

CTSA Clinical & Translational Science Awards Program

CTSA Program Steering Committee meeting
July 9, 2018, 2:30-4:00pm
Zoom Conferencing

Steering Committee Attendees:

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| Christopher Austin | Dan Cooper | Alan Green | Tim Murphy | Martin Zand |
| Ebony Boulware | Bradley Evanoff | Phil Kern | Reza Shaker | |
| David Center | Dan Ford | Donald Lloyd-Jones | Susan Smyth | |
| Barry Collier | Jennifer Grandis | George Mashour | Joel Tsevat | |

NCATS Attendees:

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| Penny Burgoon | Mike Kurilla | Samantha Jonson |
| Mary Purucker | Jane Atkinson | Stephen Siedel |

| Session | Summary Discussion | Action Item |
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| <p>Director's Update (Austin)</p> | <p>C. Austin asked that the members consider cancelling the August meeting due to summer attendance.</p> <ul style="list-style-type: none"> • The topic was revisited at the end of the meeting. Since some of the agenda topics were not covered, the August meeting will be held. <p>C. Austin gave an update on two items sitting with Congress that could affect the fiscal year 2019 budget.</p> <ul style="list-style-type: none"> • House Appropriations Subcommittee on Labor/HHS/Edu. A full House Appropriations Committee meeting has been scheduled to address the funding bill on 7/11. • Senate Appropriations Committee on Labor/HHS/Educ. All 12 funding bills were passed last month. Now the next step is for the Full Chamber to consider it on 7/11. <p>C. Austin reminded the Committee of the steps in the approval process –</p> <ul style="list-style-type: none"> ○ Subcommittee review ○ Full Committee review ○ Full Chamber consideration ○ Reconciliation review ○ President for signature. <p>C. Austin discussed the NIH Extramural "Open Mike" blog and drafted by M. Lauer, M. Kurilla and J. Atkinson on the NCATS Trial Innovation Network.</p> <ul style="list-style-type: none"> ○ A great opportunity to publicize across the NIH Community demonstrating what the CTSA Program network can do and has been doing. <p>C. Austin addressed the Domain Task Force Survey.</p> <ul style="list-style-type: none"> • The SC should urge their pods to participate in the survey <ul style="list-style-type: none"> ○ The data is most important to tell an accurate story. If the amount of data is too light, it wouldn't do too much to tell a story at all. ○ Reminder: the survey closes next week on July 16th; the results will be presented to the group on the next SC call; with a final report out and next steps presentation in October. <p>M. Kurilla provided a status overview on the Administrative Supplements. He reviewed the Priority Research Areas.</p> <ul style="list-style-type: none"> • The two most valued areas were: <ul style="list-style-type: none"> ○ The idea of using software in managing clinical trial systems. ○ Opioids due to the national interest. | |

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| | <p>M. Kurilla also outlined some limitations in the current supplement application process.</p> <ul style="list-style-type: none"> • These supplements are limited to the previous fiscal year. <ul style="list-style-type: none"> ○ The earliest start date would be July 1st ○ A lot of time will be spent considering and awarding the grant supplements. <ul style="list-style-type: none"> ▪ Most likely, the process will go through to the end of September. • Moving forward, only submissions received via ERA or email will be accepted. | |
| <p>Review Action Items List (All)</p> | <p>CLIC distributed a list of the pending action items that were updated during the June SC call. Highlighted from the list were:</p> <ul style="list-style-type: none"> • CTSA Program Review Processes <ul style="list-style-type: none"> ○ M. Kurilla, E. Rosemond and C. Schmitt met with the Program Director for the NCI Cancer Center (CC) to discuss & compare the grant review process for the CC and the CTSA Program. <ul style="list-style-type: none"> ▪ The CC requires a multi-day site visit, which is used to strengthen the applicant’s application prior to submission. ▪ CC PIs are permitted to sit on the review board for the CC in their 2nd and 3rd years of their award. ○ M. Kurilla noted the question of PIs sitting on the review committee was brought up by our review group. <ul style="list-style-type: none"> ▪ Concern that, should a negative response come from the review, the PI would be blamed. <ul style="list-style-type: none"> ➢ M. Kurilla asked the Grants Management office to review the past several years to determine: <ul style="list-style-type: none"> ✓ How many people would be involved? ✓ What sorts of conflict would have arisen in this pool? ✓ How would it have resulted in a reasonable pool of people to consider? ✓ Once the data is collected, it will be considered and reported back to the SC for discussion. • Another topic the CC brought up was the number of letters of support provided with the application. <ul style="list-style-type: none"> ○ Every such letter is considered a “conflict of interest”, making the formation of review committees very difficult. • M. Kurilla’s final topic was on branding – internal and external. <ul style="list-style-type: none"> ○ Internally – it’s been determined that for a CTSA Program hub to be a top tier academic center, it must include both a CC and a CTSA. ○ Externally – from the public and community – the CC appears to be a “stamp of approval”. <ul style="list-style-type: none"> ▪ The CTSA’s don’t have any sort of “stamp of approval”. ▪ Question: what about other than the PIs but other key personnel being part of the review board? M. Kurilla explained they are not restricted off the top, but again are affected by a possible conflict of interest. ▪ Question: didn’t the SC discuss branding in April and that it was suggested to use something like “NCATS approved” or “sponsored”?” C. Austin agreed. <ul style="list-style-type: none"> ➢ CC have an NCI designated CC trademark. <ul style="list-style-type: none"> ✓ CTSA’s to clearly reference an institution as an NIH award recipient. | <p>NCATS will review the past several years of review committees to determine how many people would be involved? What sorts of conflict would have arisen in this pool? And, how would it have resulted in a reasonable pool of people to consider?</p> |

- ✓ The key is the tagline. It defines what it converts into and what we want to convey to the public.
 - C. Austin would like to have a workgroup set up to consider this issue followed by bringing in a branding person. Will wait for the DTFs to finish.
 - Suggestion: Is it possible to review past submissions and compare rating to the number of letters of support to determine the effect?
 - Workforce Development Task Force
 - S. Smyth reviewed the goals, focus, and current membership of the Steering Committee Workforce Development Taskforce as understood now.
 - Following discussion, it was agreed that the focus of this task force will be on the sustainability of a full career.
 - S. Smyth also inquired about the expectations regarding deliverables to the SC.
 - Environmental scan
 - Recommendations
 - Suggest Priorities
 - White paper
 - C. Austin suggested that the members of this task force include a few people who are outside the SC, maybe even nay-sayers to determine the dynamics.
 - Suggestion: A member from another IC.
 - B. Collier noted that, as an advisor to NHLBI, he had tried repeatedly to convince the ICs to add K-awards to the existing educational structure rather than creating the K-awards and starting it from scratch. That way, the K awards would benefit from the existing infrastructure. He would like to explore how to better convey this to the institutes.
 - A second issue is the exploratory idea of NCATS establishing its own R01 program, so that there would be an opportunity to transition from K to R in NCATS itself rather than only in the other institutes.
 - B. Collier added the “Mod Pod” proposed ideas if NCATS established its own R01 program focused on rigorous research on the clinical research enterprise. In considering the creation of a program, it would be important to understand if ...
 - the program would separately review and allocate restricted funds for:
 - Discovery
 - Rare disease research
 - Discipline of translational and observation science.
- A sampling of potential topics that should be considered under this are:
- Informed consent and related bio-ethical issues.
 - Recruitment of research participants
 - Research nursing
 - Research pharmacy
 - Regulatory science (an orphan right now)
 - Implementation and dissemination
 - Science held disparities

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| | <ul style="list-style-type: none"> ▪ Research and Research network development & implementation science ▪ Team Science ▪ Clinical investigation ▪ Community engagement and research | |
| <p>Great CTSA Team Science Contest (DiazGranados and Trochim)</p> | <p>Great CTSA Team Science Contest – a project from the Methods and Processes DTF.</p> <ul style="list-style-type: none"> • D. DiazGranados explained the purpose and rules as to who can participate. <ul style="list-style-type: none"> ▪ Entry must include: <ul style="list-style-type: none"> ➢ The headline ➢ The descriptive paragraph ➢ The hub’s name ▪ Judges will include: <ul style="list-style-type: none"> ➢ Team Science researchers and managers of CTSA hubs. ➢ Graded on originality, importance, feasibility and impact. ▪ The prize? Bragging Rights! ▪ Timeline: <ul style="list-style-type: none"> ➢ July 2018 – Contest Opens ➢ August 2018 – Submissions Due ➢ September 2018 – Judging ➢ October 2018 – Winners announced at Fall Meeting ▪ Following a demonstration by W. Trochim of the submission system, the SC approved the distribution of this contest. | <p>SC approved the Great CTSA Team Science Contest. Workgroup should move forward for implementation.</p> |
| <p>Brainstorming Agenda Topics for Program Meeting (All)</p> | <p>Brainstorming Agenda Topics for Program Meeting:</p> <ul style="list-style-type: none"> ○ S. Jonson introduced the topic of timing of the SC meeting – start time and length of meeting. <ul style="list-style-type: none"> ▪ 10am start? ○ Program Meeting: SC members noted that their Pods have requested more face-to-face interaction surrounding the program meeting. <ul style="list-style-type: none"> ▪ Structure? It was suggested to arrange for breakout sessions perhaps with the breakouts being the Pods to avoid the timing to get to know each other. ▪ Building and trust and a collaborative environment. ▪ C. Schmitt referenced the agenda topics currently being considered: <ul style="list-style-type: none"> In the Morning: <ul style="list-style-type: none"> ➢ NCATS update ➢ SC update ➢ DTF WG report ➢ DTF Survey Results and recommendations ➢ Networking “activity” In the afternoon: <ul style="list-style-type: none"> ✓ Smart IRB presentation ✓ ACT presentation ✓ CD2H & CLIC updates possible ✓ Bring back to your POD to help find desired topics, topics they DON’T want to hear about. <p>NOTE: Offering suggestions can be done via the CLIC website, where the “Suggestion Box” link is, there is a dropdown for topics and it includes the program meeting.</p> | <p>SC meeting to be held from 10 – 5 ET the day before the Program meeting. More details to follow.</p> <p>SC members should brainstorm Program meeting agenda topics with their pods. More information has been circulated to the SC members.</p> |

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| | <ul style="list-style-type: none"> ✓ It was suggested to hear about hub successes, sharing best practices. Solid wins! ✓ What is the Hub's role within the Cancer Center – sharing of statistical resources – pros and cons. ✓ With the VA clinical research Pods – help to improve our relationship. ✓ If we are to become the non-cancer designated center, how to avoid overlapping with existing networks? <ul style="list-style-type: none"> • CLIC reminded everyone that the contract has been signed and the space is definite; will have to assess the feasibility for breakout groups. | |
| Final Thoughts (All) | <ul style="list-style-type: none"> • C. Austin noted that many important topics were not covered in today's meeting and will make it necessary to hold the August 13th meeting. • C. Austin also reported that the clinical part of the opioid issue is still in the air and he hopes to report more information soon. | |