Office of Clinical Research CRP First Friday

Overview of the Center for Clinical & Translational Science & Training (CCTST)

Friday, June 7th, 2024

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Learning Objectives:

1) Describe the organization and roles of Center for Clinical & Translational Science and Training (CCTST)

2) List ways in which the CCTST creates and disseminates innovative research programs and partnerships across institutions and communities to address health disparities and deliver the benefits of translational science to all.

3) Describe training and career support programs for translational scientists provided by the CCTST

4) Explain how a Learning health system for translational science addresses roadblocks in clinical and translational science

Target Audience:

Clinical Research Professionals (CRPs) at UC/H and Cincinnati Children's Hospital Medical Center (CCHMC): including Principal Investigators (PIs), Research Nurses (RNs), Critical Care Unit Nurses (RNs), Pharmacy Technicians and Regulatory Specialists.

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The University of Cincinnati is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Cincinnati designates this live activity for a maximum of 1 *AMA PRA Category 1 Credit*™. Participants should claim only the credit commensurate with the extent of their participation in the activity.

CRPs, NPs, PAs, and RNs can count activities certified for *AMA PRA Category 1 credit*™ for professional credit reporting purposes. Other healthcare professionals should inquire with their certifying or licensing boards.

Disclaimer Statement

The opinions expressed during the live activity are those of the faculty and do not necessarily represent the views of the University of Cincinnati. The information is presented for the purpose of advancing the attendees' professional development.

Off-Label Disclosure Statement:

Faculty members are required to inform the audience when they are discussing off-label, unapproved uses of devices and drugs. Physicians should consult full prescribing information before using any product mentioned during this educational activity.

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Speaker and Planner Disclosure Policy:

In accordance with the ACCME Standards for Integrity and Independence in Accredited Continuing Education and the University of Cincinnati policy, all faculty, planning committee members, and other individuals, who are in a position to control content, are required to disclose all relationships with ineligible companies* (commercial interests) within the last 24 months. All educational materials are reviewed for fair balance, scientific objectivity, and levels of evidence. The ACCME requires us to disqualify from involvement in the planning and implementation of accredited continuing education any individuals (1) who refuse to provide this information or (2) whose conflicts of interests cannot be mitigated.

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All relevant relationships have been mitigated. The following disclosures were made:

Planning Committee Members:

- Maria Stivers, MS; Course Director – *No Relevant Relationships*
- Nathaniel L. Harris, BS, Course Coordinator – *No Relevant Relationships*
- Heather Muskopf, CME Program Manager – *No Relevant Relationships*

Speakers

Dr. Achala Vagal, MD
Co-Chair CCTST
Executive Vice Chair and
Vice Chair of Research, Radiology
No Relevant Relationships

Dr. Jeffrey Strawn, MD
Co-Chair CCTST
Professor & Associate Vice Chair of Research,
Psychiatry & Behavioral Neuroscience
No Relevant Relationships

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Compliance Corner

Recently updated Clinical Research SOPs:

- **UCH-OCR-OPS-SOP-014-07- Prompt MIDAS Reporting of Serious Adverse Events that are both Unexpected and Related to the Research, and Reporting Emergency Use of a Research Related Treatment or Device.Linking in EPIC for Clinical Research**

All OCR SOPs are accessible at the following link.
And from the UC Health intranet home page utilizing the Policy Portal Search function or reach out to the Office of Clinical Research with any questions or concerns.

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UC/UCH Clinical Research Professional

OTR Stillhouse
2017 Branch St, Cincinnati, OH 45214

Thursday, June 13th, 2024
5:00pm – 8:00pm

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Thursday, June 20, 2024, 12:00noon - 1:00pm

IN PERSON Presentation MSB 7051

(with the option to join virtually)

Cooperative Research - Reliance Agreements and External IRBs
and
Reporting for Clinical Research in MIDAS

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We will provide a reliance process overview and review and discuss relying on an External IRB including recent updates to the process for commercial IRBs and we will also address the criteria regarding clinical research reporting in MIDAS.

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Today's Presentation:

Overview of the Center for Clinical & Translational Science & Training (CCTST)

An educational session describing the organization and roles of CCTST, with descriptions of innovative research programs and partnerships across institutions and communities addressing health disparities and the benefits of translational science. We will also address training and career support programs for translational scientists and explain how a learning health system for translational science addresses roadblocks in clinical and translational science.

Dr. Achala Vagal, MD

Co-Chair CCTST

Executive Vice Chair and

Vice Chair of Research, Radiology

Dr. Jeffrey Strawn, MD

Co-Chair CCTST

Professor & Associate Vice Chair of Research,

Psychiatry & Behavioral Neuroscience

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CCTST | Center for Clinical & Translational Science & Training

Overview: Center for Clinical & Translational Science & Training

University of CINCINNATI

Cincinnati Children's changing the outcome together

UC Health

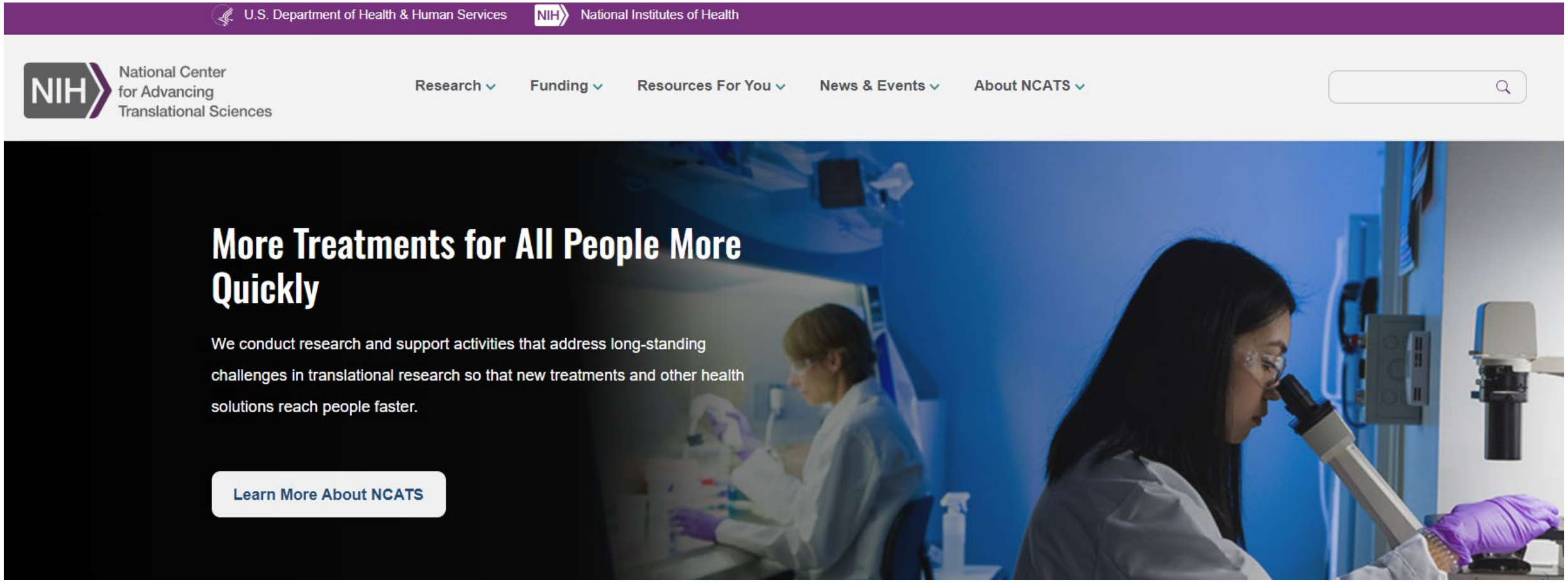
CTSA Clinical & Translational Science Awards Program

Learning Objectives

Attendees will be able to:

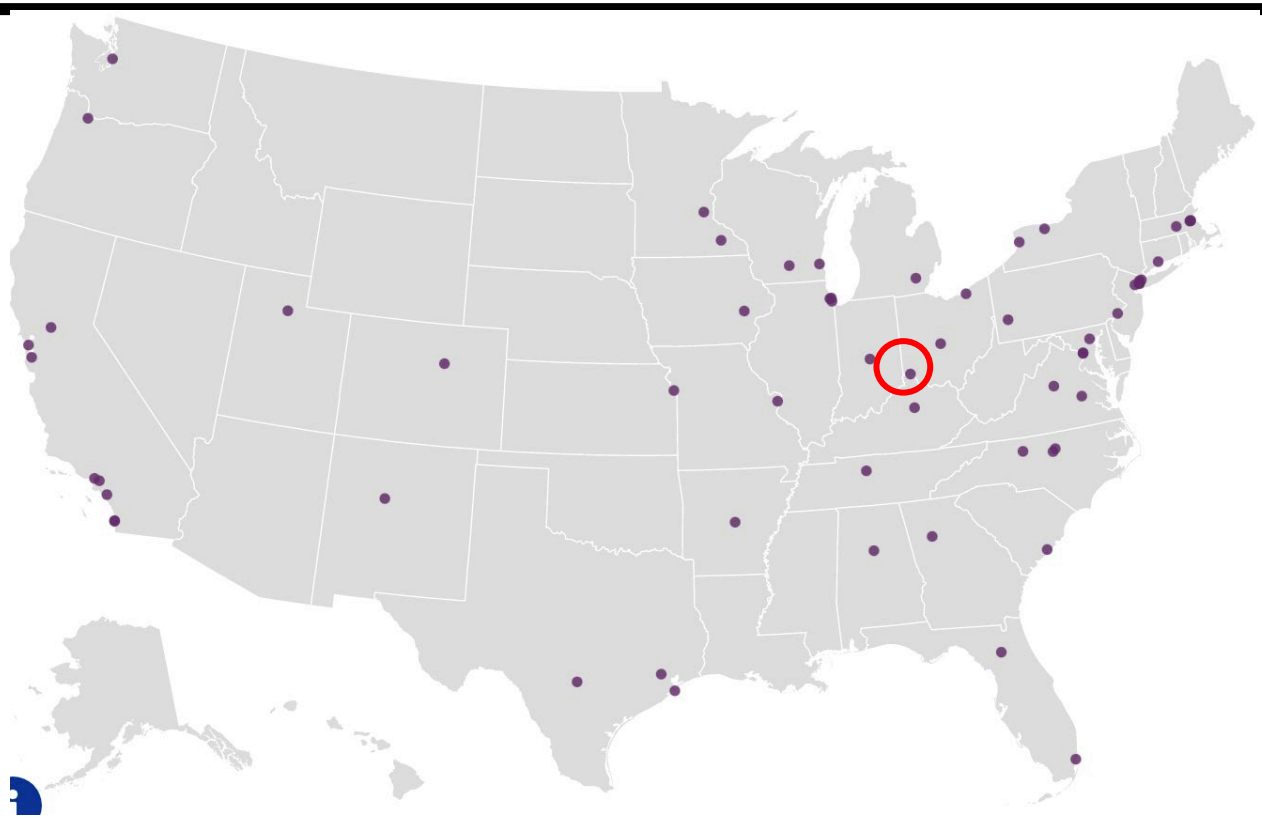
- Describe the organization and roles of Center for Clinical & Translational Science and Training (CCTST).
- List ways in which the CCTST creates and disseminates innovative research programs and partnerships across institutions and communities to address health disparities and deliver the benefits of translational science to all.
- Describe training and career support programs for translational scientists provided by the CCTST
- Explain how a Learning health system for translational science addresses roadblocks in clinical and translational science

NCATS



CCTST | Center for Clinical & Translational Science & Training

CTSA Consortium



President, UC
Neville Pinto, PhD

Dean, UC College of Medicine
Andrew Filak, Jr., MD

Chair Pediatrics, Director-CCRF, CCHMC
Tina Cheng, MD, MPH

External Advisory Committee

Executive Committee

Steering Committee

CCTST Directors (MPIs)

Jareen Meinzen-Derr, PhD,
Jessica Kahn, MD, Jeffrey Strawn, MD
and Achala Vagal, MD, MS

Director's Council

Institutional Career Development Core
KL2 MPI:
Meg Zeller, PhD

- Pilot Translational & Clinical Studies
- Community Engagement
- Ethics, Regulatory Knowledge & Support
- Biostatistics, Epidemiology, & Research Design
- Lifespan Data Integration [Optional Module]
- Biomedical Informatics
- Learning Health Systems [Optional Module]
- Community Representative
- Network Capacity [LRIC, LTICs, ACRC]
- Participant & Clinical Interactions
- Translational Workforce Development
- Center for Improvement Science

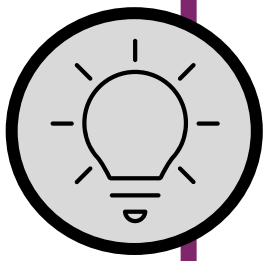
Executive Committee

MPIs

CCTST ORGANIZATIONAL CHART

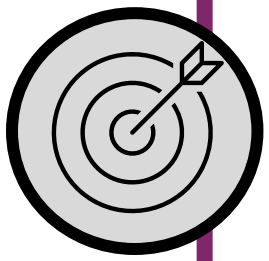
CCTST | Center for Clinical & Translational Science & Training

VISION



An integrated system catalyzing innovative clinical and translational science and training to drive excellent and equitable health outcomes.

VALUES



Embed diversity, equity, and inclusion in all our programs and services.

Cultivate a culture of collaboration between researchers, stakeholders, and patients.

MISSION

Accelerate the development, dissemination, and implementation of innovative clinical and translational discoveries that improve health across the lifespan.

Support the development of a vibrant, interdisciplinary, diverse, and resilient research workforce.

Foster boundary-spanning collaboration among researchers, stakeholders, the community, and patients.

Impact

- **>8000** academic and community members accessing services since 2009
- **350 CCTST community partners**
- Since 2009, provided **694 grants** through our Pilot Translational Core program
  - >$210M in extramural funding
  - >1000 publications
  - 155 patents
- **>600 investigators** received research methods assistance
- **44 early career faculty** supported by KL2.

- **~560** masters/certificate program students
- **>2000 CTR projects** for the Schubert Research Clinic in 2023
- **176 Team Science workshops** for CRPs
- Community Health and Community Development grants program has involved **94 community-based organizations**, serving **55,000 individuals**, **>$16M into the community**
- Trained **230 community leaders over 140 organizations** to build research and leadership skills to help improve or develop health program

CCTST website: https://www.cctst.org/

BECOME A MEMBER TODAY

JOIN CCTST AS A MEMBER AND UNLOCK THESE AND MANY OTHER PERKS!

Become a CCTST member and get access to research resources and services.

CCTST Membership includes:

1. Consultations and access to programs
2. Resources for researchers, community members, and research coordinators
3. Research tools ranging from planning and design to data analysis
4. Access to events and education opportunities
5. Extensive funding opportunities

CCTST members can benefit from most of the services above at no cost.

JOIN NOW

CCTST Resources

Translational Workforce Development

- **CTRonline:** Online educational library offering clinical and translational research training modules
- **MS and Certificate in Clinical and Translational Research:** PI and CRP track
- **Community-engaged Research Certificate**
- **R Club:** Grant writing support for new investigators submitting R grants

KL2/CT Scholars

- Career development awards to position for individual K/R awards
- **Support for 75% protected time with $25K for supplies**

Collaboration/Team Science

- Education/training, consultation, collaboration/networking

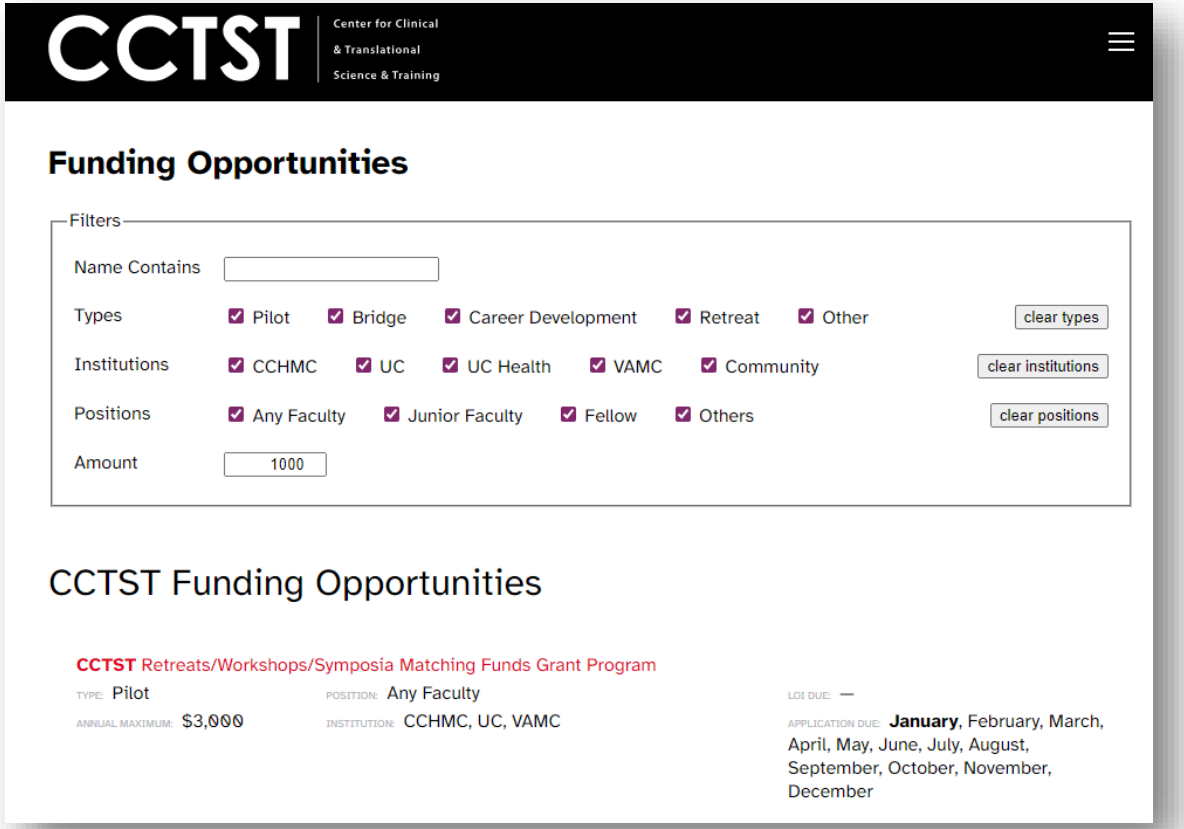
Biomedical Informatics

- RedCAP database design, support and training, incl. e-consent
- Data warehousing and de-identified or identified i2b2 datasets
- TriNetX: Realworld data for life sciences; 30,000 queries since 2018
- Education: certificate and PhD Programs in BMI

CCTST Resources

Funding Opportunities

- Pilot Translational Research Grants: $60k
- Mentored Translational Research Grant: $60K
- Processes/Methodology Grant: $5K for Step 1 and $40K for Step 2
- CReFF Grants: $20K
- Just-in-Time Core Grants: $7.5K
- Retreat Grants: $3K (+ departmental match)
- Community Health Grants: ~ $20K
- Partnership Development Grants: $5K



JRS to add website

CCTST Resources

Biostatistics, Epidemiology, and Research Design (BERD)

- One-stop shopping through Research Central
- Concierge support for investigators developing careers in biomedical research
- 1-hour consultant service to define the needs of the investigator and provide guidance and referrals
- Vouchers (up to $2,000) for biostatistical, study design , and data management
- Support focused on faculty with promising careers with K awards or working on R series awards
- Grant application support

Regulatory Knowledge and Support

- Identify methods to expedite time from protocol development to enrollment
- Reliance agreements between sites
- Templated contract language across sites
- Improve informed consent process and return of results
- GCP and DSMB training
- Centralized IRB
- IND/IDE support

CCTST Resources

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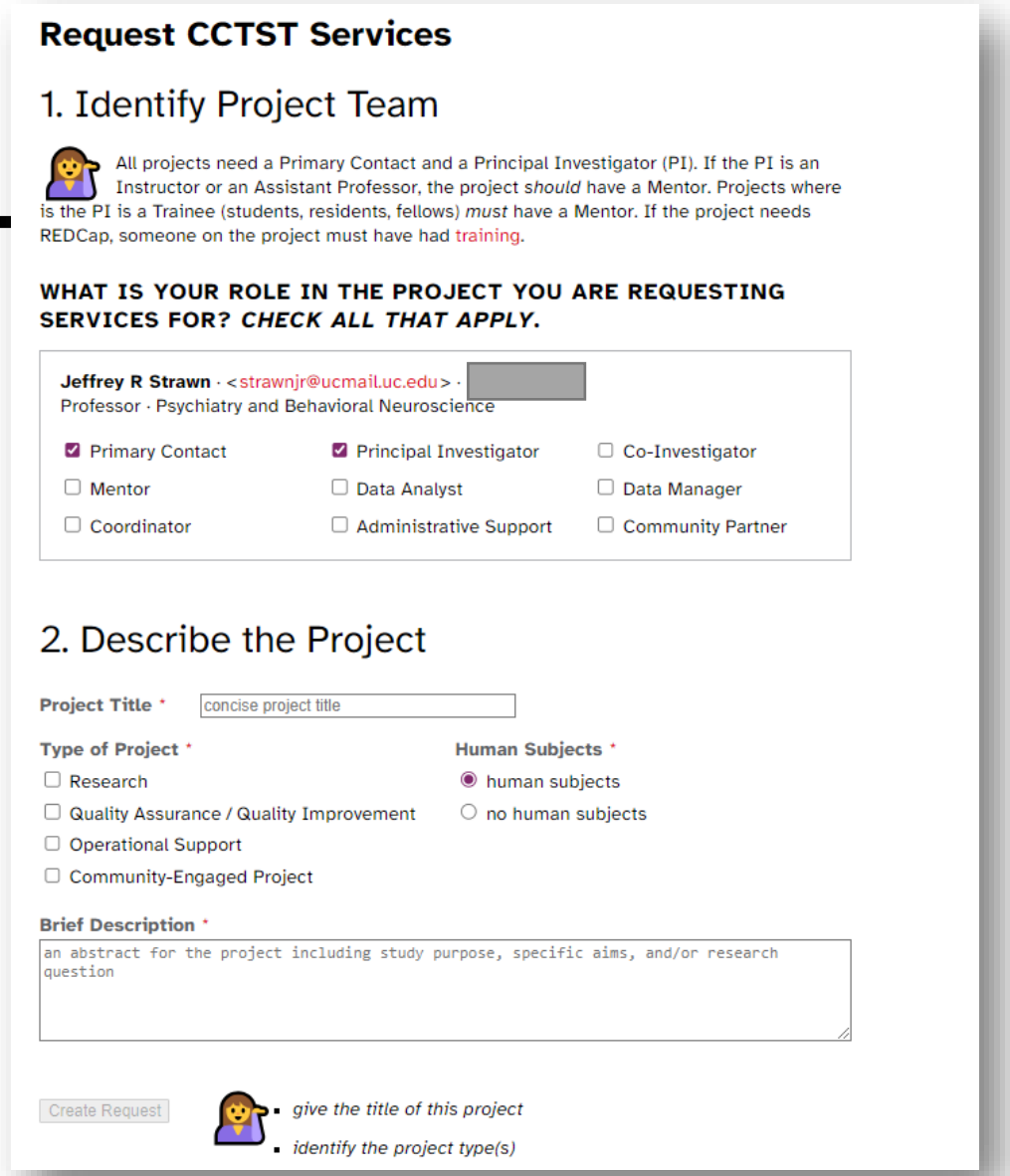

CCTST Resources

Schubert Research Center

- Supports patient-oriented research across the AHC and community
- Inpatient/outpatient facilities
- 28 patient rooms, triage bays, phlebotomy room
- Sample processing core lab on-site
- Metabolic kitchen, investigational pharmacy on-site
- Biochemistry core
- Imaging services (DXA, pQCT, CV imaging, and MRI)
- Scatter bed facilities
- Voucher support for ancillary studies/services

Acute Care Research Core (ACRC)

- Leveraging EMS and EDs for chronic disease trial recruitment
- Informatics tools for recruitment
- Training in and regulatory support for acute care research

CCTST Resources

Community Engagement

- Bidirectional partnership to foster community-engaged research
- Educational opportunities: Introduction to Community-Based Participatory Research, speaker series
- Practice-based research networks
- Community Leaders Institute – National model
- Community Health Grants

Resources

Will be shared in e-mail

CCTST Center for Clinical & Translational Science & Training

CCTST PROGRAMS & SERVICES

ACUTE CARE RESEARCH CORE
Training and consultations for acute care research professionals, collaborative research studies, regulatory or project management assistance.

RESEARCH METHODOLOGY CONSULTATION
Biostatistical and study design consulting, data management assistance and consulting.

BIOMEDICAL INFORMATICS
REDCap databases and surveys, access to pediatric and adult EHR datasets, i2b2 tools, PhD program.

ETHICS, REGULATORY KNOWLEDGE & SUPPORT
Training and assistance in navigating IRBs, FDA filings, regulatory compliance assistance.

TRAINING OPPORTUNITIES
MS & Certificate in Clinical & Translational Research, Certificate in Community-Engaged Research for Health, Grand Rounds, Nutrition Hot Topics, regulatory forums, ethics conference, and CTRonline.

CAREER DEVELOPMENT
KL2 Research Scholar program, K Club, mentorship support, Integration Committee consultations.

COMMUNITY ENGAGEMENT
Community Leaders Institute training program, Spring/Fall speaker series, practice-based learning networks, Integrating Special Populations, Cirtification, Community Engagement Network Initative, Research Participant Advisory Groups.

FUNDING OPPORTUNITIES
Over $1.2M annually for translational pilot projects, core usage, community health, processes & methods, and more.

CLINICAL STUDY RESOURCES
Schubert Research Clinic, Rare Diseases Clinical Research Network, Trial Innovation Network.

CENTER FOR IMPROVEMENT SCIENCE
Consultations, courses, workshops and trainings, team science tools, The Collaborative Network.

LEARNING HEALTH SYSTEMS
Designing and implementing a Learning Health System consultations, Dissemination & Implementation Science consultations.

ADDITIONAL SERVICES
Databases of potential research collaborators and intermural funding opportunities, and a master calendar of research events.

2/1/23

HOW DO I ACCESS SERVICES?

1 BECOME A MEMBER
Join the CCTST (free of charge): chi.uc.edu/cctst/account

2 GO TO RESEARCH CENTRAL
Once you have logged in with your username and password, you can request CCTST services through Research Central: chi.uc.edu/cctst/research

Be sure to read the guidelines and frequently asked questions. Some projects may be eligible for a voucher to defray the cost of the service.

Once you submit your request, a CCTST Consultant or REDCap Specialist will review your request and contact you.

ELIGIBILITY

The CCTST serves the entire Academic Health Center, including the University of Cincinnati, Cincinnati Children's Hospital Medical Center, UC Health, and the Cincinnati VA Medical Center, as well as University of Cincinnati main campus and the Greater Cincinnati community.

For direct services (except REDCap), accessed through our Research Central portal, you must be a full-time faculty member (full, associate or assistant professor) or a CCTST community member.

Visit our CCTST Research Resources webpage for more information on our services: www.cctst.org/research-resources

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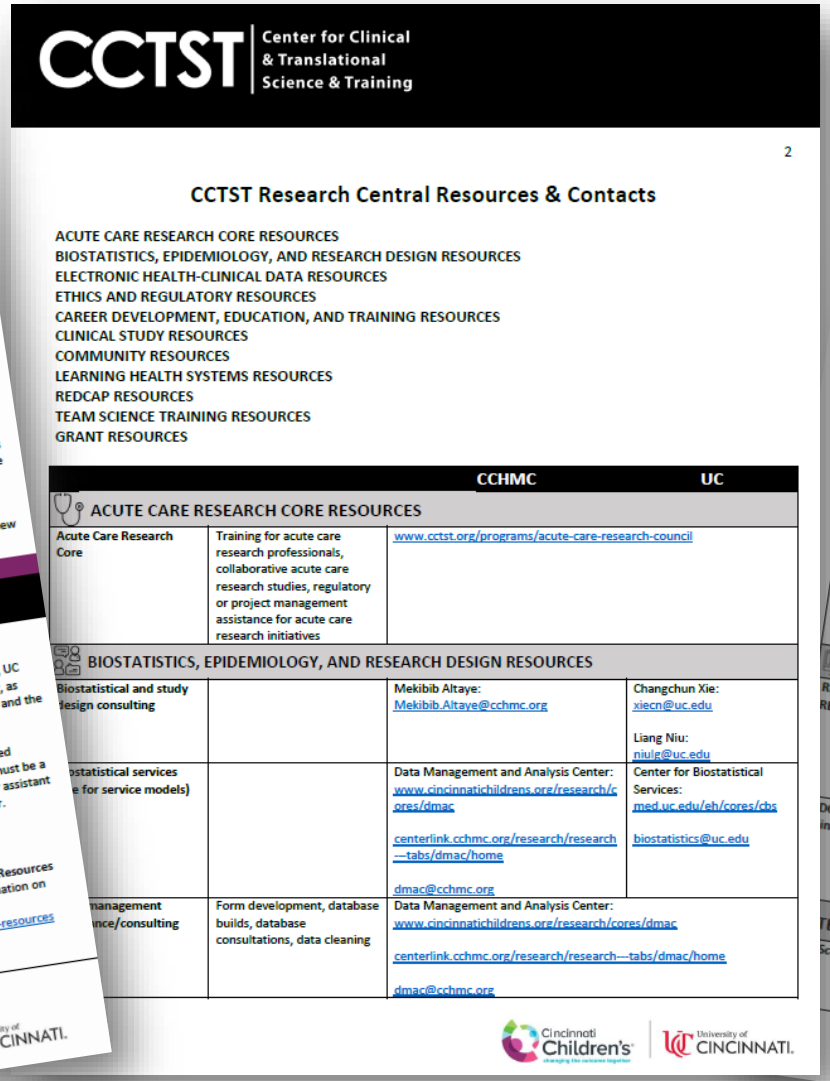

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CCTST Research Central Resources & Contacts

ACUTE CARE RESEARCH CORE RESOURCES
BIOSTATISTICS, EPIDEMIOLOGY, AND RESEARCH DESIGN RESOURCES
ELECTRONIC HEALTH-CLINICAL DATA RESOURCES
ETHICS AND REGULATORY RESOURCES
CAREER DEVELOPMENT, EDUCATION, AND TRAINING RESOURCES
CLINICAL STUDY RESOURCES
COMMUNITY RESOURCES
LEARNING HEALTH SYSTEMS RESOURCES
REDCAP RESOURCES
TEAM SCIENCE TRAINING RESOURCES
GRANT RESOURCES

		CCHMC	UC
ACUTE CARE RESEARCH CORE RESOURCES			
Acute Care Research Core	Training for acute care research professionals, collaborative acute care research studies, regulatory or project management assistance for acute care research initiatives	www.cctst.org/programs/acute-care-research-council	
BIOSTATISTICS, EPIDEMIOLOGY, AND RESEARCH DESIGN RESOURCES			
Biostatistical and study design consulting		Mekibib Altaye: Mekibib.Altaye@cchmc.org	Changchun Xie: xiecn@uc.edu Liang Niu: niulg@uc.edu
Biostatistical services (for service models)		Data Management and Analysis Center: www.cincinnatichildrens.org/research/cores/dmac centerlink.cchmc.org/research/research---tabs/dmac/home dmac@cchmc.org	Center for Biostatistical Services: med.uc.edu/eh/cores/cbs biostatistics@uc.edu
management nce/consulting	Form development, database builds, database consultations, data cleaning	Data Management and Analysis Center: www.cincinnatichildrens.org/research/cores/dmac centerlink.cchmc.org/research/research---tabs/dmac/home dmac@cchmc.org	

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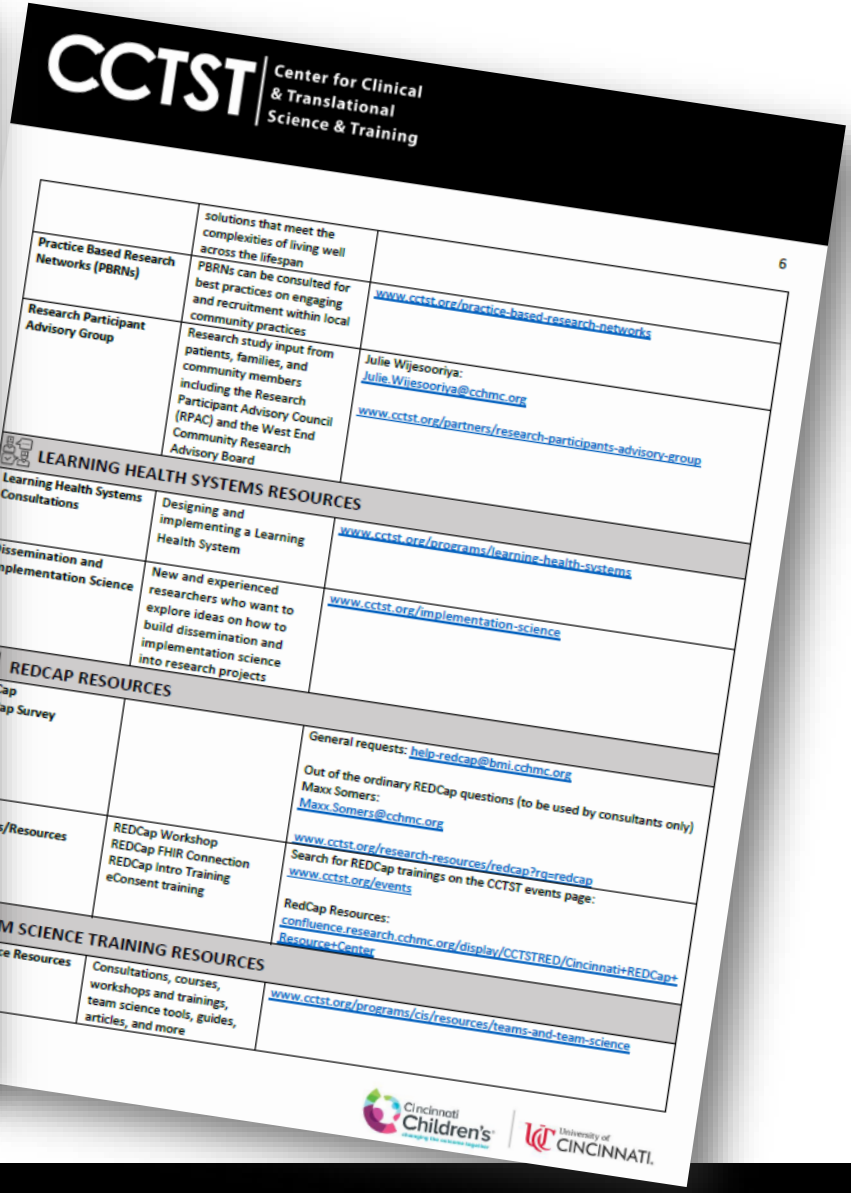

CCTST Center for Clinical & Translational Science & Training

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	solutions that meet the complexities of living well across the lifespan	
Practice Based Research Networks (PBRNs)	PBRNs can be consulted for best practices on engaging and recruitment within local community practices	www.cctst.org/practice-based-research-networks
Research Participant Advisory Group	Research study input from patients, families, and community members including the Research Participant Advisory Council (RPAC) and the West End Community Research Advisory Board	Julie Wijesooriya: Julie.Wijesooriya@cchmc.org www.cctst.org/partners/research-participants-advisory-group
LEARNING HEALTH SYSTEMS RESOURCES		
Learning Health Systems Consultations	Designing and implementing a Learning Health System	www.cctst.org/programs/learning-health-systems
Dissemination and Implementation Science	New and experienced researchers who want to explore ideas on how to build dissemination and implementation science into research projects	www.cctst.org/implementation-science
REDCAP RESOURCES		
REDCap REDCap Survey		General requests: help-redcap@bmi.cchmc.org Out of the ordinary REDCap questions (to be used by consultants only) Maxx Somers: Maxx.Somers@cchmc.org
DCap inings/Resources	REDCap Workshop REDCap FHIR Connection REDCap Intro Training eConsent training	www.cctst.org/research-resources/redcap?rq=redcap Search for REDCap trainings on the CCTST events page: www.cctst.org/events RedCap Resources: confluence.research.cchmc.org/display/CCTSTRED/Cincinnati+REDCap+Resource+Center
TEAM SCIENCE TRAINING RESOURCES		
cience Resources	Consultations, courses, workshops and trainings, team science tools, guides, articles, and more	www.cctst.org/programs/cis/resources/teams-and-team-science

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CCTST Center for Clinical & Translational Science & Training

Questions for You:

- Barriers to and opportunities for engagement with CCTST
- Suggestions for:
  - partnerships and collaborations
  - more effective training and career support
- Gaps/needs that the CCTST could fill
- Ideas for resource dissemination