

# CTSA Clinical & Translational Science Awards Program

CTSA Program Steering Committee meeting  
August 13, 2018, 2:30-4:00pm  
Zoom Conferencing

<b>SC Attendees:</b>	Kathleen Brady David Center Barry Coller Dan Cooper	Bradley Evanoff Alan Green Melissa Haendel	Phil Kern Donald Lloyd-Jones Tim Murphy Reza Shaker	Susan Smyth Joel Tsevat Martin Zand
<b>NCATS Attendees:</b>	Michael Kurilla Carol Lambert	Mary Purucker Erica Rosemond	Steve Seidel Rebecca Katz	Clare Schmitt
<b>Presenters:</b>	Deborah Ossip Erica Rosemond	Clare Schmitt Kathleen Brady	Melissa Haendel	Michael Kurilla

Session	Summary Discussion	Action Item
NCATS Director's Update ( <b>M. Kurilla</b> for C. Austin)	<p>M. Kurilla – Regarding membership, announced that Dr. Jennifer Grandis has stepped down due to restrictions of effort, and Dr. Harold Collard will be stepping in as a member of the SC and PI for the UCSF CTSA Program hub</p> <p>M. Kurilla - gave an update on two items affecting the <u>FY 2019 Budget</u>:</p> <ul style="list-style-type: none"> <li>• <b>House</b> Appropriations Subcommittee on Labor/HHS/Educ. June 14 Passed bill – slight increase in the NIH budget w/NCATS receiving a slight increase compared to prior year. July 11 – Full Appropriations committee approved bill</li> <li>• <b>Senate</b> Appropriations Subcommittee on Labor/HHS/Education June 26 Passed bill – slightly larger budget increase for NIH, and an increase for NCATS specifically and an increase to the CTSA budget. June 28 – Full Appropriations Committee approved all 12 FY19 appropriations bills.</li> </ul> <p>M. Kurilla reminded us of the four funding opportunities available for the Regenerative Medicine Innovation Project, including investigator-initiated research, investigator-initiated clinical trials, an STTR and an SBIR. All with an application deadline of October 19, 2018.</p>	CLIC to Update membership list.
In-Person Program Meeting Update ( <b>C. Schmitt</b> )	<p>C. Schmitt discussed the plan for the upcoming CTSA Program Meetings:</p> <ul style="list-style-type: none"> <li>• Fall Program Meetings will focus on priority research issues and opportunities for the consortium members to come together to share best practices.</li> <li>• Spring Program Meetings will focus on education and training for the translational science workforce.</li> </ul> <p>C. Schmitt discussed the plan for the Fall CTSA Program Meeting:</p> <ul style="list-style-type: none"> <li>• Being held at the Hilton Crystal City at Washington Reagan National Airport. The planning efforts are being coordinated by the Steering Committee with NCATS staff.</li> <li>• With the feedback from the Spring 2018 meeting, participants asked for more networking time, less report outs and more emphasis and discussion of best practices.</li> </ul> <p><u>October 22 - Day 1</u> – will include a Steering Committee and Administrators Meeting that happens concurrently.</p> <p><u>October 23 - Day 2</u> – will be devoted to the Annual CTSA Program Mtg.</p>	

	<ul style="list-style-type: none"> <li>○ <i>Morning session</i> - to include updates from NCATS, report from SC DTF Task Force, the Great CTSA Team Science Contest – winners announced and a presentation from SMARTIRB/ACT.</li> <li>○ <i>Afternoon session</i> – open solicitation from consortium of topics for best practices.</li> <li>○ <i>Networking opportunities</i> – 30 min. breaks – AM &amp; PM and longer lunch.</li> <li>○ More information at: <a href="https://cltc-ctsa.org/events/2018-ctsa-program-fall-meeting">https://cltc-ctsa.org/events/2018-ctsa-program-fall-meeting</a></li> </ul> <p><u>Timeline:</u></p> <ul style="list-style-type: none"> <li>○ 8/8/18 – Deadline for solicitation of topics via CLIC Suggestion box.</li> <li>○ 8/13/18 – SC reviewed suggestions</li> <li>○ 9/10/18 – Finalize agenda and disseminate</li> <li>○ 10/23/18 - Fall CTSA Program meeting takes place</li> </ul>	
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<p>In-Person Program Meeting Update (C. Schmitt)</p>	<p>C. Schmitt encouraged the SC members to consider the suggested topics below for discussion at either the Fall Program 2018, Spring Program 2019 or PI Webinars. Reasonably expect 4-5 topics to be discussed, and having some unstructured time to collaborate.</p> <table border="1" data-bbox="334 695 1247 1923"> <thead> <tr> <th data-bbox="334 695 1073 751">Suggestions Submitted for: CTSA Program Meeting's Afternoon Session on Day 2, October 23, 2018</th> <th data-bbox="1073 695 1247 751">Submitter (Presenter)</th> </tr> </thead> <tbody> <tr> <td data-bbox="334 751 1073 898">           Report out of best practices from FY17 sIRB administrative supplements:           <ul style="list-style-type: none"> <li>• September 12 NIH Workshop entitled "sIRB Review for Multi-Site Research Resource and Infrastructure Development"? 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	<p><u>Suggestion from CD2H – opportunity to share more information:</u> <i>by M. Haendel (on behalf of CD2H).</i> Brainstorm about CD2H priorities, engagement and community challenges; format could be small breakouts at tables. [General enthusiasm expressed by SC members]</p> <p><u>Suggestion that leaders from the Division of Preclinical Innovation (DPI) at NCATS could discuss opportunities for better collaborative efforts between DPI and the CTSA:</u> <i>by B. Collier on behalf of his Pod.</i> [General enthusiasm expressed by SC members]</p> <p><u>Suggestion about how CTSA could better collaborate with the NIGMS Institutional Development Award (IDeA) Program:</u> <i>by B. Collier on behalf of his Pod.</i> M. Kurilla is meeting with the new IDeA leadership this month and an October presentation may be too soon; however, will invite new IDeA leadership to meeting. [General enthusiasm expressed by SC members and specifically B. Collier, B. Evanoff, D. Cooper, and M. Kurilla]</p> <p><u>Overview of Child Health research Acceleration through Multisite Planning (CHAMP):</u> <i>by D. Cooper (on behalf of his Pod).</i> Would like to present 10 min overview and receive feedback from participants of the Program Meeting on CHAMP and suggestions towards the program’s sustainability. [General enthusiasm expressed by SC members.]</p> <p><u>Concept of an NCATS CTSA Program designation for hubs, similar to the NCI Cancer Center Program:</u> <i>by D. Cooper (on behalf of his Pod).</i> Good opportunity for open discussion at the Annual meeting. [General enthusiasm was expressed by SC members and specifically M. Zand, A. Green, K. Brady.]</p> <p><u>Administrative Supplements for Single IRB:</u> <i>by K. Brady.</i> NIH workshop on 9/12, interesting to distill thoughts and perspectives, is problematic for the investigators across the country; is NIH policy going forward; will be integrating into future clinical trials; clearly coming down the pipeline; begin discussions on how to solve the various obstacles; strategies taken to ensure legal/ethical compliance in sharing across institutions. [General enthusiasm expressed by SC members and specifically M. Zand, T. Murphy, and M. Haendel].</p> <p><u>VA-CTSA interest Group:</u> <i>by J. Tsevat.</i> Opportunity to add to the sIRB discussion and revive this topic with the VA that has been previously discussed with them. [General enthusiasm expressed by SC members].</p> <p><u>Integrating clinical care with clinical research:</u> <i>by T. Murphy on behalf of his Pod.</i> How to change the prevailing attitude about participation in health research to universal participation, so that enrollment in clinical care and health research are intertwined. Suggest that in addition, discussion could include the implementation of learning health system approaches. Suggest to have 3 or 4 systems that have taken different approaches to this topic to present. [General enthusiasm from SC members, specifically D. Cooper, K. Brady].</p>	
<p>Preliminary DTF Survey Aggregate Report (D. Ossip)</p>	<p>D. Ossip presented an overview of the DTF Survey. The data collection period was July 2 – July 16, 2018. Goals were to obtain feedback from PIs, Administrators, DTF Members, Working Group Members.</p> <ul style="list-style-type: none"> <li>• Survey sent to 1,250 valid email addresses/received 275 responses (22% response rate)</li> <li>• <u>Are you well informed about activities?</u> 51.5% somewhat; 37.1% no, 11.4% yes</li> <li>▪ <u>Are DTFs addressing issues important to CTSI and CTSA Consortium?</u> 54.1% somewhat; 42.5% yes; 3.4% no</li> <li>▪ <u>How valuable are DTFs?</u> Most responses fell in the moderate to high - DTFs are valuable.</li> </ul>	<p>CLIC to Send full survey results to Steering Committee.</p> <p>CLIC to Schedule SC Workgroup meeting</p>

	<ul style="list-style-type: none"> <li>• <u>Is the current structure the right structure?</u> 50.2% yes; 49.8% no</li> <li>• <u>What works well?</u> Group communicates in a robust manner. DTF calls are open and welcoming. DTF is connecting those individuals with similar interests. DTFs are setting their own agenda and following NCATS guidance. Leadership is clear and structure makes sense. Membership is enthusiastic. Assigning smaller groups to work on projects works well.</li> <li>• <u>What can be improved?</u> More clarity in the goals. More feedback loops between and across the DTFs. Getting better, but still more communication between NCATS and DTFs. Need funding for projects that are of interest to broader audience. Conference calls w/40+ people difficult, more video calls, DTF calls could focus more on interactive educational activities.</li> <li>• <u>What areas not addressed would you suggest for NCATS?</u> Right domains but little evidence of accomplishment that relates to the CTSA's. Need to cover mentoring, team science, and dissemination and implementation science. DTFs to further facilitate collaboration among the 5 domains. Suggested new DTFs included Evaluation, Administration and Team Science.</li> <li>• <u>Suggested name change</u> 49 said yes and submitted alternative ideas, and 27 said no that the name change seems less significant. The suggested names either reflected the function of the taskforce, an interest group names, or strategic initiatives. Use a name change if it helps to clarify the vision. <ul style="list-style-type: none"> <li>○ <i>The Steering Committee Workgroup will address the data and then meet fairly quickly to formulate a plan to integrate it into recommendations for the Steering Committee.</i></li> </ul> </li> </ul>	CLIC to Post Survey results on CLIC website in the future
Request to Add Administrator to Steering Committee (E. Rosemond)	<p><b><u>Request to add a single Administrator to the Steering Committee.</u></b> General discussion was enthusiastic and that the SC should take advantage of having an administrator member as this group could rapidly and effectively disseminate discussions from the SC Meeting to other Administrators (and effectively the hubs) now that their communications are being supported by CLIC. [General enthusiasm by SC members and specifically D. Lloyd-Jones, K. Brady, M. Haendel, D. Cooper, M. Zand].</p>	E. Rosemond will discuss with the Lead Team of the Administrators to appoint a member to Steering Committee.
Buprenorphine Waiver Training Review of Article (K. Brady and M. Kurilla)	<p>As prompted by last month's NEJ Primary Care and the Opioid-Overdose Crisis. Concern is lack of supervision for Primary Care Physicians in managing difficult patients. <u>Should there be an effort to have waiver training?</u> Already Underway – NIH HEAL Initiative and there are well thought-out programs around implementation/dissemination for the CTSA's – in a practice based &amp; rural setting.</p> <ul style="list-style-type: none"> <li>• <i>Idea</i> - CTSA's could take on task of promoting or partnering to increase utilization of the waivers.</li> <li>• <i>Goal</i> - How to integrate this into practice? Supervision/mentorship around difficult patients, office support for billing, making it a profitable endeavor.</li> <li>• <i>Rationale</i> - SAMSA agency has supported an organization to develop and provide this training. No barriers. 8hr Training is free, just sign-on, coalition of 20 organizations. Brown is waiver training their graduates. System already in place and designed to encourage Primary Care doctors, nurse practitioners and others to be waived. Training materials and Mentoring network is there. This would be a good dissemination/implementation project to do late phase translational research.</li> <li>• <i>Resources</i> - Group at BU have done a tremendous job in disseminating. Suggest to conduct a webinar with different models.</li> </ul>	Set up PI Webinar regarding Buprenorphine Waiver Training

	<ul style="list-style-type: none"> <li>Suggestion posed that this would be a good PI Webinar Topic. [General enthusiasm by the SC and superficially by B. Evanoff, A. Green, K. Brady, D. Center].</li> </ul>	
<p>Pod Feedback Round Robin (M. Kurilla)</p>	<p>M. Kurilla reviewed POD Feedback:</p> <p><b>Enhanced interactions between the NCATS Division of Preclinical Innovation (DPI) and the Division of Clinical Innovation (DCI):</b> NCATS DCI has initiated discussions with colleagues in DPI that includes the types of collaborations that DPI has ongoing at the moment and how to partner with CTSA. Consider for Fall CTSA Program meeting.</p> <p><b>Enhanced interactions between the CTSA Program and the IDeA Program:</b> This specific topic is currently being addressed internally at NCATS. Will have more information after meeting with IDeA leadership.</p> <p><b>Cancer-Center-like NCATS “designation”:</b> Input from the CTSA Program in terms of features that uniquely define a CTSA Program brand will require some brainstorming and iteration of ideas. Consider for Fall CTSA Program meeting.</p> <p><b>Domain Task Force Comments:</b> Looking forward to survey results.</p> <p><b>An NCATS R01 Program:</b> NCATS currently supports the CTSA Collaborative Innovation Awards (CCIA) program, which utilizes the U01 mechanism and the R21 mechanism. Other than the additional involvement of NIH staff that comes with a cooperative agreement (U), there is no meaningful distinction between this and an R01 program.</p> <p><b>Streamlining Renewal Applications:</b> NCATS is developing a comprehensive multi-stakeholder plan to receive feedback about the existing funding opportunity announcement and the Program as a whole will report back to the SC at a later time. Additional discussion focused on the differences between the NCI Cancer Center review process and the CTSA Program review process. In general, NCATS is not in position to perform in-person site reviews similar to the NCI Cancer Centers.</p> <p><b>Trial Innovation Network.</b> What is NCATS doing to get other I/C’s to use the TIN? Are there examples of specific PAs or RFAs that require the TIN to be engaged?</p> <p>TIN is well received with:</p> <ul style="list-style-type: none"> <li>126 proposals to date.</li> <li>13 different NIH institutes and centers, PCORI and funding sources</li> </ul> <p>Good examples where TIN input is valuable.</p> <ul style="list-style-type: none"> <li>Valuable input is seemingly received prior to submissions.</li> <li>Program staff level recognized the utility of TIN.</li> <li>ICC Sr. Leadership has yet to acknowledge it</li> <li>Heal initiatives are reaching out and asking how to get better engaged with TIN and CTSA.</li> <li>TIN was just highlighted in <a href="#">NIH Open Mike blog</a>.</li> <li>Still quite new with regard to clinical trials</li> <li>Biggest value is when investigators recognize an unworkable trial design prior to submission.</li> </ul> <p><b>Concern about the quality of reviews and the sense that there was insufficient expertise on the review study section panels to appreciate what CTSA do in the current environment.</b></p> <ul style="list-style-type: none"> <li>NCATS will continue to receive feedback on the review process. Very challenging to include CTSA Program hub PIs on review panels due to their personal and institutional conflicts of interests generated by collaborations, letters of support, and service on one another’s EABs, however, Review will</li> </ul>	<p>NCATS to consider Enhanced interactions between the NCATS Division of Pre-Clinical Innovation and the Division of Clinical Innovation. For Fall CTSA Program Meeting.</p>

	continue to try to expand their rolodex of reviewers and welcome suggestions.	
	<ul style="list-style-type: none"><li>• Next call September 10, 2018</li></ul>	