## Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:30</td>
<td>Welcome</td>
<td>Barry Coller, Christopher Austin</td>
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<tr>
<td>2:30 – 2:35</td>
<td>Introduction of New SC Member:</td>
<td>Rachel Hess</td>
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<td>• Rachel Hess (Utah)</td>
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<tr>
<td>2:35 – 2:40</td>
<td>NCATS Update</td>
<td>Christopher Austin</td>
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<td>2:40 – 2:45</td>
<td>DTF Workgroup Update</td>
<td>Kathleen Brady, Clare Schmitt</td>
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<td>2:45 – 2:55</td>
<td>Collaboration Engagement DTF –</td>
<td>Joel Tsevat</td>
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<td></td>
<td>Health Disparities Workgroup Proposal</td>
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<tr>
<td>2:55 – 3:15</td>
<td>CTSA Program Designation Workgroup Update</td>
<td>Barry Coller</td>
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<tr>
<td>3:15 – 3:40</td>
<td>Brainstorming: In-Person SC Meeting</td>
<td>Moderated by Barry Coller</td>
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<td></td>
<td>Agenda topics (March 4th, 10 – 5 ET in</td>
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<tr>
<td></td>
<td>Washington D.C.)</td>
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<tr>
<td>3:40 – 3:50</td>
<td>Pod Feedback</td>
<td>Hal Collard</td>
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<tr>
<td>3:50 – 4:00</td>
<td>Any other business</td>
<td>Moderated by Barry Coller</td>
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Welcome New CTSA Program Steering Committee Members!
2019 – 2021 Cohort

John Buse, M.D., Ph.D.
University of North Carolina, Chapel Hill
UL1 Member

Rachel Hess, M.D., M.S.
University of Utah
UL1 Member

Julianne Imperato - McGinley, M.D.
Weill Cornell
UL1 Member

Gerald Stacy
University of Chicago
Administrator Member

Patricia Winokur, M.D.
University of Iowa
UL1 Member
Welcome
NCATS Deputy Director
Dr. Joni Rutter
Rural Health Matters

Congress embedded language within our FY19 appropriations to encourage the CTSA Program to expand translational research efforts that address rural health disparities as well as the significant burden of conditions that disproportionately affect minority and special populations.

Recent CTSA Program Enhancements

- **January’s CTSA Program Webinar** highlighted the IDeA-CTRs and described some of the partnerships in place with CTSAs
- **University of Florida will host an Un-meeting focused on rural health and health equity on April 8, 2019**
- **NCATS Notice of Information** emphasizes the CTSA Program’s interest in improving rural health outcome and reducing health disparities. CTSA Program investigators and investigators supported by Institutional Development Award (IDeA) Program Infrastructure for Clinical and Translational Research (IDeA-CTR) awards are encouraged to work together to address translational science barriers.
DTF/WG Function & Structure 2.0:
Building on the DTF Successes
UPDATE

Kathleen Brady & Clare Schmitt
Structure 2.0 Outstanding Issues: Completed

✓ Enterprise Committee Leadership
  o Current DTF Governance
    ▪ DTF Chair: an individual from the DTF Lead Team
    ▪ DTF Co-Chair: an individual from the SC
  o Proposed EC Governance
    ▪ EC Chair: an individual from the EC Lead Team
    ▪ EC Co-Chair: none
      - Separation of SC & EC allows SC to focus efforts on SC activities, such as review of Work Group proposals and ongoing updates from Work Groups, and avoids any appearance of conflict

✓ Include references to other Consortium programs, e.g., CD2H, TIN, ACT, CLIC, in the Structure 2.0 slides – these may be tapped for consultation or support
Structure 2.0 Outstanding Issues

- Other issues before presentation to full consortium on Feb. 27
  - Program Webinar?
    - Implementation

- REMINDER: New WGs Proposed to end by Dec. 2019:
  - Proposals to SC must describe Specific Objective, Timeline w/ Milestones, Output/Deliverable, and the Broader context/goal, and should be submitted to the SC along with the charter. The SC will review proposals and approve/reject.
    - We need to flesh out the presentation/review process for 2020 and beyond…
Health Disparities WG

Co-Lead: Lloyd Michener (Duke University)
Co-Lead: Sergio Aguilar-Gaxiola (University of California, Davis)
Co-Lead: Katrina Kubicek (University of Southern California)
C/E DTF Lead Team Liaison: Laurene Tumiel-Berhalter (University of Buffalo)
Congressional Directive

Presented by NCATS (Dr. Austin & Dr. Kurilla)

- Appropriation report language:
  - **Senate: Clinical and Translational Science Awards [CTSA] Program.**—The Committee encourages the NCATS to fund, through the existing CTSA Program hubs, expanded efforts to improve translational research that address health disparities and the significant burden of conditions that disproportionately affect minority and special populations. Accelerating translational research by making it more efficient and effective will reduce the burden of disease and promote health equity. Applying the CTSA model to address longstanding regional health disparities can provide innovative, multidisciplinary approaches to reducing the burden of disease among vulnerable populations. The Committee supports the goals of the NCATS program and believes the principles that serve as the foundation of NCATS; public-private partnerships, community outreach, faster access to clinical trials, have tremendous potential for addressing the long-standing diseases associated with health disparities. The Committee encourages NCATS to fund institutions with a history of serving health disparity populations.
  - **House: Rural Health Outcomes and Health Disparities.**—The Committee notes translational science and education is critical to developing new treatments and healthcare approaches that can be disseminated to underserved and special populations to improve health outcomes across the life span. The Committee continues and encourages NCATS, through its CTSA program, to enhance its commitment to the value of translational science and funding for universities to continue to innovate by leveraging statewide resources and capabilities to improve rural health outcomes and eliminate health disparities. The Committee requests an update on the actions within the CTSA program to improve rural health outcomes and health disparities in the fiscal year 2020 Congressional Justification.
NCATS Clinical and Translational Science Awards (CTSA) Program’s Interest in Improving Rural Health Outcomes and Eliminating Health Disparities

• “accelerate clinical and translational research to address health disparities and the significant burden of conditions that disproportionally affect rural, minority, and other underserved populations.”

• The notice provides examples of project areas to meet these needs, including projects that address translational science barriers and projects designed to implement, assess and/or disseminate methods, approaches, education and training in clinical and translational science.
NEW PERSPECTIVES TO ADVANCE MINORITY HEALTH AND HEALTH DISPARITIES RESEARCH

OVERVIEW
Approaches, Vision Framework, pp. 556–524

METHODS AND MEASUREMENT
Measurements, Causality, Evaluation, Translation, pp. 525–542

ETIOLOGY
Racism, Life Course, Biology, Health Services, Social Determinants, pp. 543–571

INTERVENTIONS
Structural, Behavioral, Multilevel Adaptations, pp. 572–5104
Goals and Objectives

Goals

• Make recommendations to CTSA Consortium about opportunities for partnership and collaboration on assessing and reducing health disparities
  • Strengthen and leverage capabilities and assets of CTSAs nationwide
  • Contribute understanding of and solutions of health disparities translational research

Objectives

• Compile comprehensive list of current community and state partnerships on reducing health disparities
  • Association of State and Territorial Health Officers, CDC, HRSA Office of Rural Health, BUILD Health Collaborative
• Map this list to CTSA hubs to find opportunities to collaborate
• Facilitate these partnerships with tools and guidance
Key Deliverables

- Comprehensive assessment of CTSA and local/state/national groups regarding activities focused on understanding or addressing health disparities
- List/map opportunities or gaps in health disparities research
- Identify strategies to promote collaborations or partnerships across groups
- Generate report with recommendations based on findings
## Membership

<table>
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<tr>
<th>Role</th>
<th>Last Name</th>
<th>First Name</th>
<th>Institution</th>
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<tbody>
<tr>
<td>Co-Lead</td>
<td>Aguilar-Gaxiola</td>
<td>Sergio</td>
<td>University of California, Davis</td>
</tr>
<tr>
<td>Co-Lead</td>
<td>Kubicek</td>
<td>Katrina</td>
<td>University of Southern California</td>
</tr>
<tr>
<td>Co-Lead</td>
<td>Michener</td>
<td>Lloyd</td>
<td>Duke University</td>
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<tr>
<td>Support</td>
<td>AuYoung</td>
<td>Mona</td>
<td>Scripps Research Institute</td>
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<tr>
<td>Support</td>
<td>Thornton Matos</td>
<td>Anna</td>
<td>Case Western Reserve University</td>
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<tr>
<td>Support</td>
<td>Tumiel-Berhalter</td>
<td>Laurene</td>
<td>University at Buffalo</td>
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<tr>
<td>Member</td>
<td>Berkley-Patton</td>
<td>Jannette</td>
<td>University of Missouri - Kansas City</td>
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<tr>
<td>Member</td>
<td>Brown</td>
<td>Arleen</td>
<td>UCLA</td>
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<tr>
<td>Member</td>
<td>Carroll</td>
<td>Stephanie</td>
<td>University of Alabama Birmingham Medical Center</td>
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<tr>
<td>Member</td>
<td>Diaz Granados</td>
<td>Deborah</td>
<td>VCU Health</td>
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<tr>
<td>Member</td>
<td>Fouad</td>
<td>Mona</td>
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<tr>
<td>Member</td>
<td>Freedman</td>
<td>Darcy</td>
<td>Case Western Reserve University</td>
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<tr>
<td>Member</td>
<td>Holden</td>
<td>Kisha</td>
<td>Morehouse School of Medicine</td>
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<tr>
<td>Member</td>
<td>Holliday</td>
<td>Rhonda</td>
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<tr>
<td>Member</td>
<td>Islam</td>
<td>Nadia</td>
<td>NYU Langone</td>
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<td>Member</td>
<td>Johnson</td>
<td>Mark</td>
<td>Howard University</td>
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<tr>
<td>Member</td>
<td>Lomonaco</td>
<td>Carmela</td>
<td>University of California, San Francisco</td>
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<td>Member</td>
<td>McIntosh</td>
<td>Briana</td>
<td>Case Western Reserve University</td>
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<tr>
<td>Member</td>
<td>Nease</td>
<td>Don</td>
<td>University of Colorado Denver</td>
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<tr>
<td>Member</td>
<td>Pemu</td>
<td>Priscilla</td>
<td>Morehouse School of Medicine</td>
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<td>Rakale</td>
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<td>Member</td>
<td>Rivers</td>
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<tr>
<td>Member</td>
<td>Wadsworth</td>
<td>Martha</td>
<td>Penn State University</td>
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<tr>
<td>NCATS</td>
<td>Jones</td>
<td>Patricia</td>
<td>NCATS</td>
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CTSA Designation (aka Branding) Update
February 2019

CTSA Program “Designation” Working Group

**Leads:** Barry Coller, Clare Schmitt, Martin Zand

**Members:** Hal Collard, George Mashour

**Expected Sunset Date/Criteria:** Spring 2019

**Deliverable:** Designation Guidance
CTSA Designation (aka Branding) Update
February 2019:

1. Draft logo and Designation description
2. Draft ‘Tag Line’ for CTSA Program
3. Draft Description of the Meaning of Designation to be Used in Public Communications
4. Comparison to NCI Designation of Comprehensive Cancer Centers
5. Value Proposition of a CTSA Designation Program as Viewed from the Perspective of Different Stakeholders
6. Concerns raised at October PI meeting
7. Open discussion
Draft NCATS CTSA Designation
Logo and Description

NCATS Clinical and Translational Science Center

Designated by the National Center for Advancing Translational Sciences

NCI Comprehensive Cancer Center

A Cancer Center Designated by the National Cancer Institute
Description of the Meaning of Designation to be Used in Public Communications:
Institutions Achieving Designation as a Clinical and Translational Science Center by the National Center for Advancing Translational Science (NCATS) have demonstrated excellence in:

• Engaging patients and community members in setting research priorities as well as in the design, conduct, and interpretation of research studies.

• The ethical and scientifically rigorous conduct of Clinical Research, including human studies to evaluate new drugs and devices.

• Participation in a national network of research centers to accelerate the study of new drugs and devices.

• The training of physicians and other health care professionals to conduct a broad range of high-quality research studies designed to improve human health.
The model: NCI Designation

NCI-Designated Cancer Centers

The NCI Cancer Centers Program is one of the anchors of the nation’s cancer research effort. There are currently 70 NCI-Designated Cancer Centers, located in 36 states and the District of Columbia, that form the backbone of NCI’s programs for studying and controlling cancer. At any given time, hundreds of research studies are under way at the cancer centers, ranging from basic laboratory research to clinical assessments of new treatments. Many of these studies are collaborative and may involve several cancer centers, as well as other partners in industry and the community.

Most of the NCI-Designated Cancer Centers are affiliated with university medical centers, although several are freestanding centers that engage only in cancer research.

The NCI-Designated Cancer Centers are recognized for their scientific leadership, resources, and the depth and breadth of their research in basic, clinical, and/or population science. Comprehensive Cancer Centers demonstrate an added depth and breadth of research, as well as substantial interdisciplinary research that bridges these scientific areas. Basic Laboratory Cancer Centers conduct only laboratory research and do not provide patient treatment. There are 14 Cancer Centers, 49 Comprehensive Cancer Centers, and 7 Basic Laboratory Cancer Centers.
NCATS-Designated Clinical and Translational Science Centers

The NCATS-Designated Clinical and Translational Science Award (CTSA) Program is one of the anchors of the nation’s translational research effort. There are currently 57 NCATS-Designated Clinical and Translational Research Centers, located in 42 states, that form the backbone of NCATS programs for studying and treating a wide variety of diseases. At any given time, hundreds of research studies are under way at the CTSA centers, ranging from basic laboratory research to clinical assessments of new treatments. Many of these studies are collaborative and may involve several CTSA Centers, as well as other industry and community partners.

Find an NCATS-Designated Clinical and Translational Science Center

The NCATS Designated CTSA Centers deliver cutting-edge solutions to translational research problems, moving basic discoveries to clinical treatments in communities across the United States. Find a Center near you and learn about its patient services and research capabilities. Most of the NCATS CTSA Centers are affiliated with university medical centers, although several are freestanding centers that engage only in translational research.

The NCATS-Designated CTSA Centers are recognized for their scientific leadership, resources, and the depth and breadth of their research in basic, clinical, and/or population science. NCATS Designated CTSA Centers demonstrate an added depth and breadth of research, as well as substantial transdisciplinary research that bridges these scientific areas. As part of the Clinical and Translational Science Center Program, there are 57 NCATS-Designated Clinical and Translational Science Centers, 3 designated Research Innovation Centers, 1 Trial Innovation Center, 1 CTSA Coordinating Center, and 1 Clinical Data to Knowledge Coordinating Center.

The Importance of the NCATS-Designated Clinical and Translational Science Centers

The NCATS grant funding to the CTSA Centers supports shared research resources, provides developmental funds to advance scientific goals, and fosters translational research programs that draw investigators from different disciplines together. In addition, individual CTSA Center investigators and trainees are highly successful at obtaining research funding from NIH funding agencies and organizations. Indeed, research proposals from CTSA investigators have resulted in numerous clinical trials and translational research grants funded by NIH and other organizations, and numerous important research discoveries and clinical trials. Graduate students, clinical study coordinators, nurses and other professionals seeking specialized training in clinical and translational science also benefit from the centers.
## Cancer Centers & CTSA Centers

### Current NIH Requirements

<table>
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<tr>
<th>Requirement</th>
<th>Cancer Centers</th>
<th>CTSA Centers</th>
</tr>
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<tbody>
<tr>
<td>1. Clinical Focus</td>
<td>Cancer</td>
<td>Everything except cancer</td>
</tr>
<tr>
<td>2. Length of funding</td>
<td>5 years</td>
<td>5 years</td>
</tr>
<tr>
<td>3. Robustness of local patient support groups</td>
<td>Very robust</td>
<td>Highly variable</td>
</tr>
<tr>
<td>4. Demonstratable economic benefit to hospital/health system through increased clinical activity</td>
<td>Highly demonstratable</td>
<td>Questionably demonstratable</td>
</tr>
<tr>
<td>5. Stability of funding</td>
<td>Stable</td>
<td>Unstable/Metastable</td>
</tr>
<tr>
<td>6. Requirement for minimum number NCI/NIH funded grants (R01, R21, U01, etc.)</td>
<td>$10 million from NCI-related ICs</td>
<td>No requirement</td>
</tr>
<tr>
<td>7. Designated space required</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>8. Joint control of faculty recruitment</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>9. Report directly to Institutional Leadership</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>10. Required institutional support</td>
<td>Yes</td>
<td>Not explicit requirement</td>
</tr>
<tr>
<td>11. Local vs network commitments</td>
<td>Both</td>
<td>Both</td>
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Value Proposition of a CTSA Designation Program as Viewed from the Perspective of Different Stakeholders

A. Institutional Leaders
   1. Enhance enrollment in clinical trials
   2. Attract high quality faculty
   3. Attract new patients
   4. Market differentiator as academic centers compete with private systems claiming research

B. Local CTSA Leadership
   1. Enhance CTSA identity at the institution
   2. Attract additional resources to support programs from the institution and other sources
   3. Enhance recruitment into educational programs and identity of a translational research career
C. **Patient Advocacy Groups**
   1. Establish standard for identifying institutions of high quality in research, clinical trials, and patient care
   2. Provide access to experimental therapies

D. **Industry Partners**
   1. Establish standard infrastructure and policies/procedures for conduct of clinical trials at individual sites and in a network
   2. Establish standard for basic and early phase translational research collaborations
Value Proposition of a CTSA Designation Program as Viewed from the Perspective of Different Stakeholders

E. Medical Students, Trainees, and Other Health Care Professionals
   1. Enhance the prestige and attractiveness of careers in translational research
   2. Benchmark for professional training

F. NCATS
   1. Enhance identity within NIH Institutes and Centers
   2. Enhance identity in press
   3. Enhance identity among elected officials
   4. Enhance identity among governmental officials
Value Proposition of a CTSA Designation Program as Viewed from the Perspective of Different Stakeholders

G. CTSA PI

1. Define a stable, sustainable, and productive vision for the CTSA program
2. Enhance identity of CTSA in institution and ability to aggregate resources
Concerns Raised at October CTSA PI Meeting

1. Cancer Centers are very different from CTSAs in a number of important ways that will make it harder to establish an NCATS CTSA Designation identity: funding levels, uni-disease focus, natural advocacy group and philanthropic identity, identity of Cancer Center name in both grant and institutional branding.

2. Potential adverse effects from use of Designation on relationships with partner/collaborating institutions that compete for patients/students/faculty
Discussion

1. Concerns

2. Suggestions

3. Are there other stakeholders?

4. Are the Value Propositions complete?

5. Does the SC recommend pursuing this initiative, and if so, what should be the Working Group’s next steps?