Questions and Comments from 7/24/17 Call with CTSA Program PIs

1) Question: *"What is a type 5 award?"*

   Answer: A Type 5 award is also known as a noncompeting continuation. It is a request or award for a subsequent budget period within a previously approved project period for which a recipient does not have to compete with other applications. For example, if a grant is funded for 5 years, each award for the budget period following the first year is known as a "Type 5" award. From NIH website: https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/type-of-applications.htm.

2) Question: *"Since funding is limited, can NCATS relook at the policy of not allowing cost sharing on K awards? It would be good if we could cost share K awards with NCATS and fund half by NCATS and half by our institutions to increase number of Ks going through our programs."*

   Answer: Institutional funds may be used to support additional scholars allowing them to receive parallel training and research experiences based on the NCATS funded CTSA Program infrastructure for KL2 scholars. Institutional funds used to support these scholars would not be considered cost sharing. The additional scholars should not be promoted as CTSA Program KL2 scholars and would not be reported in xTRAIN. Similar to other career development programs at your institution, these activities may be reported in your RPPR as part of your institution's career development program environment and accomplishments.

3) Question: "*In the past, 4-year awards were sometimes made for resubmission applications. How many 4-year awards were made to institutions submitting new or competing renewal applications?*"

   Answer: In FY 2015, nine (9) 4-year awards were made – all were -01 (new or competing renewal) applications. No -A1 (resubmission) applications at all were awarded that year. In FY 2016, four (4) 4-year awards were made, 3 to -01 submissions and 1 to an -A1 submission.

4) Question: "*Why did NCATS not provide bridge funds for CTSAs that had gaps in funding from end of 5-year awards to beginning of new awards, which appeared to be the result of inefficiencies within NCATS and at no fault of the CTSA Hubs?*"

   Answer: Bridge funding was provided to CTSA Program institutions experiencing a potential gap in funding support due to the late publication of funding opportunity announcements resulting from the NCRR to NCATS transition. The first NCATS CTSA Program hub Funding Opportunity Announcement (RFA-TR-14-009) was published in November 2014. Seven months later, NCATS published a new Funding Opportunity Announcement as a Program Announcement (PAR-15-304) allowing for multiple receipt dates per year to increase the number of opportunities for institutions to submit a new or revised application. Since that time, institutions have had an opportunity to submit a new or revised application at least annually for review and funding consideration.

5) Question: "*Might we have more "trust" if the PI meetings were smaller and more interactive? Originally, they allowed for discussion and brainstorming with NCATS leadership and the PIs representing their hubs. More recently, they seem to be predominantly a series of lectures.*"

   Answer: Participation at the CTSA Program Meeting has evolved as the program has changed. For many years CTSA Program hub awards had one named PI. Since 2015, Type 1 awards have included three different named

PIs for the UL1, linked KL2, and optional TL1.   This expanding number of named investigators, and the important and unique roles all PI's play in the activities of local CTSA Program hubs and the consortium has contributed to an increase in the number of people NCATS includes in the CTSA Program Meeting. Also, many PIs have asked if other key staff at their hubs (e.g. administrators, information officers, evaluators, etc.) could attend the Program Meeting. In an attempt to be responsive to these requests and provide hubs flexibility, each CTSA Program hub currently may bring a total of 5 people to program meetings, including all named PI's. NCATS and the CTSA Program Steering Committee will discuss options for smaller group discussions to meet the different needs of the CTSA Program, investigators, and NCATS.

6) Question: *"This information is very helpful and much appreciated. Can we have this type of frank conversation about awards, budgets, and related policies on a recurring basis? That would go a long way toward building mutual trust and team approaches."*

   Answer: Yes, NCATS will develop a plan to include information related to budget, funding, and related policies during PI calls and meetings moving forward.

7) Question: *"Why did NCATS delay over half of the new Awards for 4 months in 2017, which created the need for local Hubs to identify their own bridging funds?"*

   Answer: NIH and NCATS operated under a continuing resolution and faced budget uncertainties until May 4, 2017. NCATS was unable to make funding decisions until the amount of funds provided to the CTSA Program for fiscal year 2017 was known.

8) Question: *"For future cost containment issues and also to perhaps create a more even playing field for the institutions to play on, could the T program in future be limited to pre-doctoral students which are less expensive and also more similar at our institutions. but make it mandatory."*

   Answer: NCATS is committed to having an open discussion with the CTSA Program investigators regarding the KL2 and optional TL1 programs. These discussions will begin in August 2017. NCATS will use available data on these programs and feedback from the CTSA Program stakeholders to consider future changes. We look forward to working together to strengthen the translational research workforce and encourage broad and multidisciplinary training of diverse investigators along different development points to allow early stage investigators to benefit from translational science training both at the pre-doctoral and postdoctoral level (e.g. PhDs, MDs, Pharm D's, RN-PhDs.)

9) Question: *"What mechanisms are in place to gauge the value of the funds going to the RICs and TICs rather than to the hubs, particularly given the problems associated with the 4-year funding cycle for almost half of the centers?"*

   Answer: The Trial Innovation Network Investigators and NCATS are developing metrics on the efficiency and quality of multi-site studies supported by the network. This will allow us to understand the impact of the Trial Innovation Network and find better ways to implement multi-site studies, so that more of today's science can be tested and become tomorrow's cure.

10) Question: *"Why was the largest increase in budget since 2014 in the Program Management category?"*

Answer: There are two reasons for the increase in the Program Management category, an increase in the scientific and programmatic oversight of the CTSA Program and mandatory DHHS assessments that are applied across NIH. Based on the 2013 IOM report recommendation for greater program leadership and oversight, NCATS increased CTSA Program staff levels. In addition, the CTSA Program had historically been under-assessed for its share of the DHHS costs, with the result being that other NCATS programs carried a disproportionate share of those costs. Since FY 2014, a more proportional share of DHHS costs has been assessed to the CTSA Program.

11) Question: *"Don't four year awards increase the burden of review by increasing the frequency and thus the annual number of CTSAs requiring review? While there may have been a rationale in 2015 when two years of CTSA applications were combined into one cycle, what is the rationale for continuing this practice?"*

Answer: As described on the call, NCATS is hopeful that varying the length of award based on peer review input has helped to achieve a more even number of CTSA Program hub applications competing in any fiscal year. Addressing it only in FY2015 did not solve the problem. It was still necessary in FY2016 and FY2017. Currently, the anticipated number of competing applications in a given fiscal year is relatively evenly distributed. Please note that NCATS may decide to provide shorter duration awards to CTSA Program hubs when it is determined, based on peer review and programmatic considerations, that additional oversight is required.

12) Question: "*Can you refute the recommendation by Congress to increase the sites to 64, which was based on erroneous data?"*

Answer: NCATS is engaged in conversations with congressional staff about the status of the CTSA Program.

13) Question: *"There is a concern about added administrative inefficiencies with double reviews of pilots which often slows things down."*

Answer: Consistent with NIH policy on Human Subjects Protections, NCATS grantees must seek approval from NCATS to conduct research involving human subjects that was not described in the original peer-reviewed grant application. This includes pilot projects and KL2 scholar projects supported completely, or in part, by the CTSA Program award. NCATS strongly encourages CTSA Program hub investigators to work closely with program staff to understand what information is required in the prior approval for human subjects research packets. Ensuring investigators at your hub understand this requirement and submit complete packets will speed this approval process. The NCATS website provides resources and information to grantees regarding this policy and can be found at: https://ncats.nih.gov/funding/grantees/approval-faq.

14) Question: "*Did we hear correctly that the 10% reduction in CTSA awards in FY2017 are in the process of being restored?"*

Answer: That is correct. Non-competing CTSA Program awards previously issued in fiscal year 2017 at 90 percent of the committed level will be revised to restore funds to the committed level. NCATS posted a revision to its FY 2017 funding policy that reflects the restoration on July 13, 2017, https://ncats.nih.gov/funding/review/policy.

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15) Question: "*Pre vs post docs - Can we track which gives the better roi (return on investment) of the investment of dollars?*"

Answer: NCATS is committed to having an open discussion with the CTSA Program investigators regarding the KL2 and optional TL1 programs. These discussions will begin in August 2017. These discussions can include CTSA Program PI thoughts on the balance of Pre-doctoral and Post-doctoral students in the optional TL1 program and metrics for determining impact.

16) Question: "*What percent of submissions each year are A1s?*"

Answer: In FY2016 and FY2017, approximately 25% of the applications were A1s.

17) Question: "*Could you please share all the question that were posed to the attendees on the call?*"
18) Question: "*In the interest of transparency may we please see all the questions and comments.*"

Answer: Yes, questions and answers posed during the call are included in this document. See above.

19) Comment: "*Thanks for presenting and clarifying all of the data on CTSA hubs. It is really unfortunate that we were fed information from non-NCATS sources!*"

Response: We appreciate the opportunity to provide information related to the CTSA Program award budget, funding, and policies. We encourage investigators to reach out to leadership in the Division of Clinical Innovation or NCATS with questions in the future.

20) Comment: "*This call was extremely important, modelling transparency and open communication with key data (much of it was previously unobtainable and distorted by some).*"

Response: We look forward to enhanced open communication in the future.

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