National Center for Advancing Translational Science (NCATS) Clinical and Translational Science Award (CTSA) Program Steering Committee Roles and Responsibilities As of Fall 2018

The purpose of the Steering Committee (SC) is to enable bidirectional information and idea sharing between the CTSA Program Principal Investigators (PIs) and Administrators, and NCATS leadership regarding activities of the CTSA Program to advance clinical and translational science.

Membership and Eligibility Criteria

The UL1, TL1, and KL2 PIs and Administrators are appointed by NCATS to serve up to 3 years. Terms typically begin January 1 of Year 1 and end on December 31 of Year 3.

The SC Co-Chairs lead the SC and organize meeting agendas. The SC Co-Chairs are the NCATS Director and 1 UL1 PI. The UL1 PI Co-Chair is selected with input from NCATS leadership. A UL1 SC member is eligible for appointment as a Co-Chair after serving 1 year on the SC. Therefore, the selected UL1 SC Co-Chair serves a 2-year term in this capacity.

The CTSA Program SC is comprised of 20 members: 12 UL1 PIs, 1 KL2 PI, 1 TL1 PI, 1 Administrator, 1 PI of the CTSA Program Coordinating Center, 1 PI of the Trial Innovation Network (TIN), 1 PI of the CTSA Program Clinical Data to Health Coordinating Center (CD2H), the NCATS Division of Clinical Innovation (DCI) Director and the NCATS Director. Representation of the following groups are listed in the chart below.

SC Member	Representation Group	Organized By
12 UL1 Pls	Pod group comprised of UL1 PIs	SC Pod leader
1 KL2 PI	KL2 PI/Directors Group	CLIC
1 TL1 PI	TL PI/Directors Group	CLIC
1 Administrator	Administrators Group	CLIC
1 TIN PI	Trial Innovation Centers (TICs)	TIN
	Recruitment Innovation Center (RIC)	
1 CD2H PI	Clinical Data to Health	CD2H
1 CLIC PI	Center for Leading Innovation and Collaboration	CLIC
NCATS DCI	NCATS	N/A
Director		
NCATS Director	<u>NCATS</u>	N/A

The eligibility criteria for SC appointments for PIs (UL1, KL2 and TL1) and an Administrator are as follows:

- A PI must be officially named in the Notice of Grant Award of an active CTSA Program hub
- An Administrator is the key point of contact between their institution's CTSA Program leadership and Program Directors, and NCATS personnel
- An "active" award is defined as a hub award that is not in a <u>No-Cost Extension</u> (NCE). A PI or Administrator whose hub award in an NCE is not considered eligible as there is insufficient time remaining in the award project period for initiation of an appointment.
- For both PIs and Administrator, their hub award must have at least 3 years remaining during the project period
- An eligible PI has not served on the SC since December 2014

The PIs of the Trial Innovation Network (TIN), CTSA Program Coordinating Center and the CTSA Program Clinical Data to Health Coordinating Center serve the term of their grant project period with the option to rotate an annual appointment to another named PI of their grant. For example, in instances where there are multiple or co-PIs, Dr. X can serve from 2015-2017 and transfer the SC role to Dr. Y in 2018. A PI of these three grants can self-appoint but must notify the SC coordinator of any changes.

Nomination Process

New membership nominations are solicited annually from NCATS in an open call to the CTSA Program consortium. The solicitation will be advertised in the October or November CTSA Program newsletter disseminated by the CTSA Program Coordinating Center. Eligible Administrator candidates must be nominated by their hub's PI. Coordinating Center PIs are selected by their Co-PIs and/or their respective Coordinating Centers' leadership.

When determining SC appointments, NCATS aims for a diverse representation of members, taking into consideration geography, hub size, and the nominee's professional expertise and background.

New SC members will receive a formal invitation from the NCATS Director and will be announced to the consortium in the first month of the calendar year.

NCATS Staff Attendees of SC Meetings

The following NCATS staff members support the SC Co-Chairs in preparation for upcoming meetings. These attendees may attend SC calls and provide their area of expertise during the discussion.

- Division of Clinical Innovation (DCI) Deputy Director
- DCI Director for TIN
- DCI Director for Program Hubs
- DCI Deputy Director for Program Hubs
- DCI Director of Informatics

Ad-Hoc Attendees of SC Meetings

The following "ad-hoc" members usually attend SC meetings and provide their area of expertise during the discussion:

- Director for the NCATS Office Communications, Policy, and Education
- Director for the NCATS Office of Grants Management and Scientific Review
- Director of NCATS Office of Scientific Review

Administrative Support

The Executive Secretary is an NCATS employee that supports the NCATS Director. A CTSA Program Coordinating Center coordinator provides logistics and administrative support for all SC meetings.

Meetings

The CTSA Program SC meets at least monthly via webinar, twice per year in person, and communicates as needed via email. These meetings are attended by the SC members, NCATS Staff and Ad-Hoc attendees. Meeting summaries are prepared by CLIC and the Executive Secretary, disseminated to the SC members, and posted onto relevant consortium websites (e.g. <u>the NCATS</u> <u>CTSA Program</u> and the <u>CTSA Program Coordinating Center</u>).

Role and Responsibilities

Conducting Pod Calls and Reporting Pod Feedback

In addition to reflecting their own experience and perspective on the SC, each SC PI member represents approximately 5 other CTSA Program hubs; together each SC member and approximately 5 hub PIs designate a "Pod". UL1 Pod members are strongly encouraged to include their hub's KL2 PI, their Administrator and if applicable, their TL1 PI on Pod interactions. Pod calls have two primary objectives:

- 1. SC Pod leaders relay information and updates from previous SC calls
- 2. SC Pod leaders gather ideas, concerns, and/or other feedback from their pod to be reported to the SC on its next call

Pods connect every 1-2 months via teleconference to gather perspectives and allow for small group discussions. Agenda topics are determined by the Pod group. There may be instances where NCATS or the SC may solicit feedback from the Pod group on a specific topic. In these cases, Pod leaders are required to meet and discuss the solicited topic and prepare and submit an aggregate report back to NCATS.

Each Pod leader prepares meeting notes for each of their monthly or bimonthly calls and sends them to NCATS via the <u>CLIC Suggestion Box</u> within 3 days of hosting the call. If a Pod does not meet that month, SC members are expected to note this in their monthly submissions. These meeting notes inform the SC Co-Chairs and NCATS on specific challenges/barriers experienced locally by the hubs as well as innovative methods and approaches that address and/or solve translational science problems. When feedback is aggregated at a national consortium level, NCATS is better equipped to identify emerging

topics that could be prioritized and addressed by NCATS. Further, these notes help NCATS formulate productive and engaging agenda topics for upcoming SC meetings.

Communication among the KL2 and TL1 PI/Director Group

The KL2 and TL1 SC member have regular webinar meetings with their respective PIs groups. CLIC supports the Kl2 and TL1 group with 1 in-person meeting a year. During these meetings the groups will have the opportunity to disseminate and share information. The KL2 and TL1 SC member should submit their meeting notes and feedback using the <u>CLIC Suggestion Box</u>.

Communication among the Administrators Group

The Administrator SC member have regular webinar meetings with their respective group. CLIC supports the Administrators group with 1 in-person meeting a year. During these meetings the groups will have the opportunity to disseminate and share information. The Administrator SC member should submit their meeting notes and feedback using the <u>CLIC Suggestion Box</u>.

Oversight of Domain Task Force (DTF) Activities*

NCATS appoints 1 distinct SC member for each of the DTF leadership teams as a SC Co-Chair. The SC ensures alignment of DTF activities with the those of the SC, and the mission and goals of the CTSA Program. The full SC promotes synergies among the DTFs; provides input on proposed DTF working groups (WGs) including avoidance of redundancy among DTFs/WGs; provides advice on relevant experts for WGs (including from other DTFs); and provides final approval of new WGs. The SC also reviews and approves DTF surveys, as appropriate (see Appendix D).

*This responsibility is subject to change pending the decision(s) made by the Steering Committee taskforce on the DTFs.

Survey Review and Approval

The Steering Committee reviews and approves survey requests submitted by members of the consortium. For further information, including detailed processes and procedures, please visit https://clic-ctsa.org/surveys. See Appendix D for an annotated survey review and approval chart.

See Appendix A for a current list of members of the CTSA Program Steering Committee. See Appendix B for a current list of CTSA Program Pods. See Appendix C for past Steering Committee members. See Appendix D for an annotated Survey Review and Approval Chart.

For more information see: https://clic-ctsa.org/groups/steering-committee

Appendix A – Membership of the CTSA Program Steering Committee (2018)

Member	Name	Affiliation	
Co-Chair	Kathleen Brady	Medical University Of South Carolina	
Co-Chair	Christopher Austin	NCATS Director	
UL1 Member	Ebony Boulware	Duke University	
UL1 Member	David Center	Boston University Medical Campus	
UL1 Member	Dan Cooper	University of California-Irvine	
UL1 Member	Donald Lloyd-Jones	Northwestern University at Chicago	
UL1 Member	George Mashour	University of Michigan	
UL1 Member	Reza Shaker	Medical College of Wisconsin	
UL1 Member	Harold Collard	University of California, San Francisco	
UL1 Member	Tim Murphy	State University Of New York At Buffalo	
UL1 Member	Phil Kern	University of Kentucky	
UL1 Member	Barry Coller	Rockefeller University	
UL1 Member	Bradley Evanoff	Washington University	
TL1 Member	Susan Smyth	University of Kentucky	
KL2 Member	Joel Tsevat	University of Texas Health Science Center at San Antonio	
Trial Innovation Network Member	Dan Ford	Johns Hopkins University	
Center for Data to Health (CD2H) Member	Melissa Haendel	Oregon Health and Science University	
CTSA Program Coordinating Center Member	Martin Zand	University of Rochester	
NCATS	Michael Kurilla	NCATS Division of Clinical Innovation Director	
Emeritus	Alan Green	Dartmouth College	

Appendix B – CTSA Program Pods (2018)

UNIVERSITY OF MICHIGAN SC Pod Leader: George Mashour Email: gmashour@med.umich.edu

UNIVERSITY OF MIAMI SCHOOL OF MEDICINE

EMORY UNIVERSITY

VIRGINIA COMMONWEALTH UNIVERSITY

UNIVERSITY OF IOWA

ROCKEFELLER UNIVERSITY SC Pod Leader: Barry Coller Email: collerb@mail.rockefeller.edu DARTMOUTH COLLEGE INDIANA UNIV-PURDUE UNIV AT INDIANAPOLIS UNIVERSITY OF MINNESOTA

UNIVERSITY OF WISCONSIN-MADISON

MAYO CLINIC

NORTHWESTERN UNIVERSITY	
SC Pod Leader: Donald Lloyd-Jones	
Email: dlj@northwestern.edu	
UNIVERSITY OF NORTH CAROLINA	

UNIVERSITY OF ILLINOIS

VANDERBILT UNIVERSITY

WAKE FOREST UNIVERSITY

MEDICAL COLLEGE OF WISCONSIN SC Pod Leader: Reza Shaker Email: rshaker@mcw.edu
HARVARD UNIVERSITY
OHIO STATE UNIVERSITY
UNIVERSITY OF PENNSYLVANIA
YALE UNIVERSITY
CASE WESTERN UNIVERSITY
UNIVERSITY OF ALABAMA

UNVERSITY OF CALIFORNIA - SAN FRANCISCO
SC Pod Leader: Harold Collard
Email: harold.collard@ucsf.edu
UNIVERSITY OF NEW MEXICO
UNIVERSITY OF UTAH
UNIVERSITY OF COLORADO
UNIVERSITY OF CALIFORNIA - DAVIS

UNIVERSITY OF BUFFALO		
SC Pod Leader: Tim Murphy		
Email: murphyt@buffalo.edu		
STANFORD UNIVERSITY		

JOHNS HOPKINS UNVIERSITY

UNIVERSITY OF WASHINGTON

UNIVERSITY OF ARKANSAS

WEILL MEDICAL COLL OF CORNELL UNIV

UNIVERSITY OF CHICAGO

DUKE UNIVERSITY SC Pod Leader: Ebony Boulware

Email: ebony.boulware@duke.edu

NEW YORK UNIVERSITY SCHOOL OF MEDICINE

UNIV OF MASSACHUSETTS MED SCH WORCESTER

UNIVERSITY OF KANSAS

GEORGETOWN - HOWARD UNIVERSITY

UNIVERSITY OF KENTUCKY
SC Pod Leader: Phil Kern
Email: philipkern@UKY.EDU
UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON
UNIVERSITY OF TEXAS HELH SCI CTR HOUSTON
UNIVERSITY OF CINCINNATI
UT SOUTHWESTERN MEDICAL CENTER
UNIVERSITY OF TEXAS MEDICAL BR GALVESTON
UNIVERSITY OF FLORIDA
UNIVERSITY OF TEXAS - HEALTH SCIENCE CENTER
UNIVERSITY OF CALIFORNIA, IRVINE
SC Pod Leader: Dan Cooper

UNIVERSITY OF CALIFORNIA, INVINE
SC Pod Leader: Dan Cooper
Email: dcooper@uci.edu
UNIVERSITY OF CALIFORNIA LOS ANGELES
UNIVERSITY OF CALIFORNIA SAN DIEGO
SCRIPPS RESEARCH INSTITUTE
OREGON HEALTH & SCIENCE UNIVERSITY

BOSTON UNIVERSITY		
SC Pod Leader: David Center		
Email: dcenter@bu.edu		
TUFTS UNIVERSITY		
UNIVERSITY OF PITTSBURGH		
CHILDRENS NATIONAL INSTITUTE		
MOUNT SINANI SCHOOL OF MEDICINE		
PENNSYLVANIA STATE UNIVERSITY		

WASHINGTON UNIVERSITY AT ST. LOUIS SC Pod Leader: Bradley Evanoff

Email: bevanoff@wustl.edu

UNIVERSITY OF SOUTHERN CALIFORNIA

EINSTEIN-MONTEFIORE

COLUMBIA UNIVERSITY

UNIVERSITY OF ROCHESTER

Appendix C – Past Steering Committee Members

The CTSA Program Steering Committee was restructured in 2014. The initial 2014 cohort comprised of PIs who served 1-year and 2-year terms. This was done to allow rapid turnover so that many of the PIs had the opportunity to serve on the Steering Committee over the course of time. In 2015, the Steering Committee changed the 2-year terms to 3-years terms. Half of the 2015 cohort extended their term an additional year (to serve a full 3 years) to allow continuity of the work conducted thus far. From 2016 on, all SC appointments serve 3-year terms.

2014 Cohort

Term Length	Last Name	First Name	CTSA Program Hub
1 year	Blazar	Bruce	University of Minnesota
1 year	Clore	John	Virginia Commonwealth University
1 year	Disis*	Nora	University of Washington
1 year	Kieburtz	Karl	University of Rochester
1 year	Luzuriaga	Katherine	University of Massachusetts
1 year	Toto	Robert	University of Texas Southwestern
2 year	Barohn	Richard	University of Kansas
2 year	Nadler	Lee	Harvard University
2 year	Reis	Steve	University of Pittsburgh
2 year	Selker	Harry	Tufts University
2 year	Shanley	Thomas	University of Michigan
2 year	Green**	Alan	Dartmouth College

Terms: 2014 (1 year) and 2014 – 2015 (2 year)

*SC Co-Chair (2014)

**SC Co-Chair (2015 – 2016). This term was extended to 3 years when terms were modified.

2015 Cohort

Terms: 2015 – 2016 (2 year) and 2015 – 2017 (3 year)

Term Length	Last Name	First Name	CTSA Program Hub
2 year	Byington	Carrie	University of Utah
2 year	Jackson	Rebecca	Ohio State University
2 year	Solway	Julian	University of Chicago
3 year	Clark	Robert	University of Texas Health Science Center at San Antonio
3 year	Khosla	Sundeep	Mayo Clinic
3 year	Shamoon	Harry	Einstein-Montefiore

2016 Cohort

Last Name	First Name	CTSA Program Hub		
Boulware	Ebony	Duke University		
Brady*	Kathleen	Medical University of South Carolina		
Center	David	Boston University		
Cooper	Dan	University of California Irvine		
Li**	King	Wake Forest University		

Term: 2016 – 2018 (3 year)

*SC Co-Chair

**Left CTSA Program. Slot not replaced due to timing.

2017 Cohort

Term: 2017 – 2019 (3 year)

Last Name	First Name	CTSA Program Hub	
Grandis^	Jennifer	University of California San Francisco	
Collard	Harold		
Lloyd-Jones	Donald	Northwestern University	
Mashour	George	University of Michigan	
Murphy	Tim	University of Buffalo	
Shaker	Reza	Medical College of Wisconsin	
Smyth (T)	Susan	University of Kentucky	
Tsevat (K)	Joel	University of Texas Health Science Center at San Antonio	

[^]Left Program. Dr. Collard filled Dr. Grandis' slot after her departure in the summer of 2018. Collard will serve the remaining term.

2018 Cohort

Term: 2018 – 2020 (3 year)

Last Name	First Name	CTSA Program Hub		
Coller	Barry	Rockefeller University		
Evanoff	Bradley	Washington University of St. Louis		
Kern	Phil	University of Kentucky		

Coordinating Center PIs (Length of award)

Last Name	First Name	Coordinating Center CTSA Program Hub
Ford	Dan	Trial Innovation Network (TIN) Johns Hopkins University
Handel	Melissa	Clinical Data to Health (CD2H) Oregon Health and Science University
Zand	Martin	Center for Leading Innovation and Collaboration (CLIC) University of Rochester

Appendix D – Annotated Survey Review and Approval Chart

Survey Review and Approval

Survey Type	e Target	Reviewed by	Approved by	Distribution	
A. DTF Survey	DTF (Including those developed by work groups)	Lead Team of the DTF	DTF NCATS Program Officer	CTSA Program Coordinating Center (will support up to 3	
	Other DTFs	Lead Team of the Other DTFs	DTF NCATS Program Officer	surveys, per DTF, per year)	
	CTSA Program PIs	CTSA Program Steering Committee	Leadership of the Division of Clinical Innovation, NCATS		
B. CTSA Program Consortium Grantee (not Hub) Survey	CTSA Program (Described in Grant Application)	CTSA Program Steering Committee	N/A	CTSA Program Coordinating Center	
	CTSA Program (Not Described in Grant Application)	CTSA Program Steering Committee	Leadership of the Division of Clinical Innovation, NCATS	CTSA Program Coordinating Center	
C. CTSA Program Hub or Partner Survey	CTSA Program Hubs	CTSA Program Steering Committee	Leadership of the Division of Clinical Innovation, NCATS	CTSA Program Coordinating Center	
D. Other Internal Survey	CTSA Program groups (e.g., Administrators, Coordinators, Communicators, Evaluators, etc.)	Self-reviewed	Self-approved	The group specific to the survey	
E. NCATS DCI Survey	Consortium-wide	CTSA Program Steering Committee	Leadership of the Division of Clinical Innovation, NCATS	CTSA Program Coordinating Center	
F. CMI Survey	CTSA Program hubs		NCATS Metric representative and NCATS CMI Lead	CTSA Program Coordinating Center's CMI Team	
G. Evaluations for Meetings and Events	Participants at CTSA- related Meetings or Events		CTSA Program Coordinating Centers Survey Research Team or Executive Committee	CTSA Program Coordinating Center or other group sponsoring the meeting or event	
H. External Survey	Any CTSA Program related group or activities	CTSA Program Coordinating Center; NCATS Project Scientist; CTSA Program Steering Committee	Leadership of the Division of Clinical Innovation, NCATS	CTSA Program Coordinating Center	

Full Guidance: https://clic-ctsa.org/sites/default/files/NCATS%20CTSA%20Program%20Guidance%20for%20Surveys_Final.pdf