Welcome and Overview

Michael W. Konstan, MD
November 14, 2019
External Advisory Committee Meeting

SCHOOL OF MEDICINE
CASE WESTERN RESERVE UNIVERSITY
Cleveland Clinic
University Hospitals Cleveland Medical Center
MetroHealth
Louis Stokes Cleveland VA Medical Center
CTSC Clinical & Translational Science Collaborative

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Patrick Flume, MD
Medical Univ South Carolina


James Heubi, MD
Cincinnati Children's


Victoria Tifft, MBA
Clinical Research Mgmt.


Philip Payne, PhD
Washington University


John Yates, PhD
Scripps Research Institute


Daniel Cooper, MD
Univ of California-Irvine


Rebecca Jackson, MD
The Ohio State University


Sean Mooney, PhD
Univ of Washington


Julian Solway, MD
Univ of Chicago

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Structure and Expectations for EAC Meeting

1. Response to 2018 EAC Recommendations
2. Breakout Sessions
   - Research Methods – BERD and RKS
   - Clinical Research - HUB Research Capacity and Network Capacity/TIN
3. Training Programs
4. Collaborative Opportunities
5. Open Discussion
6. Executive Session with EAC members only
7. Feedback and recommendations to leadership

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Questions for EAC

Need your thoughts, ideas, recommendations

- Does our program continue to match NCATS goals?
- Have we leveraged our best assets?
- Are we innovative?
- What are we missing?
- How can we improve?

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Community and Collaboration: Team Science with Stakeholder Engagement Response to 2018 Recommendations

Elaine A. Borawski, PhD

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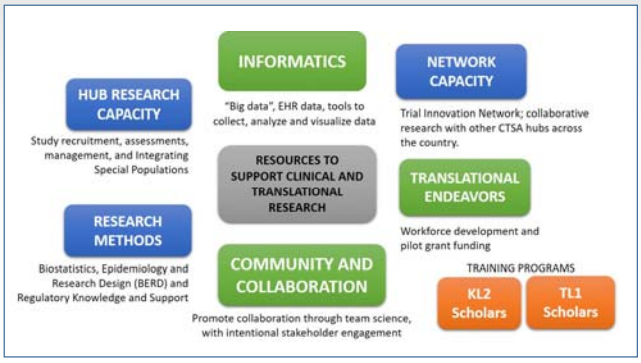
Our Structure

- Community and Collaboration Component (Elaine)
  - Promotion of Interdisciplinary Team Science
  - Integration of Stakeholder Engagement in Team Science
- Translational Endeavors (Mark)
  - Workforce Development
  - Pilot Grants



C&C AIMS

- Aim 1: Develop and support a pipeline of collaborative teams (interdisciplinary teams with engaged stakeholders) to form and produce novel and relevant translational research;
- Aim 2: Increase awareness and capacity of STAKEHOLDERS to engage in team science research;
- Aim 3: Increase awareness and capacity of INVESTIGATORS (faculty, staff and trainees) on importance of team science with stakeholder engagement;
- Aim 4: Cultivate team science with stakeholder engagement as a valued institutional norm.

Challenges

WITH "TRANSLATION"

- Scientists don't always like to be asked to look beyond their experiment or focus. "Why do I need to be concerned on where my science is going next?, or how my research will impact health?"
- Some fields are more open to it than others (e.g., engineering).
- NCATS revised definition of translation very helpful – casted a wider, more inclusive net.
- Increased visibility of this definition is helping with messaging.
- We still lack a comprehensive framework for showing translation in action, especially with stakeholders as part of the model (working on this).

Challenges

WITH TEAM SCIENCE:

- Confusion between the role of a "team scientist" and interdisciplinary collaboration = team science.
- "We'll see more of it when we value and incentivize it". CAPT still highly individual reward focused.
- Increasing use of Co-PI roles is helping to promote true collaboration.

WITH STAKEHOLDER ENGAGEMENT:

- Broadening definition of stakeholder to go beyond the "community" to include industry, health systems, patient advocacy etc.
- Helping all scientists identify their relevant stakeholder groups and seeing the value of including them from the beginning of the research process.

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Communication: Plasma Screens

GOAL - TO INCREASE AWARENESS OF:

- TRANSLATIONAL RESEARCH
- INTERDISCIPLINARY TEAM SCIENCE
- STAKEHOLDER ENGAGEMENTS

WHILE ALSO DEMONSTATING INSTITUTIONAL SUPPORT FOR THE APPROACH AND ACTIVITIES.

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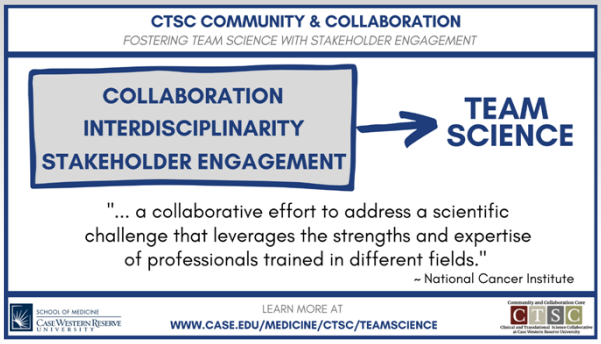
Communication: Plasma Screens



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C&C AIMS

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Yr2 C&C Pilot Grants

- EAC Comment: "The pilot program is meant to be the start of a collaboration; drawing on the team development resources can further reinforce the value of the collaboration and their focus".
- C&C funds two, $30k pilot awards per year
  - Investigators must represent 2 or more fields/disciplines
  - Team must include at least one stakeholder (as part of the investigative team)
  - Project must meet the definition of translational research (translating an observation into an intervention).
  - Investigators are asked to describe how their project contributes to improvements in the public's health and/or reduces health disparities.
  - If awarded, investigators must agree to
    - present research progress and results at a seminar planned by and associated with the CTSC.
    - be available to the C&C staff for informational interviews regarding their team process, the engagement of stakeholders and the progress of their translational science project.

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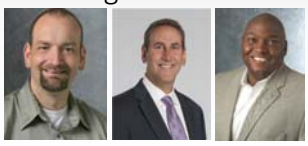
Yr2 C&C Pilot Grants

- Funded two projects:
  - Translating A Product That Prevents Surgical Adhesions into a Large Animal Model
    - Horst von Recum, PhD, Professor (CWRU Biomedical Engineering)
    - Michael Rosen, MD, Professor, Surgery, Cleveland Clinic (Investigator & Stakeholder)
    - Julius Korley, PhD, MBA, CEO of Affinity Therapeutics, Cleveland, OH (Stakeholder)
    - Community of local surgeons (stakeholders)



  - Virtual Assistant System to Enhance Patient Self-Medication Outcomes
    - Colin Drummond, PhD, Professor (CWRU Biomedical Engineering)
    - Shanina Knighton, PhD, RN, Celeste Alfes, DNP, RN, and Elizabeth Zimmermann, DNP, RN (CWRU School of Nursing)
    - Scott Frank, MD, MS, Assoc Professor (CWRU, PQHS, Family Medicine)
    - Miriam L. Pekarek, BS (Outpatient Therapy, and Ohio Living Home Health and Hospice@ Breckenridge Village (Stakeholders)
    - Patients and their Caregivers at Breckenridge (Stakeholders)

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Fostering NEW Interdisciplinary Teams

Feedback from investigators: "we need time, space, and support to come together to brainstorm and plan".

Response: Collaborative Working Retreats

- 4-hour professionally facilitated work session, tailored to each team based on pre-retreat discussions.
- Minimum of 5 participants.
- Priority given to groups with defined goals and outcomes.
- Expectation is group will finalize team goals and sketch out 3 translational science projects during retreat.
- Submission of written plan of 3 projects (2 months later)

YEAR 1
- Conducted 6 team retreats
- Involved 81 investigators
- Investigators represented 4 of our 5 institutional partners and all 7 schools of the university
- 28 external stakeholders.

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Year 1 Team Retreats

- Human Fusions Initiative *(Dr. Brian Gran, Sociology)*
- Reinventing Health Surveillance to Leverage Developing Technology for Health Improvement *(Dr. Scott Frank, PQHS)*
- Team Science for Interprofessional Education *(Dr. Catherine Demko, School of Dentistry)*
- Building a Translational Research Agenda to Promote Environmental Health in NE Ohio (*Dr. Darcy Freedman, PQHS)*
- Achieving Health Equity through Cross-Sector Collaboration Focused on Systems Change (*Dr. Heidi Gullet, Family Medicine)*
- Addressing Tobacco Use Disparities in Cleveland (*Dr. Elaine Borawski, PQHS)*

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Metrics for Tracking Team Progress

	Team Development →			Team Activities →		Outputs →		OUTCOMES	
	1 New group with shared health topic, but have not formally met	**2** Group completed initial brain-storming, Agrees to move forward	**3** Group advanced from initial meeting but still in planning stages	**4** Team Formalized, Collaborative work begins	**5** Collaborative Work	**6** Collaborative Papers or Presentations Submitted	**7** Research Funding Sought	**8** Funding awarded/ Research in process	**9** Research output
	• Shared health topic • Interdisciplinary investigators • Stakeholders identified • Group is seeking support from the CTSC	• Consensus to move forward • Clear vision/mission • Identified TRPs • Stakeholders engaged	• Additional meetings held • Working on outlines of TRPs, Action Plan and a working agreement.	• Formalized working agreement • Evidence of a formal action plan and written TRPs • Ongoing routine meetings • Adhering to timeline • Funding identified	• Group is collectively working on one or more grant applications, papers or presentations • Ongoing routine meetings	• Group has submitted a collaborative paper or national presentations • Submission include investigators from 2 or more fields and at least one stakeholder	• Submission of funding applications for pilot funding, federal grants, or non federal grants	• Work is being conducted as a collaborative team. • Ongoing communication • Continued stakeholder engagement	• Présentations • Publications • Patents • Protocol changes
New Consults*	N=4								
Retreat Groups	N=1	N=2	N=2		N=1				
Pilot Awards								N=3**	

*Groups coming through online consultation requests
**Includes Better Health Partnership (Yr1)

Teams will be:

- Assessed every three months
- Provided additional support if not moved in 2 consecutive periods.
- Metric itself will be re-evaluated every 12 months

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Aim 4: Institutional Change is Hard

- Currently no system for tracking (1) interdisciplinary collaboration or (2) stakeholder engagement.
- P&T policies (in SOM) distinguishes only between independent and team scientists (those who do not lead, but contributes significantly to team research). No specific annotation on collaboration.
- Exploring possible mechanisms for collecting and analyzing these data.
- Joined two national groups focused on fostering and measuring team science in academia:
  - CTSC Working Group (Institutional Readiness for Team Science)
  - INSciTS (science of team science) – at least 3 different groups collecting APT policies; well over 100 universities included.
- Questions to EAC members – how is this being addressed at your institutions?

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CTSC Resources to Support C/T Research

HUB RESEARCH CAPACITY

Study recruitment, assessments, management, and Integrating Special Populations

RESEARCH METHODS

Biostatistics, Epidemiology and Research Design (BERD) and Regulatory Knowledge and Support

INFORMATICS

"Big data", EHR data, tools to collect, analyze and visualize data

RESOURCES TO SUPPORT CLINICAL AND TRANSLATIONAL RESEARCH

COMMUNITY AND COLLABORATION

Promote collaboration through team science, with intentional stakeholder engagement

NETWORK CAPACITY

Trial Innovation Network; collaborative research with other CTSA hubs across the country.

TRANSLATIONAL ENDEAVORS

Workforce development and pilot grant funding

TRAINING PROGRAMS

KL2 Scholars

TL1 Scholars

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Translational Endeavors
Response to 2018 Recommendations

Mark Chance, PhD
November 14, 2019
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Translational funding programs de-risk assets

$350 million in University Research

↓

CAHH NCAI TMU CTSC CCTRP OTF/CTF

Translational Funding Opportunities

Vetting Projects

Project Mgmt

Marketing

↓

Deals!

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Problem: Changing culture to orient faculty to development of their discoveries to promote turning **observations to products.**

Approach: Extend unified translational research and education program ecosystem development led by CTSC/Office of Translation and Innovation.

Solutions: CTSC annual pilot grant now harmonized with other funding programs under OTI. Unified review teams, bootcamps, and project management functions. Building investigator teams.

Investment: CTSC $ spent on bootcamps and PM functions.

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2019 – Translational Research Programs

TMU-CTSC Pilot (5)
CTSC Annual Pilot (7) *
Coulter Awards – full and pilot (11) *
CWRU Target Validation & Start-Up Fund Pilot (3) *

* 4 of 5 translational funding programs offer entrepreneurial bootcamp as part of award

26 projects awarded in 2019 so far
$15,000 - $165,000 each
$1.2M total awarded in translational funding this year

Plus $150,000 expected for 2 CAHH Accelerator Fund Awards * in October

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Problem: Lack of understanding of biotech in Cleveland slowing development of translational assets. Companies developed elsewhere.

Approach: Translation Council composed of local business-persons and government officials convened to brainstorm fund formation, state and local support $, and ecosystem development.

Solutions: Better communication of success stories, development of smart incubators, identification of new funding sources, identification of entrepreneurs.

Investment: CTSC $ for meeting, travel, administrative support, and consultants. Considering idea for U01.

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Engagement with Funding Sources

- VenRock
- Hatteras Ventures
- Fletcher Spaight/CID (Peter Kleinhenz)
- Massachusetts Life Science Accelerator
- CORTEX St. Louis
- LabCentral Boston
- Mark Foundation
- EvoTec
- 1819 Innovation Hub and CincyTech
- Penn State Venture & IP Conference

Massachusetts Biotechnology Council

- Reaching outside Mass. to develop new relationships
- Eager to work with CWRU to match technologies with local Mass. companies
- Mark Chance joined the Academic Steering Committee

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Problem: Additional needs for entrepreneurial support for biotech and biotech industry orientation in CTSC and across region.

Approach: Multiple entrepreneurship programs to engage entrepreneurs at all levels.

Solutions: Alphabet soup of new initiatives and experiments.

Investment: CTSC $ on coordinators, trainers.

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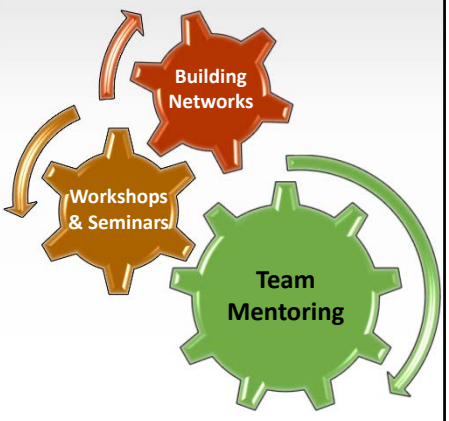
Entrepreneur Training Opportunities

- Strong need for business training and education of researchers; need for participation of many schools
- Entrepreneur bootcamp provided with translational funding for investigators and teams (C3i & iCorps)
- Medical student pathway in I&E
- Open happy hour club for casual discussion of entrepreneurship (BIEC)
- Mentoring program for entrepreneurial leads (CVMP)
- New Veale Institute can help coordinate



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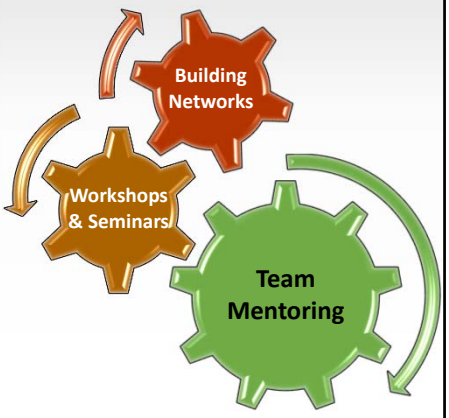
CWRU Venture Mentor Program

- With the support of Dr. Allan Green and MIT's VMS Outreach Program, created CWRU Venture Mentor Program (CVMP)
- Mentoring CWRU entrepreneurs in developing ventures for biotech related discoveries since 2017
- Team mentoring from local industry experts focused on translational research and transitioning projects to industry or clinic. We need you!



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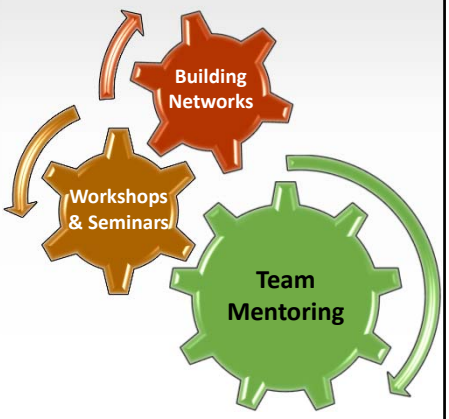
CWRU Venture Mentor Program

- 11 entrepreneurs connected since 2017
  - Several have "graduated" out to entrepreneurial jobs
  - 5 new entrepreneurs ready to on-board
- 23 potential mentors on-boarded
  - 18 currently active
  - 4 new mentors ready to on-board and train
- Thanks to recruiting this year, both mentors and entrepreneurs are finding us!



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Pushing the Pipeline: Next Steps

Meeting the needs of translational research programs going forward

- Pipeline of projects backed by continued hiring and acceleration
- Enhance education and entrepreneurship training

Entrepreneur assistance around startups:

- Artificial Intelligence and Immuno-, Cell Therapy projects

Cleveland Smart Incubator

- CWRU, BioEnterprise partnership
- Develop shared lab space and facilities based on successful models
- Bringing experienced entrepreneurs to Cleveland from all points.

Identifying New Funding Sources

Cleveland Biomedical Development Corporation

- Proposed partnership with Cleveland Foundation
- optimize conditions for formation of start-up companies
- for-profit corporation – invest in startups from academic hub

Alumni Venture Group

- Partnership with TTO, Peter Tippett ,and CWRU Development
- Engage and activate Alumni as investors and entrepreneurs
- Can engage national efforts and alumni venture networks

Informatics
Response to 2018 Recommendations

Jonathan Haines, PhD and David Kaelber, MD, PhD, MPH, FAAP, FACP
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Specific Aims

Aim 1: Provide Informatics tools to support and accelerate clinical and translational research

Aim 2: Educate and train researchers, trainees, and staff in biomedical informatics tools and resources

Aim 3: Enable collaborative research and data sharing within the CTSC and across the nation

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Response to EAC Comments and Suggestions

- Leveraging the informatics and resource tools, reducing redundancy, and greater harmonization, could lead to improved collaboration and efficiency
  - REDCap is widely used and previously was installed separately at each institution. The CWRU and MHS REDCap instances are now being merged as a first step toward consolidation.
  - SHED is a secure data management environment that is available to researchers at all institutions. We continue to encourage usage, particularly for new studies (e.g. CADRC)
  - Harmonization can be accomplished by:
    - Encouraging the use of standardized forms within SHED (e.g. reuse existing forms)
    - Encouraging the use of REDCap standard data capture libraries (e.g. PhenX)
    - Mapping EHR data to the OMOP common data model
    - Implementing external data portals: ACT, TriNetX, I2B2, LEAF

Response to EAC Comments and Suggestions

- Streamlining the data governance and decision-making process and testing transferability of approaches
  - Initial discussions are beginning to develop the framework for data access and data sharing.
  - OMOP mapping from multiple EHR systems (AllScripts, EPIC)
  - Refining the TIN process is continuing.

Response to EAC Comments and Suggestions

- Adopting the Assemble, Integrate, Create model
  - Assemble
    - Instituting OMOP EHR mapping helps assemble data across systems
    - Encouraging the use of common systems brings data together and starts harmonization
  - Integrate
    - Identifying additional data sources (social, governmental, environmental, etc.) that can be connected to EHR data. Connections may be made through a unique individual ID, geolocation, SES class
    - Work within OHDSI consortium so that our OMOP data is compatible with data from many other systems.
    - Install additional data portals (ACT, TriNetX, I2B2, LEAF)
  - Create
    - Further development and deployment of the hashed ID algorithm
    - Use EHR data to address issues in population health and population health management

Education and Training

- CICB Center for Education and Training in Health Informatics (CETHI) supports
  - Clinical Informatics Fellowship
    - 2 fellows per year
    - Reaccredited in January, 2019
  - Formal graduate training in Biomedical Health Informatics
    - MS, Ph.D. programs approved January, 2019
    - Certificate (5 completed)
    - MS (2 enrolled)
    - Ph.D.(2 enrolled)
  - SHED tutorials are online
  - Piloted “EHR for research” module in the University MD program
  - Continue with user studios

BREAKOUT SESSIONS
Research Methods and Clinical Research

Serpil Erzurum, MD
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BREAKOUT SESSIONS
Methods & Processes

1. Research Methods

- Biostatistics, Epidemiology, & Research Design (BERD)
- Regulatory Knowledge & Support (RKS)

(Stay here!)

2. Clinical Research

- Hub Research Capacity
- Network Capacity / TIN

(Proceed to Rm 932)

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Research Methods

Biostatistics, Epidemiology, & Research Design and Regulatory Knowledge & Support

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Biostatistics, Epidemiology and Research Design (BERD) Subcomponent

Gerald Beck, PhD

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BERD Component Leadership

- Director: Gerald Beck, PhD - Cleveland Clinic
  - Tanujit Dey, PhD, Jennifer Gassman PhD, Bo Hu PhD, Peter Imrey PhD, James Bena, MS
- Co-Director: Curtis Tatsuoka, PhD - CWRU/UH
  - Ming Li PhD, Zhengyi Chen, PhD, MS
- Co-Director: Douglas Gunzler, PhD - MetroHealth
  - Stephen Ganocy PhD, Joseph Sudano PhD

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BERD Research Strategy
Specific Aims

- Aim 1: Collaborate with CTSC investigators to ensure use of optimal study designs and appropriate development of statistical analysis plans
- Aim 2: Educate and mentor investigators in study design and statistical analysis methods
- Aim 3: Develop novel study designs and statistical methods for clinical translational research
- Aim 4: Collaborate with CTSC components and other CTSA hubs to leverage resources and to disseminate BERD innovations

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BERD - Accomplishments Year 1

- Assisted 128 investigators on 147 studies across 62 departments

  (In Year 2, Quarter 1 assisted 76 investigators on 101 studies)
- Published 36 papers with BERD supported authors from studies previously assisted upon
- Received 15 funded grants with support for BERD members worth over $28 million in total awards (see list below)
- Received 20 funded grants with support for non-BERD members at Cleveland Clinic worth over $30 million

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BERD - Accomplishments Year 1 (cont.)

- BERD supported faculty taught 10 research/statistical courses
- Gave 9 seminars
- Gave 6 workshops/presentations at national meetings including:

  Peter Imrey – faculty member of Joint Statistical Meetings 2018 a 1.5 day course: Writing Workshop for Junior Investigators
- Mentored 12 masters, doctoral or medical students
- Published 3 statistical methods papers by BERD members
- At MetroHealth participated in monthly CTSC Leadership meetings
- Co-leads participated in the ACTS BERD SIG monthly calls

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Funded grants with BERD support (1)

- Pallavi Tiwari, Systems biology approach to predicting and assessing response to chemo-radiation for brain tumors, DOD CA171074, 8/1/18, $549,219
- Yanming Wang, Dual PET imaging to monitor demyelination, NINDS R21NS111433, 4/1/19, $440,000
- Svetlana Pundik, Transcranial direct current stimulation for post-stroke gait rehab, VA, 10/1/18, $1,500,000
- Susan Mazanec, Building family caregiver skills using a simulation-based intervention for care of patients with cancer, NCI 1 R01 CA240707, 7/1/19 -7/1/2023, $2,347,011
- Alex Huang, Targeting myeloid and lymphoid immune tolerance in metastatic osteosarcoma. St. Baldrick's Foundation Osteosarcoma Collaborative Initiative, 11/1/18 – 10/31/2021, $1,350,000

Funded grants with BERD support (2)

- Lan Zhou, Hes1-loss promotes dysregulation of epithelial homeostasis and inflammation in a serrated adenocarcinoma model, NCI R01CA215852, 7/1/18 - 6/30/23, $1,250,000
- Angela Ciccia, School transition after traumatic brain injury (STATBI): evaluating the impact of participation in a formal return-to-school program for K-12 students, CDC, 9/1/19-8/31/23, $2,302,258
- Martha Sajatovic, Improving adherence in adolescents and young adults with bipolar disorder, NIMH MH117206-01A1, 6/1/19-5/31/22, $843,171
- Yanming Wang, Characterization and quantification of myelin in the central nervous system, NINDS 00221722, 10/1/18-9/30/22, $2,325,521
- Lynn Singer, "1/6" planning for the HEALthy Early Development Study, NIDA, 9/14/19-3/13/21, $560,000

Funded grants with BERD support (3)

- Curtis Tatsuoka, Supplement for Cognitive and neural correlates of mathematics problem solving using diagnostic modeling and dynamic real-time fMRI, NSF, 8/1/19-7/31/20, $200,000
- James Leverenz, Cleveland Alzheimer's Disease Research Center, NIA, 7/1/19-6/30/21, $4,230,000
- Kurt Spindler, BEAR-MOON: A Two arm non-inferiority blinded randomized clinical trial comparing ACL repair with BEAR device vs. standard of care autograft patellar tendon ACL reconstruction, NIAMS, 8/01/18 - 7/31/23, $6,065,905
- Angela Ting, Understanding the full spectrum of epigenetic vulnerability in cancer through the delineation of DNA methylation function in gene 3' end, NCI R01CA230033, 2/01/19 - 1/31/24, $2,001,566
- Jay Alberts, Cyclical lower extremity exercise for Parkinsons trial, NINDS, 2R01NS073717, 5/15/19 – 4/30/24, $3,200,000

BERD - Goals for Year 2

- Provide timely and quality support to investigators on the design of research studies being submitted for funding
- Educate and mentor investigators in study design and statistical analysis methods
- Continue development of novel methods
- Collaborate more with CTSC components and other CTSA hubs to leverage resources and to disseminate BERD innovations
- Interact/participate more with the ACTS BERD SIG

BERD - Barriers/Challenges & How to Address

- Adequately responding to BERD requests with existing resources
  (# FTEs supported: 1.3 doctoral, 0.4 MS)
  Maintain or expand current institutional support
- Collaboration with other CTSA hubs has been limited
  Actively encourage and support external CTSA collaboration
- Inter-CTSC collaboration remains minimal
  Promote communication and collaboration between components

Discussion Points/Questions

How can BERD:

1) Adequately respond to requests with existing resources
2) Collaborate better with CTSC components
3) Collaborate with other CTSA Hubs
4) Count metrics (only BERD supported members?) to be consistent with other Hubs

Questions?

Gerald Beck – beckg@ccf.org

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Regulatory Knowledge and Support (RKS) Subcomponent

Philip A. Cola, PhD

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RKS Component Leadership

- Director: Philip A. Cola, PhD - CWRU
- Co-Directors:
  Suzanne Rivera, PhD – CWRU
  Joan Booth, RN – Cleveland Clinic
- Key Personnel: MetroHealth Medical Center (MHS): Carey Gorden, JD, MA; University Hospitals (UH): Jenna Arlow, MS, CCRP (to 7/1/19); and CWRU: Kim Volarcik and Ellen Divoky. Team Lead: Susie Stein, RN (CC)

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Regulatory Knowledge and Support (RKS)
Specific Aims

- Aim 1: Harmonize cross institutional policies and infrastructure to improve quality of subject protections and create culture of responsibility among all CTSC investigators.
- Aim 2: Streamline regulatory review process to promote research collaboration and facilitate translational research
- Aim 3:Provide innovative educational opportunities in regulatory sciences

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RKS - Accomplishments in Year 1
Within CTSC Hub

- Implemented changes to the Common Rule (all institutions)
  - **Institutional:** Revised policies, practices, websites
  - **IRBs:** Improved efficiency with more Exempt Review and less Continuing Review
  - **Investigators:** Reduction of requirements in Consent Forms
  - **Research Participants:** Improved clarity/content in Consent Forms (simplification)
  - **Research Community:** Presented at the April and October 2019 Regional and National meetings of the Society for Research Administrators International (SRAI).
- Reduced investigator workload with transition to new electronic IRB system (i.e., Sparta IRB at UH & CWRU)
- Utilized SMART IRB agreements and/or platform (all institutions)

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RKS - Accomplishments in Year 1
Within CTSC Hub

- 10 new IND/IDE submissions with 100% acceptance rate
- IRB turnaround time minimized through IRB efficiency
- >200 studies utilized single IRB model
- 118 students completed Research Management/Regulatory Science courses in Certificate/Master's/Doctoral Programs and 3 internships
- 3,563 participants completed internal research staff training seminars

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RKS - Accomplishments in Year 1
Outside CTSC Hub

- UH **submitted data for publication with 13 CTSA hubs** from Scientific Review Committee (SRC) grant pilot to improve regulatory quality and study design review processes
- CC involved the CTSC in the **Clinical Trials Transformation Initiative** organized by Duke University's CTSA*****
- CWRU collaborated with the **Multi-Regional Clinical Trials Center** of Harvard University's CTSA in a **workgroup** to address racial & ethnic disparities in trial participation
- CWRU partnered with the **Consortium to Advance Effective Research Ethics Oversight** at the University of Pennsylvania, to **improve effectiveness of IRBs and Human Research Protection Programs (HRPPs)** in protecting rights and welfare of research participants

***Group has worked on trial design, simplification of consent documents, recruitment, mobile technology, investigator site identification, central IRBs, data analyses, etc.**

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RKS – Goals for Year 2

Through the formation of the CTSC Regulatory Steering Group:

- Strengthen communication within RKS component
- Continue collaboration to reduce regulatory burden
- Further increase use of e-regulatory tools
- Work with other CTSC components and CTSA hubs on best practices
- Increase involvement in collaborative clinical trial opportunities through the Trial Innovation Network
- Broadening of Workforce Development definition and increase CTSC internal hub collaboration

RKS – Barriers/Challenges

- Single IRB model - increased burden and complexity
- Gaps in learning/understanding in researchers
- Sharing solutions within our own CTSC hub/across various institutions
- Consistent Scientific Review Processed – increased burden and complexity

RKS – Discussion Points/Questions

Topic: The single IRB model was intended to reduce regulatory burden, but it seems to have increased burden and complexity in many ways*

Progress: Created policies/SOPs to define investigator and IRB staff processes; offered education sessions; developing flow charts as aides

Ideas: Explore impressions/experiences/feedback from investigators/study teams; enhance policies/tools supporting the process; improve understanding of the process; decrease time to study activation for studies using sIRB review; increase number of studies using home institution as IRB of Record

Question: What area of effort would make the largest impact?

*Example: Cola, P.A., & Williams, M. (2019, October). *How Much Does that Cost? Costing Considerations for Single IRB (sIRB) Review.* Society of Research Administrators International, 53rd Annual Meeting, San Francisco, CA.

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RKS – Discussion Points/Questions

Topic: Overall goal to reduce regulatory burden to investigators, coordinators, study managers, and institution

Progress: Have approached this by updating internal policies, using technology, providing education, organizing operations and adding new staff members/roles to optimize investigator support

Ideas: Regulatory Steering Group to identify other areas where we can make a difference; seek feedback from community of researchers regarding where they see the barriers

Question: What method of approaching researchers would summon the widest response (e.g., survey, interviews)? How can we encourage input? How can we do this with transparency and have investigators trust the mission?

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RKS – Discussion Points/Questions

Topic:	Leveraging technology to streamline the regulatory process
Progress:	Transitioned to new electronic IRB submission system at UH/CWRU; planned upgrade to electronic IRB submission at MH; use of alerts in EMR to assist study teams at CC; electronic file-sharing and e-signature software (Complion) in use for IND/IDE submissions to FDA at UH/CWRU/Metro; provide researchers with online training modules
Ideas:	Develop new ways to enhance regulatory compliance with new technologies (e-consent, e-regulatory binders, apps or systems to promote regulatory compliance, protocol builder with links to experts/resources for protocol development); promote and facilitate Part 11 compliance in electronic records/signatures
Question:	How can legally separate institutions agree to share platforms and access to institutional information in a secure confident way (see Sparta IRB model)?

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Questions?

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Clinical Research
Hub Research Capacity and Network Capacity/TIN

November 14, 2019
External Advisory Committee Meeting

School of Medicine Case Western Reserve University | Cleveland Clinic | University Hospitals Cleveland Medical Center | MetroHealth | Louis Stokes Cleveland VA Medical Center | CTSC Clinical & Translational Science Collaborative

Hub Research Capacity (HRC)

Grace McComsey, MD, FIDSA

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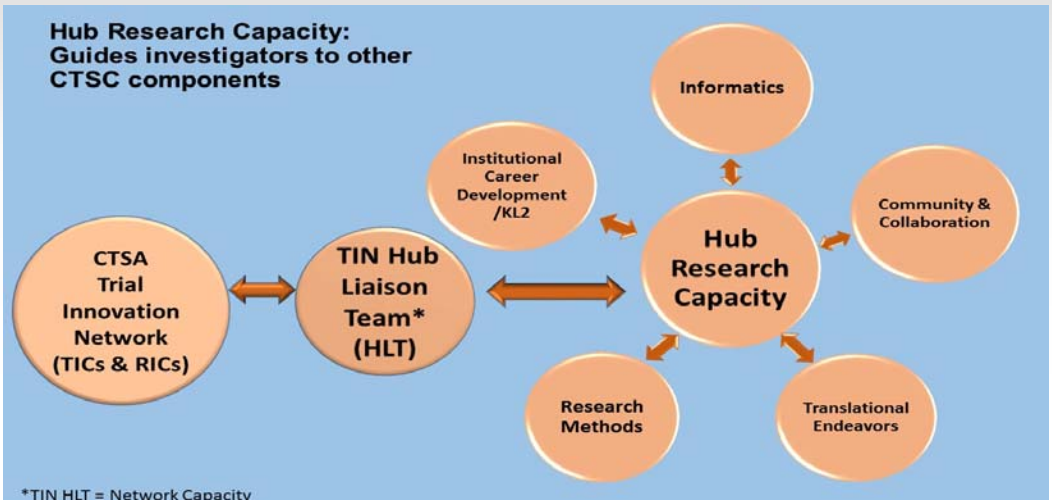
HRC: Gateway to Other CTSC Components



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Two HRC Components

Integrating Special Populations (ISP)	Participant & Clinical Interactions (PCI)
Aim 1: Pair investigators with Participant Recruitment Specialists and Point Persons, to engage special populations in new proposal and ongoing research studies.	**Aim 1:** Oversee and assure quality environments (personnel, facilities and equipment) for the conduct of funded research.
Aim 2: Facilitate investigator training and access to existing, underutilized recruitment tools to better integrate special populations and achieve full enrollment.	**Aim 2:** Provide project stewardship and oversight for an entire project's lifecycle,
	Aim 3: Broaden participant recruitment processes, in general, with digital tools to increase efficiencies and decrease cost of recruitment.

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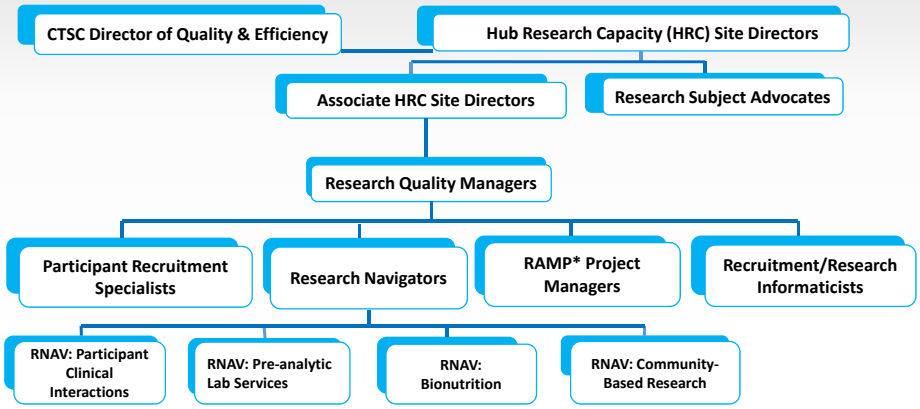
Yr01 Success: Creating structure
HRC Leadership Structure & Roles



*Research Accelerated Management Process

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Yr01 Success: Created Job Descriptions/ Staffed/Trained

Role	CC	MH	UH
Director, Hub Research Capacity		Wilson Tang, MD	
ISP Component Lead		Nora Singer, MD	
HRC Site Directors	Wilson Tang, MD	Nora Singer, MD	Grace McComsey, MD
HRC Associate Site Directors	Lara Jehi, MD Katherine Dell, MD		Mahboob Rahman, MD
Research Subject Advocates	Sumita Khatri, MD	TBD	Mahboob Rahman, MD
CTSC Dir, Quality & Efficiency		Charlotte Bhasin	
Research Quality Managers	LaTasha Bolden	Noreen Roman	Megan O'Neill Miller
Participant Recruitment Specialists	Kassandra Spates-Harden	Elizabeth Lopez Nicole Jones	Rebecca Weintraub
RNAV: Participant Clinical Interactions	Melanie Ramos	Talitha Dotson	Barbara Demagall, RN, BSN, BS, CVRN
RNAV: Pre-analytic lab services	Teresa Markle	Judi Minium	Sarah Scott, MS
RNAV: Bionutrition		Alicia Thomas, MS, RDN, LD, GXMO	
RNAV: Community Outreach		Gelise Littlejohn, JD, MS	
RAMP Project Mgr (Lead)	Megan Villarreal Robert Hartley	Emma Barnboym Nicole Jones	Karen Iacianci Corby Sarah Dawson. MS
Recruitment/Research Informaticists	Chuck Trunick	Kimberly Schach	Sheree Hemphill

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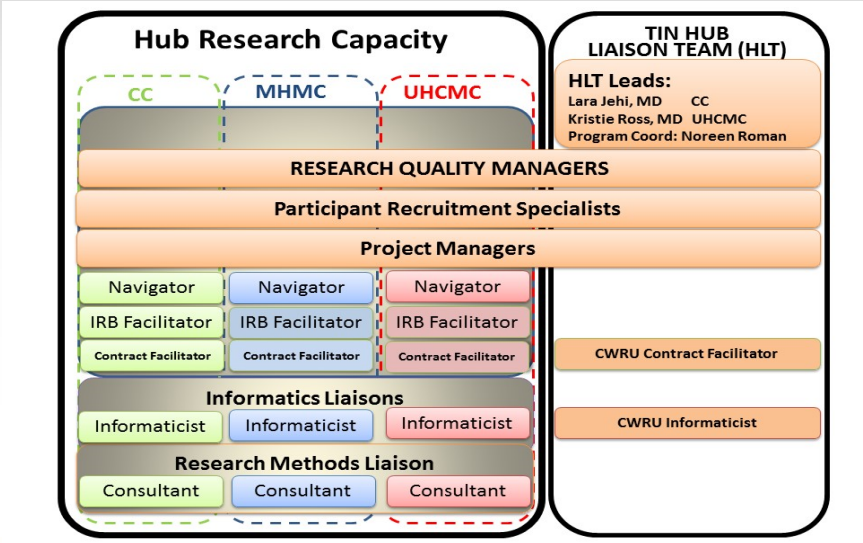
Yr01 Success: Shared Governance across Cores



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Accomplishments

ISP Aim 1: Pair investigators with Participant Recruitment Specialists (PRS) and Point Persons, to engage special populations in new proposal and ongoing research studies.

- Large scale review of studies not meeting enrollment targets to identify study teams who would benefit from recruitment strategies
- Recruited 6 community sites to participate in NIH study
- Toll-free 1-800 number for potential participants to call
- Targeted Community events: Diversity health fair, Minority Mental Health Awareness, PRIDE in the CLE-LGBTQ, National Women's Health Week
- 3 months into 2nd/final year of NIH trial, PRS asked to help create recruitment plan to achieve enrollment of 60. Through use of ResearchMatch/EMR query, identified 300 new potential participants

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Accomplishments

ISP Aim 1: Pair investigators with Participant Recruitment Specialists (PRS) and Point Persons, to engage special populations in new proposal and ongoing research studies.

Expanding Research into the Community

Lunch and Learn with Community Physicians

Research Kiosks: Community Physician offices

Community Physician survey to assess barriers to research

Research Booths at Community Health Fairs

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Accomplishments

ISP Aim 1: Pair investigators with Participant Recruitment Specialists (PRS) and Point Persons, to engage special populations in new proposal and ongoing research studies.

CTSC Sites (for Yr02Qtr01)	CC	MH	UH
#PRS Recruitment Consultations	9	3	14

- Availability of PRS to assist study teams in creation of recruitment plans/logistics has been advertised/publicized to investigators via study team consultations with site Research Quality Managers, research newsletters and research center leadership.
- Research leadership has implemented system-wide policy of research study feasibility assessment.
- Annual minority recruitment goals as institutional metrics

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Accomplishments

ISP Aim 1: Pair investigators with Participant Recruitment Specialists (PRS) and Point Persons, to engage special populations in new proposal and ongoing research studies.

Yr02 Successes using PRS (continued):

- Participant recruitment REDCap surveys for PRS request intake
- Processes for tracking research volunteer referrals to study teams and follow-up on recruitment success of those referrals process.
- Creation of a site-specific research subject registry - currently contains more than 450 subjects. PRS manually matches registry subjects with difficult to recruit trials and follows up with study teams to evaluate success of match.
- Recruitment plan presentations to study teams
- SPARC descriptions provided for CWRU CTSC website to enhance ease for investigators to request services

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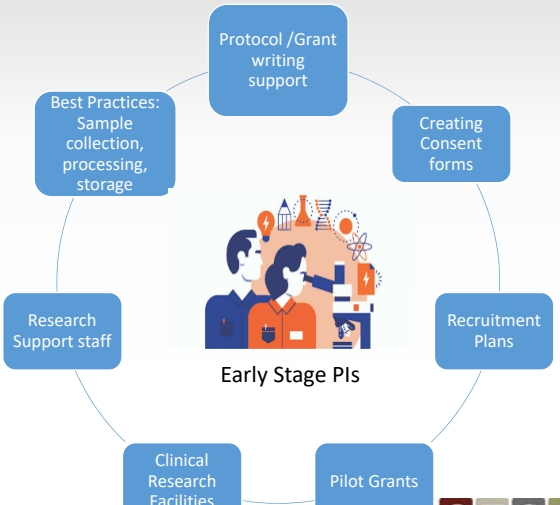
Accomplishments

ISP Aim 2: Facilitate investigator training and access to existing, underutilized recruitment tools to better integrate special populations and achieve full enrollment.

General Tools:
Web-based Investigator Training modules
Web-based recruitment toolkits
Access to Participant Recruitment Specialist (PRS)
Research subject registries
Trial Finder apps for Physicians and Patients
EPIC and AllScripts EMR “alert” systems used



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Accomplishments

PCI Aim 3: Broaden participant recruitment processes, in general, with digital tools to increase efficiencies and decrease cost of recruitment.

Digital Tools:

Feasibility assessment tools

- TriNetX (@UH: Jan-Nov 2019 = 289 queries)
- Deep 6 AI
- EPIC Slicer/Dicer
- Explorys
- REDCap

PCI: Accomplishments

PCI Aim 1: Oversee and Assure Quality Environments (personnel, facilities and equipment) for the conduct of research

	Year 01	Year 01		
	Combined	CC	MH	UH
Protocols served	780	369	105	306
Pis & Co-Is served	1,044	498	145	401
Visits	8,294	1,737	633	5,924
Visit Hrs	18,911	5,483	1,801	11,627
YTD Year 02Qtr01	**Combined**	**CC**	**MH**	**UH**
Outpatient Visits	1,493	484	190	819

Research Quality Managers plus Nursing, Bionutrition, Lab, and Analytics Navigators

PCI: Accomplishments

PCI Aim 2: Provide project stewardship and oversight for an entire project's lifecycle from idea conception through study closure and dissemination of results

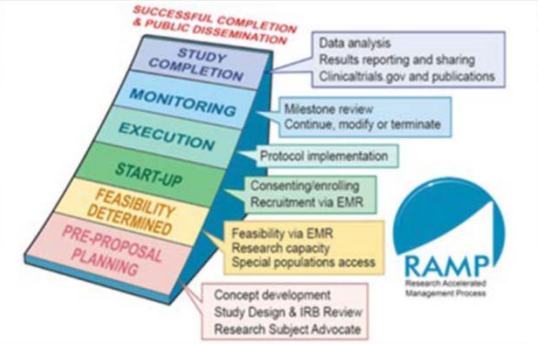

Figure 1: RAMP – Research Accelerated Management Process, is led by Research Quality Managers and executed by Research Navigators, Project Managers and Participant Recruitment Specialists.

RAMP Service Support

KL2 Scholars	CTSC Pilot awardees	TIN Multi-Center studies Incoming & Outgoing	(Investigator-Initiated) High Risk /Complex Studies (IND/IDE)

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PCI: Accomplishments

PCI Aim 2: Provide project stewardship and oversight for an entire project's lifecycle from idea conception through study closure and dissemination of results

YTD Year 02Qtr01	Combined	CC	MH	UH
Number of new projects receiving HRC project management involvement with study teams	55	26	1	28
Number of projects assigned specific Project Management oversight* (does not include 6 TIN EOIs completed)	10	8	1	1

Project Management used:

- to significantly reduce time of new study implementation for Phase I oncology studies.
- to provide consultation to study teams for budgeting, start-up logistics, study closure, best practices in sample handling and storage, data cleaning and analysis and direction to other CTSC resources (regulatory, biostatistics, SMART IRB)

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PCI: Accomplishments

PCI Aim 2: Provide project stewardship and oversight for an entire project's lifecycle from idea conception through study closure and dissemination of results

Project Management:

- Jeffrey Negrey assumed Project Manager responsibilities for an IND pediatric study. He facilitated and documented meetings between multiple departments, including the PI, Pediatrics, Emergency Medicine, Regional Hospitals, Pharmacy, C5 and the FDA. He secured information and organized large amounts of regulatory documentation needed for FDA, internal reviews and IRB submission and saw to the study becoming registered on clinicaltrials.gov. He was the point of contact for the creation of CRFs, EHR smart texts and patient-facing documents. He has received recognition for this excellent work from internal QA reviews and monitoring visits with little or no observations being found. The Investigator noted: *"…has done a spectacular job coordinating the groups involved, and in documenting successful efforts of having coordinated appropriate study initiation visits with attendance logs, detailed documentation of responsibilities, and well-written minutes summarizing all those efforts… offer to share all this clear, outstanding documentation of the well-coordinated achievement of the goals outlined in this memo".*

Goals for Year 2

- Unify and formalize consultation infrastructure for Participant Recruitment Specialist and Project Manager which may include:
  - Establish SOPs and associated workflows for maintaining quality-based services and for communicating Trial Innovation Network processes
  - Forums for introduction of investigators to resources ("open house", department Research Brown Bag luncheons, focus groups "how can we assist investigators")
  - Develop stronger communication strategies with Community & Collaboration to be notified of and support KL2 scholars, Pilot projects
  - Job Aids for:
    - how to create a recruitment plan to integrate special populations
    - Use of web-based IT tools/help desk

Goals for Year 2

- ResearchMatch: Increase quantifiable PIs and define specific goals for use
- Evaluate creation of Community Advisory Board for Recruitment
- Trial Finder on CTSC website (for use by recruitment specialists/Study coordinators, navigators)
- Create a workflow for use of Point Persons with special population expertise.
- Create workflow for management of IND/IDE studies to include project management and PRS services
- Create Department presentation on project management and one-stop-shopping resource for research
- Further development of MyChart tools with testing

Barriers/Challenges

- Creating "experiments" to assess impact of operational changes to research infrastructure processes
- Creating a "Culture of Research" in the community: for both physicians and potential research participants
- Resistance to project management services post study implementation
- So much opportunity…Need to maintain focus

Network Capacity

Kristie Ross, MD

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Network Capacity

AIM 1: Establish a multi-faceted Trial Innovation Unit, TIU (=TIN Hub Liaison Team)

Objective 1a: Rapid identification of trial site PI & site activation.

Objective 1b: Shorten time to completion of budget and contract negotiations.

Objective 1c: Conduct CQI for all multi-site clinical trials.

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Network Capacity

AIM 2: Establish a Multi-faceted Recruitment Innovation Unit (RIU)

Objective 2a: Hire & Onboard Participant Recruitment Specialists at each CTSA institutions

Objective 2b: Enhance trial participation through new technological platforms.

Objective 2c: Develop patient registry for eligibility and study update delivery

Objective 2d: Expand EHR systems for feasibility assessments & recruitment

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Network Capacity Services

TIU Services	RIU Services
TIN Hub Liaison Team Services	Participant Recruitment Specialist Team Services
	Project Management Services

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Network Capacity Accomplishments

AIM 1: Establish a multi-faceted Trial Innovation Unit (TIU)

Objective 1a: Rapid identification of trial site PI and site activation

- **Hub Liaison Team formed and expanded** to include: Contractor/ Negotiator, CTSA PI, Regulatory Coordinator, CTSA Affiliate Institutional Points of Contact and IT representatives.
- **TIN POC** assists with organization of Hub Liaison Team, EOI Requests, Metrics and serves as Liaison for investigators and CTSA to TICs and RIC.
- **Trial Innovation Network Responses and Submissions (See Table 1.)** In the first 15 months, the Local TIN Hub Liaison Team met monthly fifteen (15) times and responded to 16 TIN Expressions of Interest (EOI) and 3 HEAL initiatives (19 EOIs) in 5 areas of interest, Cardiovascular Diseases, Neurology and Infectious Disease, Pediatrics and Internal Medicine.
- **RedCap Database Phase I** created by TIN HLT with possibility of to track, store and report the information provided with the TIN Expressions of Interest (EOI) and progress on studies that are supported by the TIN.

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Network Capacity Accomplishments

AIM 1: Establish a multi-faceted Trial Innovation Unit (TIU)

Objective 1a: Rapid identification of trial site PI and site activation

- **Hub Liaison Team formed and expanded** to include: Contractor/ Negotiator, CTSA PI, Regulatory Coordinator, CTSA Affiliate Institutional Points of Contact and IT representatives.
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Success: Staffing the Structure

Network Capacity Structure

Trial Innovation Unit (TIN Hub Liaison Team)			
Role	CC	MH	UH
TIN HLT Co-Directors	Lara Jehi, MD		Kristie Ross, MD
TIN HLT Project Coordinator		Noreen Roman, MBA	
CTSC PI	Michael Konstan, MD (Case)		
CTSC Executive Director	Ginny Petrie (Case)		
CTSC Dir. Quality & Efficiency	Charlotte Bhasin		
Director of Regulatory and Compliance	Ellen Divoky (Case)		
Sr. Dir, Office Grants & Contracts	R. Erin Fogarty, MA, CRA (Case)		
Sr. Dir, Planning, Outreach, Operations & Technology	Mark Beno, MSM (Case)		
Research Quality Managers	LaTasha Bolden, MBA	Noreen Roman, MBA	Megan O'Neill Miller
Recruitment Innovation Unit			
Recruitment Specialists	Kassandra Spates-Harden	Elizabeth Lopez, RN Nicole Jones RN	Rebecca Weintraub
Project Managers	Megan Villarreal Robert Hartley	Emma Barnboym Nicole Jones	Karen Iancianc Corby Sarah Dawson, MS

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TIN By the Numbers: Y1 + Y2, Q1 (May 2018-July, 2019)

Table 1.	Y1	Y2Q1	TOTAL
# of TIN/HEAL Studies Evaluated	15	4	19
# of Responses to the TIN (breakdown below)	52	26	78
PIs Identified as interested	19	2	21
Electronic Cohort Responses	8	8	16
Budget Reviews	2	2	4
Feasibility Questionnaires	8	2	10
Protocol Reviews	15	12	27
# TIN studies started	3	0	3
# TIN studies in process	3	1	4
# TIN studies still pending notification			5
# TIN Studies Submitted	1	0	1
# services received from the TIN	2	0	2

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Network Capacity Accomplishments

AIM 1: Establish a multi-faceted Trial Innovation Unit (TIU)

Objective 1b: Objective 1b: Shorten time to completion of budget and contract negotiations

- **Budgeting POC:** Established Case Sr. Dir Case Grants & Contracts as the established point of contact for all TIN contracting and joined TIN Hub Liaison Team
- **New Personnel:** Onboarded New Director of Regulatory, Compliance and Contracting and joined Hub Liaison Team
- **Contracts Executed:** 2 contracts centrally executed for MH & UH TIN (DOSE study)
- **Average Days Contract received to contract execution:** 70 days;

Network Capacity Accomplishments

AIM 1: Establish a multi-faceted Trial Innovation Unit (TIU)

Objective 1c: Conduct CQI for all multi-site clinical trials

- Our **CTSC Hub Liaison Team** nimbly adapts and responds to the growing and changing needs of the national TIN (TICs and RIC) to facilitate efficiencies in study onboarding and support.
- As the national TIN grows and evolves in their processes, we are using Continuous Quality Improvement (CQI) to enhance and expedite local communications to TINs for Expression of Interests (EOIs) requests and replies.

Network Capacity Accomplishments

AIM 2: Establish a multi-faceted Recruitment Innovation Unit (RIU)

Objective 2a: Hire and Onboard Participant Recruitment Specialists (PRS) at each CTSC affiliate Institutions

- **Hired + Trained RIU Personnel:** The RIU hired/trained 5 Participant Recruitment Specialists (PRS) and 4 Project Managers (PMs) at the 3 affiliate CTSC sites (Completed in Y1)
- **Toolkits Developed:** Detailed Institutional Toolkits rolled out and posted electronically for ease of investigator use.
- **Recruitment Consultations:** The Y2 RIU conducted 26 (CCF, 9; MH 3; UH 14) Recruitment Consultations and supported 10 (CCF, 6; MH 3; UH 1) studies with Project Management.
- **CTSA Hub Collaboration:** June 12, 2019 PRS and PMs traveled to Ohio State University (OSU) CTTS to learn best practices from OSU Office of Recruitment + Retention.
- **Intra CTSC Collaboration:** Cross – City PRS and PMs meet quarterly to share institutional best practices and harmonize services across the CTSC. Most recent meeting, September, 2019 to discuss top level goals, processes and streamlining PRS and PM services to investigators.

Objective 2b: Enhance trial participation through new technological platforms

- **Training:** PRS are training with tools such as Slicer-Dicer, TriNetX, Explorys, RedCap and Research Match.
- **Research Match** in process of transferring from IRB support to PRS support at MetroHealth.
- **TriNetX requests** at UH are submitted using REDCap surveys. TriNetX is now used for all TIN feasibility requests at UH with usually a 48-hour response.

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Network Capacity Accomplishments

AIM 2: Establish a multi-faceted Recruitment Innovation Unit (RIU)

Objective 2c: Develop patient registry for eligibility and study update delivery

- **Preparation for Research Match Expansion:** PRS at MetroHealth transferring Research Match administration from IRB to PRS to expand and enhance numbers of studies and patients enrolled in RM.
- **Site Specific Patient Subject Registry**: PRS at UH has created a site-specific research subject registry - currently contains more than 450 subjects. PRS manually matches registry subjects with difficult to recruit trials and follows up with study teams to evaluate success of match.

Objective 2d: Expand electronic health record systems for feasibility assessment and recruitment

- **New Query Tool Established:** TriNetX rolled out in 2 institutions (UH, April 2019 & MH, July, 2019); 199 TriNetX feasibility requests completed in 2019 through Y2Q1 (first year of use).
- **An additional tool:** Deep6 AI (queries EMR notes using AI and Natural language processing) is in testing phase for oncology clinical trial recruitment and being used by the UH Coordinator Core for pediatric and hard-to-recruit studies.
- **New Policies for Feasibility:** UH implemented system-wide operating policy mandating feasibility assessment with IRB submission. REDcap survey in use to capture feasibility requests with 48 hour turn around time .

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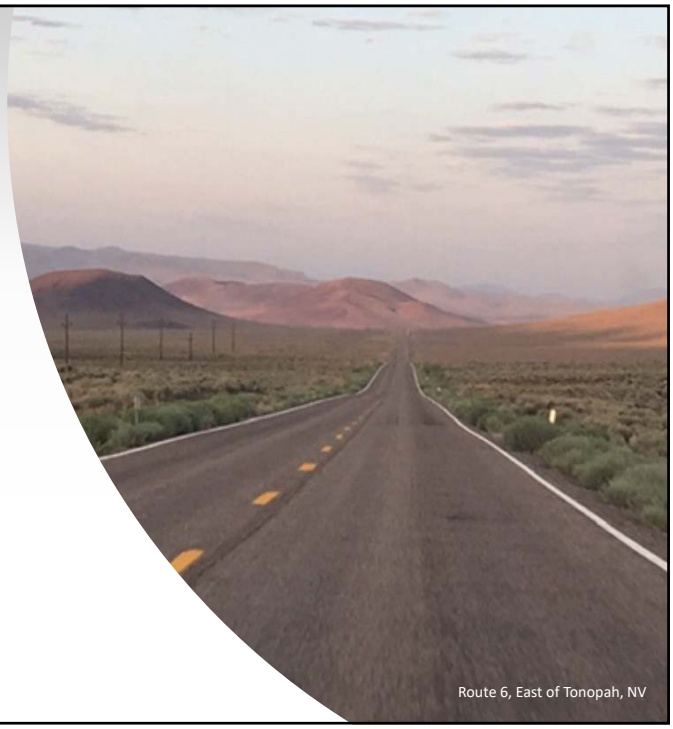
Next Steps: The Journey Ahead

- Goals for Year2
- Barriers/Challenges
- Discussion Points & Questions



Route 6, East of Tonopah, NV

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Goals for Y2:

Continue to build & refine

TRIAL INNOVATION UNIT

- **Complete Phase II build of the TIN RedCap database**
  - allow real-time capture of progress through the life cycle of the TIN study facilitate evaluation of TIN studies.
- **Engage Translational Workforce** to increase awareness of and incr. # proposals TO the TIN
- **Create directory of Trial Experts** to rapidly assign trial PIs
- **Track and Decrease** "Contract Received to Contract Execution"
- **Evaluate TIN study performance** Collect CQI and Metrics Data on TIN studies in progress

RECRUITMENT INNOVATION UNIT

- **Enhance trial participation** through technological platforms
  - 'Study Finder' on CTSA main site
  - Add Recruitment Toolkit
- **Expand Recruitment Services Education and Outreach to Study Teams** number of Recruitment Consultations, Number of studies supported. Does it make an impact?
- **Expand EHR system capabilities** for feasibility assessments and recruitment

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Barriers/Challenges

Trial Innovation Unit

- Adapting to evolving national TIN.
- Responding to TIN Expressions of interest/budgets without accompanying indirect costs

Recruitment Innovation Unit

- Incorporating Recruitment Services (Teams) into the clinical trials workflow (i.e. feasibility)
- Educating study teams and integrating services of both Recruitment Team & Project Management Team

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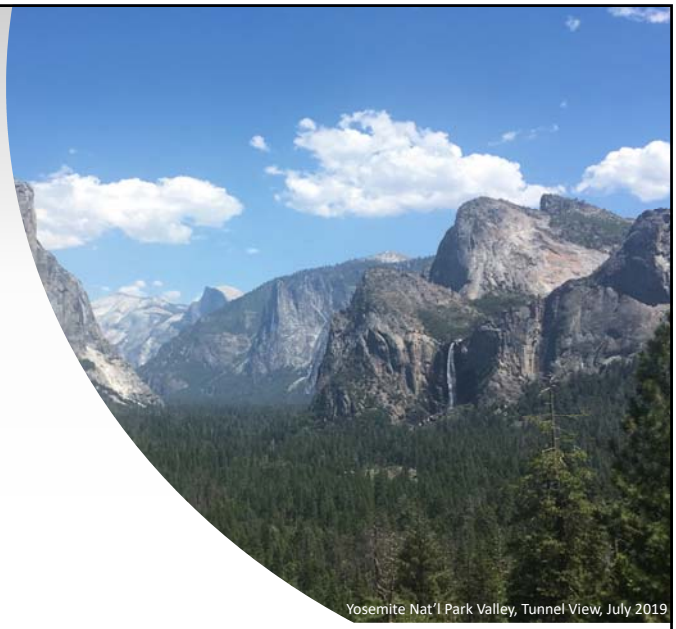
Discussion & Questions

Thank you!



Yosemite Nat'l Park Valley, Tunnel View, July 2019

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CTSC KL2 Program

Raed Dweik, MD
November 14, 2019
External Advisory Committee Meeting

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MetroHealth
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CTSC KL2 Aims

- Aim 1: Further enrich and expand our integrated CTSC-wide innovative and individually tailored KL2 program in C/T research
- Aim 2: Prepare the next generation of investigators with the multidisciplinary skills required to lead cutting edge C/T research
- Aim 3: Build the multidisciplinary workforce of the future by collaborating with KL2 programs at other CTSA Hubs to share best practices, set the standards, and innovate in C/T career development

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Current KL2 Program:
Postdoctoral Training in Multidisciplinary Clinical and Translational Research

- 4 year program (11 total)
- Purpose is to transition to R funding in clinical and translational science
- Emphasizes multidisciplinary, team-based research
- Research and career mentors
- Cohort interaction and collaboration

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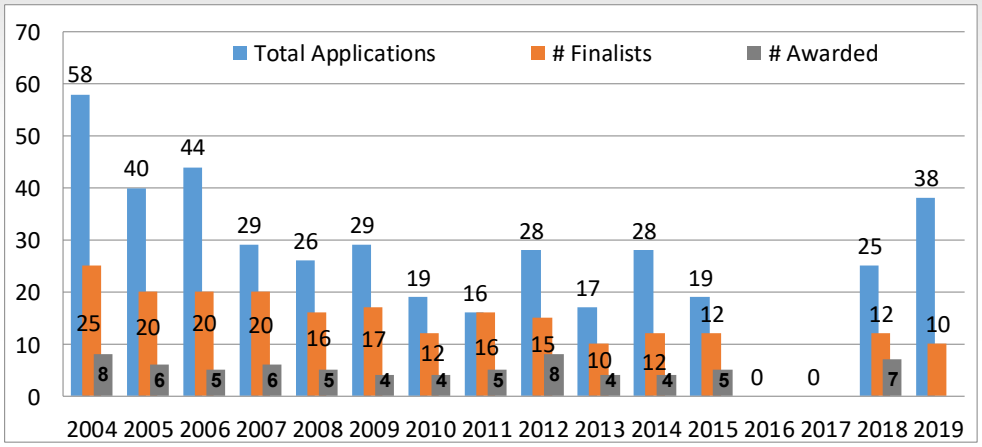
KL2 Applicants & Scholars-over time



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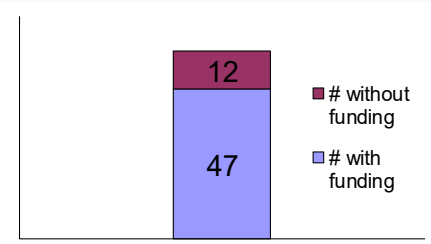
KL2 Scholars: Home Institution and Success Transitioning to Independent Funding

KL2 Scholar Alumni 2004-19 n=59	
Location	Number (%)
CWRU	19 (32%)
CCF	21 (36%)
UH	11 (19%)
MHMC	6 (10%)
VA	2 (3%)

Funding Status (All Funding) For our 59 KL2 Alumni



80% total funding rate

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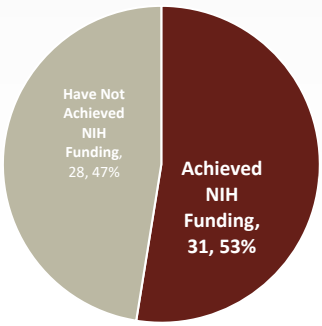
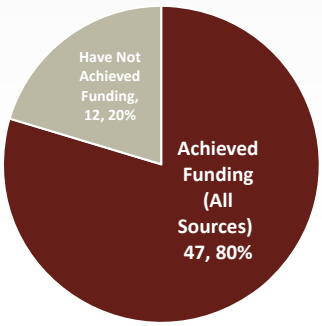
CTSC KL2 Scholars Achieving Independent Funding

KL2 Scholars Achieving Funding: NIH



KL2 Scholars Achieving Funding: All Sources



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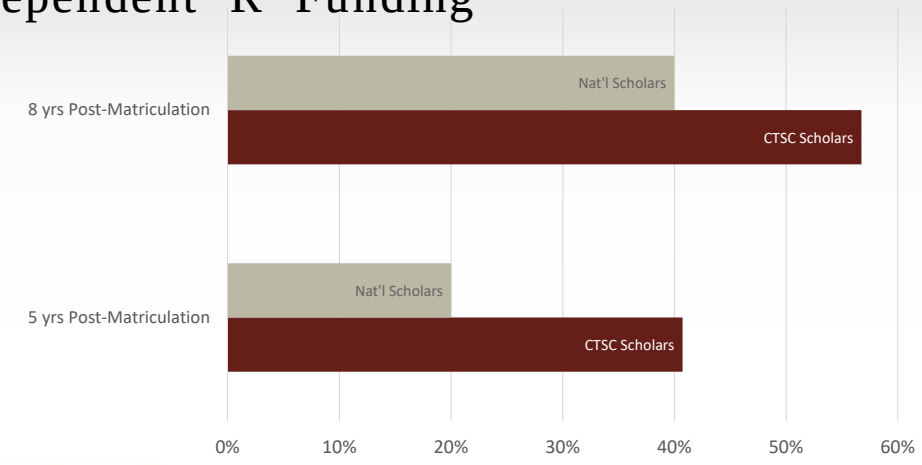
Comparison of CTSC Scholars to National Transition Rate from Mentored "K" to Independent "R" Funding



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CTSC KL2 Progress To-Date

- Accomplishments:
  - KL2 Seminar now includes increased leadership presence
    - Also inviting K23's, MENTR, TL1 Post Docs, Alumni
  - Revamped Scholar Orientation
    - Shorter, process oriented
  - Successful Orientation of Mentors
  - Human Subjects Research Prior Approval Process (HSRPA)
    - Submitted Scholar projects for successful approval
- Goals & Challenges:
  - Implementing RCR programs
  - Collaborating with other CTSA Hubs
- Discussion Points: National KL2 Data; national data of transition to R

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Collaborative Opportunities

Michael W. Konstan, MD, Mark Chance, PhD, Serpil Erzurum, MD

November 14, 2019

External Advisory Committee Meeting

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FY20 NCATS CTSA Program Collaborative Suite of Awards

		Eligibility	Review Type	Purpose
Foster research collaboration to **develop, demonstrate and disseminate** innovative, experimental approaches to overcoming translational science roadblocks.	Collaborative Innovation Award (R21)	2 or more CTSA Program hubs	External Peer Review	Collaborative Innovation – High Risk/ High Reward
	Collaborative Innovation Award (U01)	3 or more CTSA Program hubs	External Peer Review	Collaborative Innovation
Provide support for the **demonstration, and/or dissemination, and/or implementation** of translational science projects that have been tested and validated at a specific hub or institution.	Competitive Revision (Administrative Supplement)	1 or more CTSA Program hubs	External Peer Review	Demonstration and/or Dissemination and/or Implementation

August 2019

NIH National Center for Advancing Translational Sciences

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Collaborative Innovation Award (U01)

I-Corps@NCATS (Pending)
Center for Clinical and Translational Science
University of Alabama at Birmingham
(Chance, Fening, Reizes)

Competitive Revision (Administrative Supplement)

SPARC - 3UL1TR001450-05S1 (Funded)
South Carolina Clinical & Translational Research Institute (SCTR)
Medical University of South Carolina
(Konstan)

Enabling Next Generation Research Analytics at CTSA Hubs (Pending)
Institute of Translational Health Sciences
University of Washington
(Haines)

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Collaborative Innovation Award (U01)

U01 proposal – potential submission 3/2020

Problem:
Ohio's pre-clinical development of biomedical technologies is world class; but we lag in capital attraction and formation required to start companies commensurate with the rate of pre-clinical development of technologies.

Solution:
The **Ohio Innovation Network** will be established to promote a statewide innovation ecosystem to both train entrepreneurs and attract them to Ohio based innovation.

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Collaborative Innovation Award (U01)

U01 proposal – potential submission 3/2020

Approach:

Aim 1: Expand MIT Venture mentoring service, a validated ecosystem intervention, to all 3 Ohio CTSAs. Maintain a biomedical focus for VMS. This approach will **develop** entrepreneurs currently in Ohio to accelerate translation of translational assets.

Aim 2: Expand existing entrepreneur programs to focus on talent attraction to promote company formation; using a statewide pipeline of assets. This approach will **attract** entrepreneurs from outside Ohio to develop companies around Ohio assets.

Up to 400K/year available from NCATS will be coupled to state and foundation based activities that provide support across the 3Cs.

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Other Collaborative Opportunities?

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