement
- Pilot/core programs made grants of $6.3 M to foster collaboration between investigators resulting in > $55 M in extramural grants
- CCTST leadership directed recruitment of Peter White, PhD to Chair the new Department of BMI; implemented a PhD graduate program in BMI
CTSA Consortium Mission/Vision: CTSA Version 2.0

• Mission: To strengthen and support the entire spectrum of translational research from scientific discovery to improved patient care

• Efforts directed at:
  – Translational research training
  – Data sharing and informatics tools
  – Innovative collaborations
  – Multi-study regulatory hurdles
  – Patient recruitment
  – Other key areas related to research in humans
Aims for CTSA Renewal

Aim 1: Empower stakeholders in the process of integrating research with healthcare practice and community wellness
Aim 2: Create the workforce of the future
Aim 3: Optimize efficiency and effectiveness of clinical research
Leadership
Research Education
Research Education

• MS in Clinical and Translational Research
  – 30 hours + thesis
  – Tracks
    • Clinical epidemiology/clinical effectiveness
    • Molecular epidemiology
    • Clinical trials
    • Translational research
    • Clinical research informatics

• Certificate in Clinical and Translational Research
  – 14 credit-hours
  – Course available on-line version and can be applied to MSCTR if desired
Research Education

• Research on Demand
• Fellowship (and residents) research training
  – Covers 14 competencies as defined by ABP/ACGME
• High school, college, and health professional student programs
• Educational Forums
Career Development

• K23 Development Award preparation program
  – Library of funded grants
  – Technical writing assistance
  – Internal reviews

• KL2 program
  – Funding for career development as intermediate between faculty appointment and individual K or R award
  – Support for 75% protected time with $25K for supplies
  – Number of scholars dependent upon size of program
  – 2-year appointments with some programs longer

• K Scholars mentoring
• K Club
KL2 Award: Requirements

• Application
  – Competitive LOI
  – 12-page K23-type application
  – Interview

• 3rd-year 75% protected time guarantee by home department

• Mentor training – University of Wisconsin 8-hour program (also available to KL2 graduates)

• Mentor contracts and individual development plans
KL2 Program – New Features

• Externships
  – Pharma, e.g., Eli Lilly
  – Contract research organizations, e.g., Medpace, CTI
  – FDA
  – IRB, internal study sections
  – Community organizations, e.g., Madisonville Place Matters neighborhood
  – Other CTSA hubs, e.g., ATRN sites, University of Iowa Venture School, Johns Hopkins

• KL2 Pipeline Scholars program in the Colleges of Nursing, Allied Health Sciences, and Pharmacy
• Core curriculum, including Team Science training
• KL2 orientation
• Career Development Council
Translational Workforce Development

• PhD in Biomedical Informatics – Fall 2015
• Team science education: MS course, workshop
• CER/PCOR: MS course, workshop in collaboration with Iowa CTSI
• Health Research on Demand
• Orientation to the Research Process (Research 101) course, 2-day Clinical Trials Boot Camp
• Education Wizard
• Pipeline programs: Pathology and Molecular Medicine, IMSTAR, Peds residents
CCTST Funding Opportunities
Pilot Grants

- T1 grants @ $60k
- “Mentored” T1 grants @ $60K
- Processes/Methodology Grants (NEW)($10-20K)
- Methodology/Research Ethics grants @ ~$8-10K
- GCRC CReFF grants @ $20K
- Just-in-Time core grants @ $7,500K
- Retreat grants @ $3K (+ departmental match)
- Community Health grants: @~ $10-15K
- Outcomes/Health Services grants @ $60K
New Directions for Pilot Grants

• Funding priorities
  – New clinical/translational investigators
  – Basic scientist/clinician collaborations
  – Interdisciplinary studies, esp. multi-institutional (UC-CCHMC-VAMC)

• New initiatives
  – Processes/Methods
    • Novel methodologies in informed consent, streamlining review process, returning results of genetic studies, tools to enhance research at bedside, enhanced recruitment techniques
Biomedical Informatics

• Data warehousing
  – De-identified or identified i2b2 datasets
  – Genomics datasets
  – Protein modeling/small molecule screening datasets
• Support for other functions with the Hub
• Education
• REDCap
• Secure, web-based application designed to support data capture for prospective clinical research studies, built using open source products PHP and MySQL with an EAV data model.

• Metadata-driven software which relies upon a unique metadata-gathering methodology and automated code writing.

• REDCap was initially developed at Vanderbilt University, which holds the copyright, and is now licensed to partner institutions that provide collaborative support.

• Today REDCap supports 191,000 projects with 263,000 users from 1,573 institutions in 92 countries from all of REDCap’s collaborating institutions http://project-redcap.org
What REDCap provides

- A simplified methodology for building databases quickly and easily: modifications are available in 2 working days
- An intuitive interface for data entry (with data validation)
- Audit trails for tracking data manipulation and export procedures (HIPAA compliant)
- Automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R)
- Create surveys to collect data with analysis capabilities
- Library of surveys that can be used for research
REDCap Practical Matters

1. Submit Project Intake Form

2. Requirements
   - System Access
   - Non-employee REDCap access for external users
   - Training (~2 hr) for primary contact
   - Responsible use of a limited resource

3. Cost to investigator
   - Cite grant for support
   - No direct cost to investigator
   - Ask PI to request funds in new grant

Biostatistics, Epidemiology, and Research Design (BERD)

• One-stop shopping through Research Central – National model
  – Serves as a concierge service to support investigators working to develop careers in biomedical research with focus on grant submissions
  – 1 hour consultant service to define needs of investigator
  • Support focused on faculty with promising careers with K awards or working on R series awards
  – Vouchers for up to $2,000 given for needed services with biostatistical, study design and data management
Research Commons
“Mall”

- Get Information
- Consultation
- Browse Services
- Store manager

CTSA Clinical & Translational Science Awards. CTSA is a registered trademark of DHHS.
General Procedures for “Shopping” at Research Commons

• “New” users get general information about how the Commons works from online information services (ie., written descriptions or talking with a “customer service”)

• Experienced users complete service request for specific resources or talk with a triage/customer service

• “Window shoppers” can browse service web pages to learn more about specific services.
  – If they wish to use a particular service or services, they will be directed back to the service request page to complete a request application
  – They may also wish to speak to a customer service person.
Key Functions of the Commons

• Incorporate analytics throughout the Commons and individuals service sites in order to…
  – Monitor traffic
  – Assess patterns of use
  – Gather service notes from sites and central triage

• Develop a strong “Quality” brand and maintain high levels of customer service throughout the Commons

• Create a strong service “managers” team to improve coordination, oversee service evaluation, and develop Commons improvements

• Coordinate business models across all services
Team Science

- Formally created the Center for Improvement Science
  - Home for Team Science
  - Developing services for investigators developing research in translational areas related to QI, Health Services Research, Outcomes Research, and CER.

- Governing Council is meeting regularly
- Developing Web Page for CIS services
- Hired an Administrative Director for CIS
- Partnering with UC VP for Research to schedule visits by Team Science Experts
  - Stephen Fiore scheduled for October 19th
  - Others being recruited for Spring 2016
- Assessing CCTST expertise in Team Science via Survey
Regulatory Knowledge & Support

- Identify efficient methods to expedite time from development of protocol to first enrolled subject
  - Reliance agreements between sites
  - Templated contract language across sites
- Special symposia on research ethics topics (COI, responsible authorship, research vs. standard of care)
- Improve informed consent process and return of results
- Standardize GCP training and provide DSMB training
- cIRB
- Expand IND/IDE support
Participant and Clinical Interactions

• Support patient oriented research across the AHC and community
• Inpatient/outpatient facilities
  – Specialized services: metabolic kitchen, DXA, imaging, processing samples, core laboratory
• Scatter bed facilities
• Voucher support for ancillary studies/services
• Identify opportunities in the community
Participant and Clinical Interactions

- Research Participant Advisory Council
  - Advise and engage CCHMC/UC/VAMC in needs of participants and priorities for research
- Research environment for training in patient oriented research
  - New T location for CTRC
- Optimize Clinical Research
  - Protocol assessment
  - Quality reviews
  - Epic registration and billing in EMR
  - Enrollment tracking
  - Timely completion of studies
  - Lower overall costs
Community Engagement

- Bidirectional partnership between AHC and community to foster CBPR
- Broader definition of “community” to include initiatives developed by PCOR and Learning Health Networks like ICN
- Expand and optimize AHC community engaged research,
  - Via Learning Networks, and
  - Increased engagement in Practice-Based Research Networks (PBRNs)
- Integrate community engagement into institutional policies (RPT)
- Educational opportunities: CBPR on-line module: Introduction to Community Based Participatory Research
- Practice-based research networks
- Speaker Series
- Community Leaders Institute – National model
- Community Health Grants
What is researchmatch.org?

• A national partnership to create a centralized, web-based recruitment registry that will connect willing volunteers with researchers and their studies
  – An initiative funded by the NCATS Clinical & Translational Science Awards
  – Launched September 2009
Program Objectives

- Provide a **free, disease-neutral** meeting place through a national web portal for willing volunteers to express their interest in becoming engaged with research
- **Eliminate barriers** to bidirectional access for both participants and researchers
- Develop a **useful tool** for measuring and monitoring successful recruitment methods and strategies
- **Educate and engage** volunteers in a **culturally-sensitive** and competent manner with efforts within the research community
- Give volunteers a **tangible way** of assisting with research and its ability to impact the future of their community
- Serve as a **complementary tool** to existing recruitment efforts
- **Fill a gap** in existing recruitment efforts, especially with respect to rare diseases
Optional Modules

• Up to 3 areas that CTSA hub focuses efforts
  – Acute Care
  – Diseases across the lifespan
  – CHAMP: Multiple pediatric sites working together for multisite trials

• Dan Cooper, UC Irvine; Lisa Guay-Woodford, National Children’s-GW
ACUTE CARE RESEARCH

- Acute Care Research Council
- Leveraging EMS and EDs for chronic disease trial recruitment
- Informatics tools for research recruitment
- Training in practical aspects of acute care research
- Regulatory support for acute care research
Reducing Infant Mortality and Improving Maternal Health (Via Lifespan Data Integration)

- Seamless integration of individual and transgenerational data for analysis
- Leverage existing collaborative data
  - (March of Dimes Prematurity Research Center Ohio Collaborative, Cradle Cincinnati, Best Babies Zone, Start Strong-Avondale, etc.)
- Connect regional neonatal, pediatric, obstetric and adult care programs (maternal health) to support hypothesis testing and QI
- Accelerate discovery and implementation via data exchange between institutions, government agencies (Dept. of Health, etc.), and the community
- Educate providers/researchers on utilizing the lifespan data integration for research advancement and to improve health
Evolving the Program to Transform Clinical Translational Science

CTSA Hubs

TIC: Trial Innovation Centers
Central IRB
Contracting
Budgeting
Other support PRN

RIC: Recruitment Innovation Centers
Feasibility Assessment
Recruitment Plan and Implementation

Multi-site Study funded by NIH IC or others

Clinical Lead
Stats/Data Management

No need to re-build trial components each time
Regional/National CTSA Networks

• Emphasis on CTSA hubs working together
  – Support multicenter trials through TICs
  – Support recruitment efforts through RICs
  – IRB reliance agreements
  – cIRBs
  – Common contracting language
Support for Multicenter Trials

• New elements within CTSA FOA for support of multicenter trials and recruitment:
  • RICs
    – Fund up 3 sites to support recruitment across CTSA consortium
  • TICs
    – Fund 3 central cores to support multicenter trials including creating cIRB and common contracting
    – Plans for geriatric, adult and possibly pediatric
Multisite Trial Support

• Creation of Cinci-HERO (Cincinnati HEalth Research Office)
  – Liaison to CTSA-support centers and CTSA Network Recruitment Centers (CT-SCs and CT-RCs)
• Central expertise for efficient study implementation, coordination, and accrual
• Facilitation of multi-site research
• Network creation, including learning networks
• Applied for Pediatric TIC
Multisite Study/Recruitment

- Specific emphasis on supporting multicenter trials funded by PHS or foundations
- Provides support for regulatory issues and recruitment
- Support for recruitment of specialized populations
- Each Hub will have specific response to this requirement
Recruitment of Research Subjects

- Provide feasibility assessments and support for optimal recruitment in all clinical trials
- Provide easy ways for potential subjects to gain information and volunteer for studies of interest
- Professional development of research staff to be employed in CINCH-HERO for recruitment and retention functions
- Teaching investigators recruiting and retention tactics and principles
- Maximize subject accrual and retention
- Build the Cincinnati research participant registry (optimize and combine existing registries, including “opt-in” CCHMC program) and link to ResearchMatch
- Scientific study of optimal subject accrual and retention in our community
- Dissemination of best practices locally and to the CTSA network
CTSA Communications Structure

- Limited number of groups and voluntary participants
- Outcomes-driven
- Organizationally guided by the SC

Lead Team
- Workforce Development

Lead Team
- Collaboration Engagement

Lead Team
- Integration Across the Lifespan

Lead Team
- Methods/Processes

Lead Team
- Informatics

62 CTSA Hubs
Budget

• NIH Budget $4.26M total/year x 4 years
  - UC: $1.82 M
  - CCHMC: $2.44 M

• Institutional Commitments
  - UC: $2.26 M
  - CCHMC: $2.5 M + CTRC space
  - VAMC: $24K + CRU space
  - UC Health: $149K