Overview of Plans for New CTSA Suite Submission/Oversight and Leadership

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Cleveland Clinic

University Hospitals Cleveland Medical Center

MetroHealth

Louis Stokes Cleveland VA Medical Center

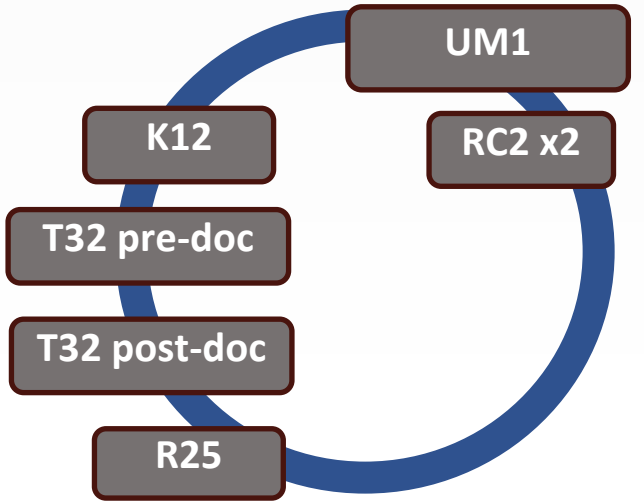
CTSC Clinical & Translational Science Collaborative

CTSA Program Focus

- Develop, demonstrate, and disseminate innovations that turn science into medicine faster
- Provide a national resource for the rapid response to urgent public health needs
- Promote impactful partnerships and collaborations
- Promote training and career support
- Address health disparities
- Nurture field of translational science

National Center for Advancing Translational Sciences

New CTSC Structure: Separating UM1 from training grants



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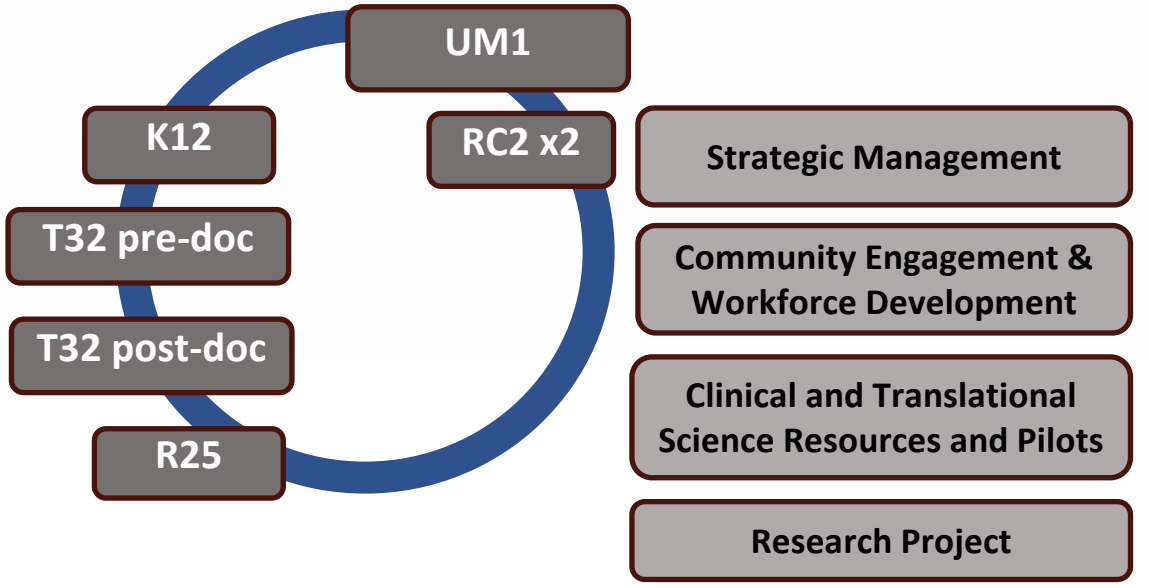
New CTSC Structure: UM1 separated into elements



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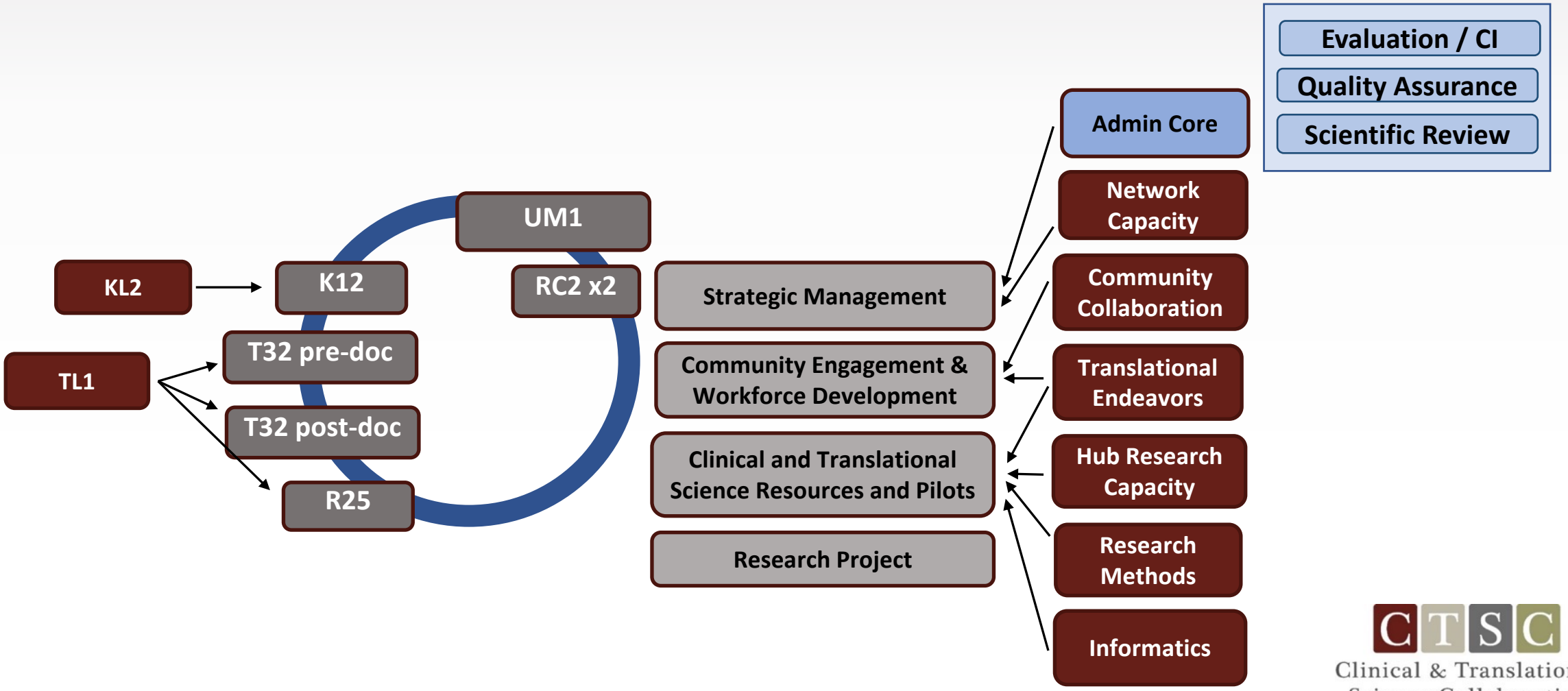
New versus Old CTSC Structure



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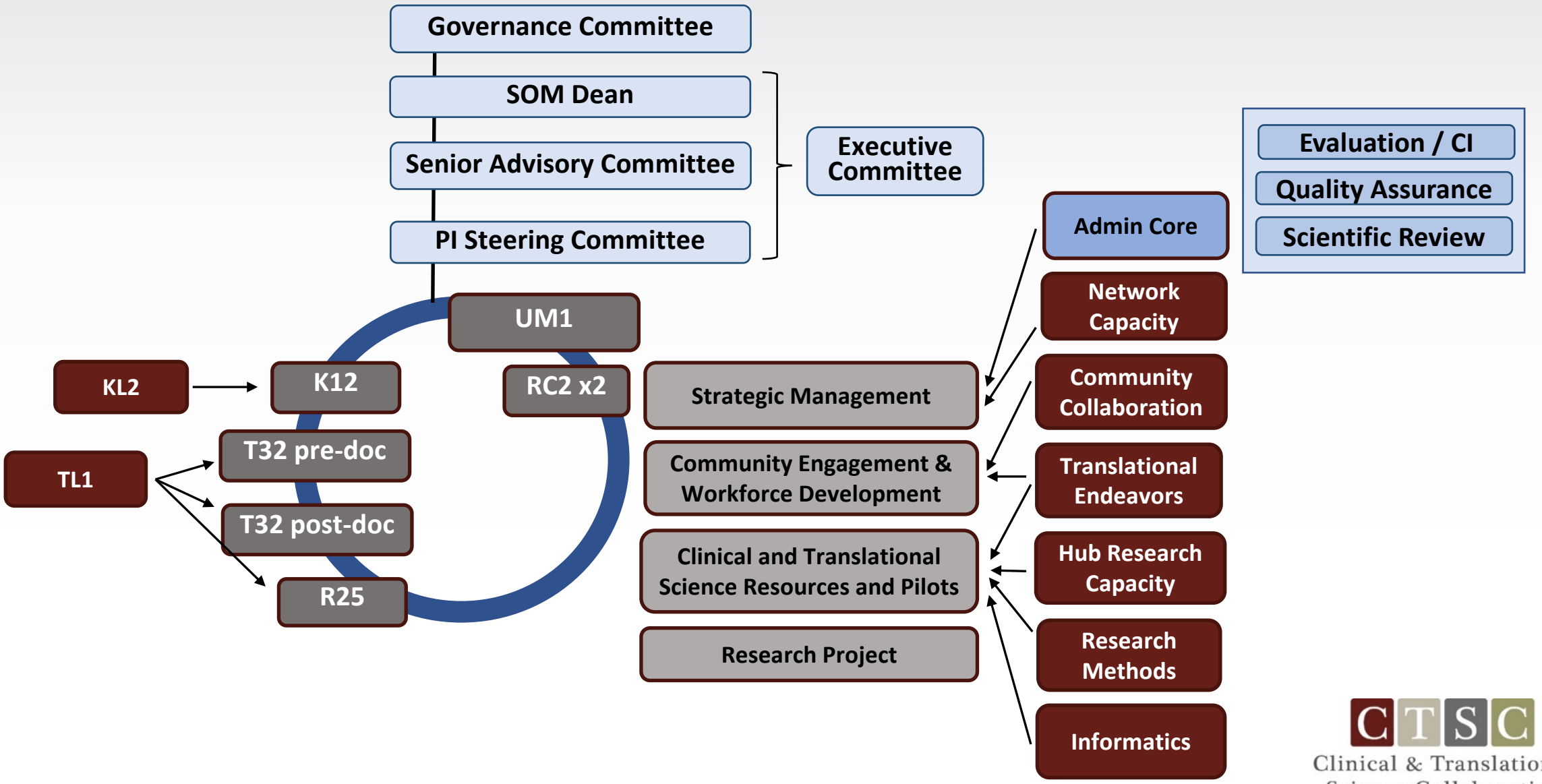
Structure of the Oversight Committees of new CTSC



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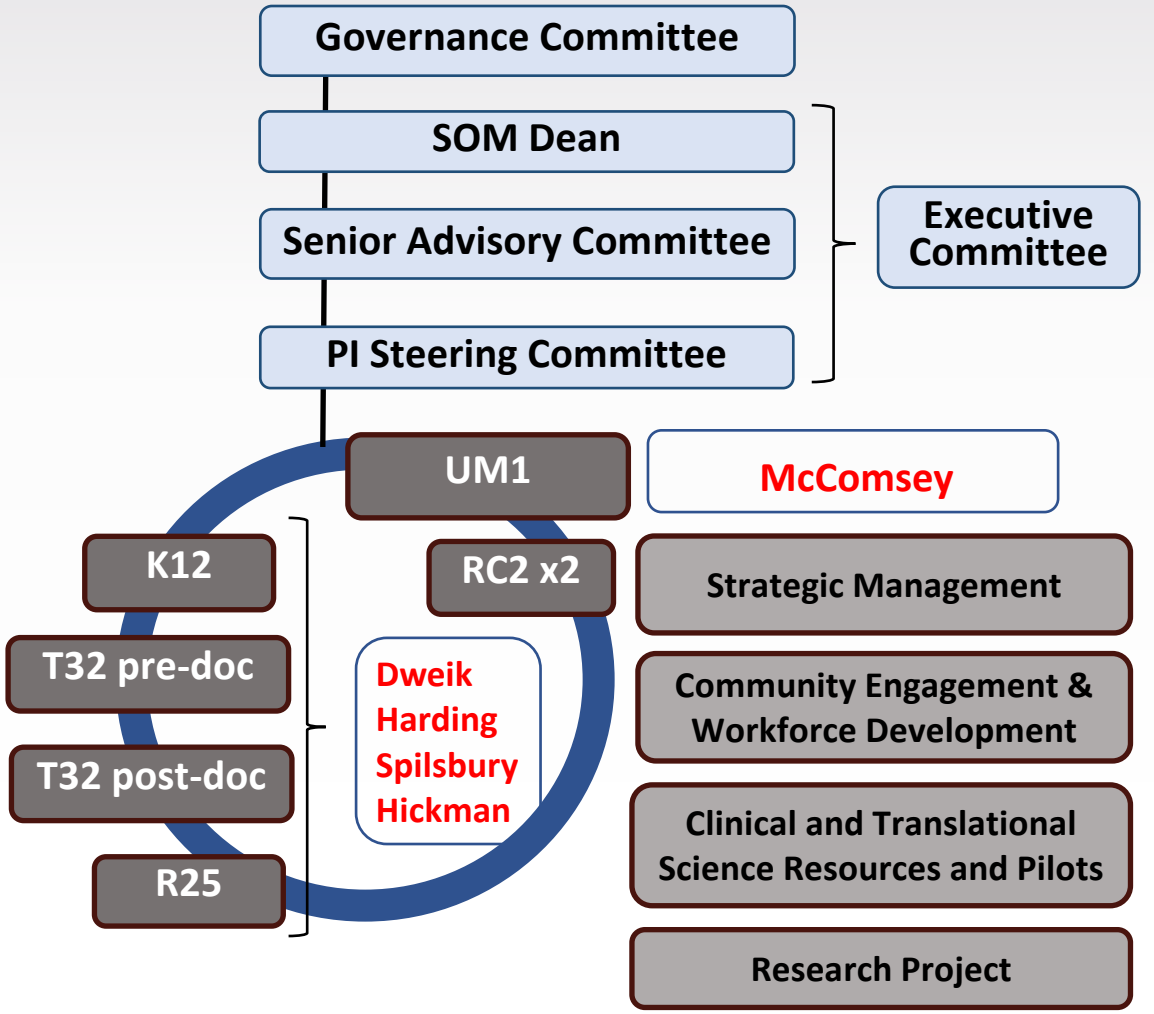
New Leadership



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UM1 FOA Diagram

Section I
FOA Description

Key Terms, Definitions and Uses in this FOA

Background

CTSA Program

CTSA Program UM1 Hub Application Structure

Required and Optional Career, Training and Research Education Opportunities

Resources Provided by NCATS

Section II
Award Info

Section III
Eligibility Info

Section V
Review Information

Section IV: Application and Submission Information
[includes Page Limitations, Facilities & Other Resources, Data Tables, Partner Institutions, Budget, Research Plan (Specific Aims + Research Strategy)]

Element A: Overview	Element B: Strategic Management	Element C: Training & Outreach	Element D: CTS Resources & Pilots	Element E: CTS Research Program
6 pgs	12 pgs	12 pgs	18 pgs	6 pgs
Essential Characteristics of Successful CTSA Hubs	Strategic Management Module *(Module Leader & Application PI)*	Workforce Development for Clinical Research Staff Professionals Module *(Module Leader)*	Resources & Services Module *(Module Leader)*	CTS Research Program *(Program Leader)*
Vision, Strategic Goals, & Impact		Community & Stakeholder Engagement Research Module *(Module Leader)*	CTS Pilot Module *(Module Leader)*	
Track Record in CTS			Health Informatics Module *(Module Leader)*	

NOTES:
>PER APPLICATION:
-One budget with budget justifications broken down by Element & Module
-One set of criterion scores and one overall impact score

July 2021

Proposed UM1 Modules and Leadership Structure

Committees

1. Training Committee
2. Health Equity Committee (Internal)
3. Internal Advisory Committee
4. External Advisory Committee
5. Community Advisory Board

Element A. Overview	
Element B. Strategic Management	**McComsey,** Freedman, Konstan, Singer
Element C. Training and Outreach	1. **WFD for Clinical Research Staff Professionals**: **Dolansky,** Dell 2. **Community & Stakeholder Engagement: Bolen,** Freedman
Element D. Resources and Pilots	1. **Resources & Services: Tang**, Singer (Includes HRC, BERD, RKS, BIOETHICS) 2. **CTS Pilot: Borawski,** Strohl 3. **Health Informatics: Kaelber**, Haines
Element E. CTS Research Program	**Program Leader**: **Farrell,** Rao

†**Lead**, Co-Lead

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Overview of UM1 Module Goals/Leadership

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Workforce Development for Clinical Research Staff Professionals

- Provide development, training, and educational activities in CTS, emphasizing collaborations and team science
- Targets CTS research teams and other clinical professionals such as clinical investigators, nurses, pharmacists, administrators, coordinators, consultants, data managers, regulatory affairs, etc
- Enhances diversity of workforce
- Institutions to create a culture of collaboration and recognition of CRS (promotion, career ladder).
- It is expected that KL2/Ts/R25 activities will be conducted as an integrated endeavor with the WFDCRP.

Module leads: KL2 alum, established PhD researcher in Nursing school & Peds nephrologist and vice chair Research at Pediatric institute at CCF-with staff training and CRU experience

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Community and Stakeholder Engagement

- NCATS is specifically committed to accelerating CTS research to address the burden of conditions that disproportionately affect rural, minority, other underserved populations.
- Promoting health equity, developing an underrepresented workforce, enrolling underserved populations in research. While hubs are expected to innovate in this area, an extensive research program is not required.
- Hypothesis-driven observational/interventional studies to determine how best to build trust and increase participation in clinical research/trials and integrate members of underrepresented communities into TR
- Collaborate with other CTSAs to identify, adopt &utilize new tools for engaging underserved populations
- Provide tailored materials to help researchers recruit and retain underserved populations in clinical trials
- **Module Leads**: an MD- KL2 alum and a PhD (both MPH) with significant work in this area who currently lead several centers for community based research and health equity

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Resources and Services Module

- Provide core resources and services that address the many stages of CTS research, including planning, conduct, analyses, implementation and dissemination.
- Provide discrete resources or services that are separate from support for distinct, well-described projects under the Research Program or the Pilot modules.
- Module must promote broad access and provide clear funding expectations.
- A formalized management plan is required that addresses policies for solicitation, review, prioritization, funding level with justification, progress tracking, and evaluation.
- The use of R&S to augment research activities supported by other funding sources, i.e., non-NCATS funding, does not require NCATS prior approval.

Module Leads: established cardiologist, research director at CCF Heart/Vascular Institute, who currently leads Hub Research Capacity & established rheumatology researcher at MH who co-leads HRC

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Pilot Module

- Pilot Module supports both the management and oversight of the CTS Pilot Program and the Pilot projects.
- Funded pilot projects should be relevant to CTS. i.e., focused on understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research.
- Translational research projects for a particular target or disease **not allowed**.
- A management committee representing all aspects of the CTSA hub must be appointed
- Only the CTS Pilot Module should be described; no specific projects.

Module Leads: CWRU established PhD community researcher who currently leads Community and Collaboration & Pulmonary/sleep medicine researcher (UH/VA) who co-leads the Pilot program

Health Informatics Module

- Focus on areas of Health Informatics, Clinical Research Informatics, and Translational Bioinformatics, Big data including genomics.
- CTSA hubs/partners are expected to embrace a culture of Open Science and Data Sharing that promote the F.A.I.R. principles.
- Expected practices: Sharing of data, tools, algorithms, methodologies, governance principles and policies, and software; making research tools compatible with common data elements, etc..
- Encouraged to use the Fast Healthcare Interoperability Resources (FHIR®) standard to capture, integrate, exchange clinical data for research purposes, and to enhance capabilities to share research data

Module Leads: MHS Clinical Informaticist (MD, PhD, MPH), and established researcher & CWRU established researcher and Chair of PQHS Dept who currently leads Informatics

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Clinical and Translational Science Research Program

- Supports discrete research project(s) that address a significant roadblock in CTS (one project per hub is required).
- Program must be focused on CTS rather than on basic discovery research.
- Should not only address a translational research question in a particular disease or intervention development/dissemination context, but also provide generalizable CTS innovations or insights that can be applied to other translational research projects.
- The described Program is intended to be of the type of CTS research that the applicant considers to be of high priority.

Module leads: Two NIH funded established investigators; KL2 alum, CCF OB/GYN and Vice Chair Research in Women's Health Institute & Chair of Family Medicine at UH

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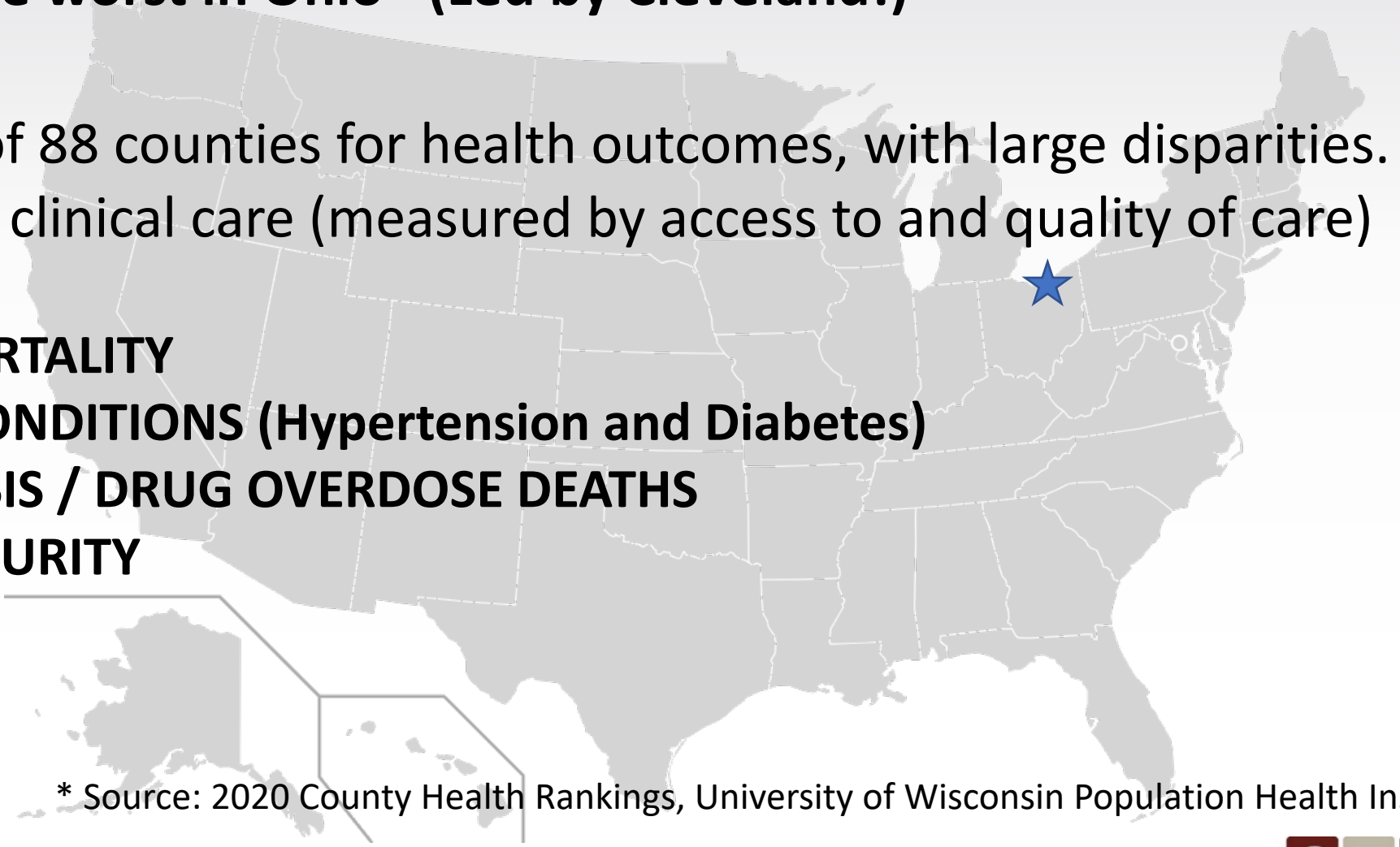
Overall Aims of the CWRU UM1 Submission

Ohio ranks poorly for health outcomes, and Cuyahoga County amongst the worst in Ohio* (Led by Cleveland!)



- 75th out of 88 counties for health outcomes, with large disparities.
- Top 10 for clinical care (measured by access to and quality of care)

INFANT MORTALITY
CHRONIC CONDITIONS (Hypertension and Diabetes)
OPIOID CRISIS / DRUG OVERDOSE DEATHS
FOOD INSECURITY

* Source: 2020 County Health Rankings, University of Wisconsin Population Health Institute

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UM1 Overall Aims

- To understand underlying barriers to the suboptimal recruitment of underrepresented groups* in clinical trials, and test and scale interventions aimed at breaking down these barriers to diversify study engagement. *AAs, Hispanics, rural areas, persons with disability, seniors 75+, LGBTQ+
- To facilitate and expedite innovation in multicenter clinical and translational research, including fully integrated community and stakeholder partners, and to ensure that this research results in health improvements for all.
- To disseminate and implement novel and responsive research programs across clinical and community settings to advance access to health interventions that aim to reduce health disparities.
- To create and disseminate inclusive and high impact educational and training programs for translational research professionals of all disciplines and levels, both in clinical and community settings.

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Planned Partners and Collaborators

- Reaching out to partners in the Community, focus on African Americans, Hispanics, and LGBTQ+ serving organizations
- Better Health Partnership, Kent State University, First Year Cleveland, Lincoln West and other Cleveland Metropolitan School System schools
- Other CTSA Hubs? Ideally OSU!

RC2: High Impact Specialized Innovation Programs (SIPs) in Clinical and Translational Science for UM1 CTSA Hub Awards

- Each UM1 allowed 0-2 RC2 applications. Each budget up to $500K/yr X 5 yrs.
- The purpose is to support the development and demonstration of unique hub capabilities, research platforms and/or resources to address in a timely manner critical gap areas and/or roadblocks in CTS at awarded UM1 Hubs
- Support novel approaches in areas that address specific knowledge gaps, scientific opportunities, new technologies/platforms, data generation, or novel research methods that will advance CTS and research at CTSA hubs and beyond.
- Requires the participation, interaction, coordination, and integration of activities within a CTSA UM1 hub
- Examples: telehealth, regulatory science, clinical informatics, genetics and genomics, pragmatic trials, dissemination and implementation, rural health and health disparities, community outreach and engagement, and other areas of need for specialized programs.

RFA for Letters of intent will be sent out – EC will review and decide which 2 will move forward

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Training Grants: 4 Separate Grants/4 PIs

- **KL2**: mandated submission with UM1. Provides an intensive mentored research career development experience that leads to full research independence and leadership positions in clinical and translational science. Support is for 2-5 years of consecutive funding per scholar.
- **T32 Predoc**: The objective is to equip trainees with the knowledge, skills and abilities to advance diagnostics, therapeutics, clinical interventions, and behavioral modifications that improve health (8 slots)
- **T32 Postdoc**: The objective is to equip trainees with the knowledge, skills and abilities (KSAs) to advance diagnostics, therapeutics, clinical interventions, and behavioral modifications that improve health (4 slots)
- **R25**: Short term 10-15 weeks of research experience relevant to NCATS' mission, including undergrads, post docs, residents, or junior faculty ($100K/yr up to 5 yrs).