

Croker, Jennifer

From: Kimberly, Robert P <rkimberly@uabmc.edu>
Sent: Thursday, March 24, 2022 9:03 AM
To: Laird, Rebecca L
Cc: Ezequiel, Stephanie (NIH/NCATS) [C]; Croker, Jennifer (Campus)
Subject: Pod notes

Rebecca, Stephanie

Here are the POD call notes for UAB, UIC, Rockefeller, Rutgers, Rockefeller and Vanderbilt

CTSA POD Call

Monday, March 21, 2022

Attachments:

- CTSA SC Meeting 2022Feb 28 Slide Deck
- CTSA SC Meeting 2022Feb 28 Summary
- CTSA SC Meeting 2022Mar 14 Slide Deck

Feedback on UM1 RFA

- Observation that expectations of CTSA PD/PIs to report to high-level institutional official and have the ‘authority and influence’, as articulated in previous RFAs (see comparison below), have been lost in the UM1 FOA
 - e.g., PAR-18-464 & PAR-18-940 (U54), “It is expected that any UL1 award PD(s)/PI(s) will be an established clinician/scientist who reports directly to an official with broad trans-institutional authority, and who personally has the authority and influence necessary to successfully promote translational and clinical research locally”
 - e.g., PAR-21-293 (UM1), “All PD(s)/PI(s) are expected to be research scientists with recognized stature and relevant subject matter expertise in his/her scientific discipline with the demonstrated ability to ensure quality control, administrative oversight, and integration of all elements of a Program.”
- There was recognition that, as NCATS was removing such language, NCI is strengthening the expectations of comprehensive cancer center PD/PIs

ACTION:

- The Pod wished to underscore that language setting an expectation for CTSA Leaders, (chiefly PD/PIs), to be empowered with authority and influence through top level reporting structures is pivotal to the distinction that CTSA are ‘not just another grant’, but rather are essential for effective institutional change and advancement of the translational science mission. The group encourages NCATS to reconsider this language in the new UM1 program announcement.

DEI Task Force

- The Pod was very appreciative of the DEI Task Force’s considerations of institutional, programmatic, community-centered and social/cultural/environmental focus areas and guiding principles

ACTION:

- Proposed Phase I DEI Survey should include an assessment of climate of inclusiveness / belonging, an institution’s readiness for change, etc.

- Meaningful (not pro forma) implementation of DEI recommendations will rely on accountability of CTSA Steering Committee and NCATS to influence CTSA as a consortium

Informative Clinical Trials (ICT)

- There is widespread commitment to continuous quality improvement of the processes to conduct high-quality clinical investigation
- RIC Publication: Cook, S., ... Harris P. (2022). What we wish every investigator knew - Top 4 recruitment and retention recommendations from the Recruitment Innovation Center. [Journal of Clinical and Translational Science, 1-12.](#)
 - ICT Task Force, led by Dr. Laura James, discussing a possible JCTS Themed Issue; also considering other means of dissemination and engagement (eg, videos)
- ICT Challenges – one size does not fit all
 - Expectations of outcomes and impact should be tailored to the nature of project (e.g., Phase 3 trial vs pilot study)
 - Variable understanding by PIs and Institutions of the issues affecting clinical research success (perception that there is no problem)
- Brief discussion of a potential National Academies of Medicine report on the Implementation of Core Site Standards, which may signal recommendations for institutional certifications
 - Unclear if the NAM recommendations will be guidelines or requirements, will apply to select projects supported by CTSA in some form or all projects within an institution
 - While there is appreciation that CTSA have been recognized as stakeholders, they should be considered partners and facilitators in a change management process; If there are standards established, the burden of enforcement must fall to institutions to implement, not CTSA
 - The Pod noted there may be more effective ways to arrive at a commitment to excellence that does not rely on a separate and onerous institutional accreditation process;
 - Proposed expectations could serve as review criteria for CTSA

ACTION:

- The Pod would appreciate clear articulation by NCATS of their current expectations and/or intentions related to core site standards

Fall CTSA Meeting

- The 2022 CTSA Fall Meeting has been tentatively scheduled for Nov 2-4 in Washington, D.C.
- The Pod briefly considered topics
 - Several expressed surprise to see ‘Metrics for CTSA’ as a potential topic, given the sun-setting of the Common Metrics program and perceptions that process fell short of evaluating metrics that matter (e.g., impact on communities)
 - Trans-NIH approaches like those in COVID (CEAL, RECOVER, RADx, etc.) were briefly discussed, with interest to learn more of how NCATS and CTSA might consider future pandemic planning, including support mechanisms

ACTION:

- Please consider ‘Pandemic Preparation’ as an additional topic for consideration at the CTSA Fall Meeting
- Pod members agreed to continue to deliberate and forward meeting topic ideas to Dr. Kimberly and Dr. Croker (rpk@uab.edu; jcroker1@uabmc.edu)

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