

# CTSA Program Steering Committee

December 10, 2018

2:30 – 4:00 ET

# Agenda

2:30	Welcome	Kathleen Brady, Christopher Austin
2:35 – 2:40	Domain Task Force Update	Kathleen Brady Clare Schmitt
2:40 – 4:00	Discussion <ul style="list-style-type: none"><li>• Pod Feedback Discussion</li><li>• Lessons Learned From Outgoing Steering Committee Members<ul style="list-style-type: none"><li>◦ Ebony Boulware</li><li>◦ Kathleen Brady</li><li>◦ David Center</li><li>◦ Dan Cooper</li></ul></li></ul>	Facilitated by: Kathleen Brady Christopher Austin Michael Kurilla



# Reminders

## POD EXERCISE #1: Common Metrics Initiative Assessment

**Instructions:** CLIC is seeking responses from PIs on how to strengthen the Common Metrics Initiative. Each hub in your Pod should review the attached CM document and complete the assessment at this link: [Common Metrics Initiative 2.0 PI Pod Exercise](#) by **COB, Friday, December 14, 2018**.

The CLIC Common Metrics team is currently conducting an assessment on CMI 2.0. The goals of this assessment are to:

- Take a pulse on how well the metrics are implemented and utilized at each hub;
- Engage with the consortium on ways to improve the metrics and the initiative overall; and
- Determine a process on how to move progressively forward with the initiative with the goal of measuring how well the consortium is doing as a collective across the metrics.

## POD EXERCISE #2: Alliance for Clinical Research Excellence and Safety (ACRES) Engagement

**Instructions:** NCATS has been approached by the Alliance for Clinical Research Excellence and Safety (ACRES). NCATS would like feedback from each Pod on whether we should engage with this group. Aggregate feedback from each Pod is fine. Please provide your Pod's feedback via the [CLIC suggestion box](#) by **COB, Friday, December 21, 2018**.

### **Resources:**

[Alliance for Clinical Research Excellence and Safety \(ACRES\) Website](#)

[ACRES Site Accreditation & Standards Initiative \(SASI\)](#)

[NEJM Article: Voluntary Site Accreditation – Improving the Execution of Multicenter Clinical Trials](#)

[NEJM Article: Accreditation of Clinical Research Sites – Moving Forward](#)




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# NIH Helping to End Addiction Long-Term (HEAL)<sup>SM</sup> Initiative


- Pain Management Effectiveness Research Network Funding Opportunity (NS-19-021):  
<https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-19-021.html>
- TIN Resources:  
<https://trialinnovationnetwork.org/heal-pain-ern-other-heal-foas/>


Funding Opportunity Title	HEAL Initiative: Pain Management Effectiveness Research Network: Clinical Trial Planning and Implementation Cooperative Agreement (UG3/UH3 Clinical Trial Required)
Activity Code	UG3/UH3 Exploratory/Developmental Phased Award Cooperative Agreement
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	RFA-NS-19-021

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## NIH HEAL INITIATIVE<sup>SM</sup> PAIN MANAGEMENT ERN & OTHER NIH HEAL FOAs


The NIH launched the HEAL (Helping to End Addiction Long-term) Initiative<sup>SM</sup> to speed scientific solutions to stem the national opioid public health crisis. The NIH HEAL Initiative will bolster research across NIH to improve treatments for opioid misuse and addiction and enhance pain management. The HEAL Pain Management Effectiveness Research Network (ERN) will address pain management by supporting clinical trials that compare the effectiveness of existing therapies, including combinations or novel approaches using existing therapies, to prevent or manage pain in ways that reduce the risk of addiction. Clinical trials will be conducted within the existing NCATS CTSA Program - Trial Innovation Network.

### FUNDING / OPPORTUNITIES

**HEAL Initiative: Pain Management Effectiveness Research Network: Clinical Trial Planning and Implementation Cooperative Agreement (UG3/UH3 Clinical Trial Required) RFA-NS-19-021**

A list of current and future HEAL Funding Opportunity Announcements is available [here](#).

### Things you need to know:

 Due to the timing of the HEAL Pain Management ERN FOA and to avoid any conflicts of interest, the Trial Innovation Network (TIN) will not accept proposals requesting initial consultations for RFA-NS-19-021.



# Domain Task Force Update

Kathleen Brady, Clare Schmitt



# Domain Task Force (DTF) Update

## Next workgroup meeting:

- December 14, 2:00 – 3:00 ET

## Notification sent to DTFs:

- DTF Elections may take place.
- Work Groups
  - Existing: Continue; you are encouraged to scale remaining activities/objectives for completion by Dec. 2019.
  - New
    - Three new iDTF Work Groups were presented at the Fall Steering Committee meeting and have completed charters. These three may proceed with the understanding that the activities/objective(s) will be scaled for completion by Dec. 2019.
    - Other DTFs considering new Work Groups
      - DTFs are encouraged to focus on one or two new, targeted areas over the next 12 months.
      - New Work Groups may be proposed to the Steering Committee; request must include:
        - Specific Objective/Challenge to be addressed
        - Broader context/goal
        - Timeline w/ Milestones (**completion by Dec. 2019**)
        - Output/Deliverable



# Pod Feedback and Discussion



To: Steering Committee  
Date Received: 10.11.18  
From Who: **Susan Symth**  
Affiliation: CTSA Affiliation  
Hub/Location: University of Kentucky  
**Would you like a response from NCATS: YES, Discussion at Steering Committee Level**  
Suggestion for: FOA (PAR-18-940), Long Term future of TL1 & KL2s  
NCATS Response/Notes: NCATS is preparing a formal response and will add this topic to the November Steering Committee call agenda.

The following concern was raised to the Lead team of the workforce DTF - discussion at the level of the SC seems warranted and would be appreciated.

We are getting deeper into writing our competitive renewal at our (small) hub. We are going after the minimum amount (now \$3M direct costs). In this FOA (PAR-18-940), that amount now includes total for the U54 and the KL2, combined (the TL1 remains separate at \$400K).

The FOA give budget guidance (as % of total direct costs) for each of the components (or functions, or whatever we call them now), as summarized below:

- Admin Core, including TL1 staff support, 10%
- Informatics, no limit, budget rec-big as possible
- BERD/REKS (Res Methods) 15%
- TWD/PTC (Trans Endeavors) 15%
- CE, Team Sci (Community and Collab) no budget rec
- ISP/PCI (Hub Res Cap) 25%
- HLT (Network Capacity) 10-15%

Doing the arithmetic, the specified percentages would total \$2.25-2.4M (75-80% of total) + Informatics (big) + Comm & Collab (unspecified) + KL2 (+ optional module) = \$3M

So, if following percentage recommendations, there is (only) \$600-\$750K for KL2 + Informatics + CE and Collab (+/- optional module). The KL2 budget guidance also required at least 20% FTE for the PD/PI and a max of \$180K for each scholar (max of \$120K salary (? fringe), \$25-50K res expenses, and \$10K mentor expenses).

We have, in the past, discussed concerns about the long term future of the TL1, but it seems to me that this FOA would actually shut down KL2s at the small hubs (which make up about 50% of the total KL2 slots currently).

Any thoughts, suggestions, utility in discussing on our next call, or on bringing this concern to the SC or to NCATS?





To: Steering Committee  
Date Received: 10.15.18 @ 4:23pm  
From Who: **Susan Smyth**  
Affiliation: CTSA Affiliation  
Hub/Location: University of Kentucky  
Would you like a response from NCATS: **Would like it to be added to the Steering Committee Agenda for discussion.**  
Suggestion for: Steering committee  
**NCATS Response/Notes: NCATS is preparing a formal response and will add this topic to the November Steering Committee call agenda.**

**Question/Comment:** For steering committee call - there is confusion among the TL1 director's about the new FOA and the number of TL1 positions allowable. The group is concerned that the new FOA (PAR-18-940) is limiting numbers of T-trainees supported through the programs and would like the SC to discuss the impact of limiting T trainees. The group would also request that someone from NCATS speak with the group on their next monthly call (arranged by CLIC)

To: Steering Committee  
Date Received: 10.17.18 @ 10:58 am  
From Who: **Susan Smyth**  
Affiliation: CTSA Affiliation  
Hub/Location: University of Kentucky  
Would you like a response from NCATS: **Would like it to be added to the Steering Committee Agenda for discussion.**  
Suggestion for: Steering committee  
NCATS Response/Notes: NCATS will add this topic to the November Steering committee call agenda.

As we are reviewing work of DTFs, it would also be useful to hear from the CCIA and CCIA Admin Supplement.

To: Steering Committee  
Date Received: 10.18.18 @ 10:58 am  
From Who: **Ebony Boulware**  
Affiliation: CTSA Affiliation  
**Would you like a response from NCATS?** **No**  
Hub/Location: POD Call

**NCATS Response/Notes:** NCATS will add these topics to the November Steering committee call agenda.

This is a series of items we recently discussed as concerns the PIs in my POD would like addressed:

I. **Administrative Supplements:**

1. One PI wanted to know why administrative supplements about opioids did not get. They got a lot, and then it said it made a lot more sense for NIDA to fund.
2. Another PI: how did you find out about the funding decisions? We were told to sit and wait. If you hadn't heard anything by Sept 1, it will not be funded. Tried to push program officer. Told it would be more by end of October. Making rolling awards.

Q: How many opioid related supplements were funded? This should be updated at the annual meeting.

Q: How many supplements funded overall? Areas funded and numbers.

**Concern:** Large \$\$ going into equipment grants. But then equipment grants not apparently funded. A lot of effort for no real return. Very unrewarding to have submitted a proposal. Original priorities not adhered to. Process needs to have a little more integrity.

II. **CTSA (overall competitive renewals or new applications) review process:** Reviews of concerning quality. Would love steering committee and NCATS leadership to address

III. **PI calls:** Listening. Most useful part of the PI call is the CLIC presentation. Provides communication about opportunities and requirements. CLIC is trying to do a good job in meeting investigator and site needs. Much of the rest of it feels like NCATS talking to us and filler. Better transparency and better eye on the bottom line. What are we accomplishing?

\* **DTFs are huge**— are there great work products? But what has come out of them? Success rates of clinical innovation awards? We have no idea what the acceptance rates are? Let's stop talking about the processes? What % of grants are you funding? How big is that pot?

- What have we achieved?

IV. **DTFs:** We don't know where they are doing? Where are the work products parked? Survey— we need to know what the DTFs are talking about. What do the DTFs Do? Very few of PIs answered the DTF survey and mostly it was participants in the DTFs— you are getting a skewed response.

**Recommendation:**

- \* It would be nice if the work products were saved online on the CLIC website. Could be searchable and available to all of the hubs
- \* Annual reports or briefs that get disseminated. If the work products were there, they don't need an annual report.
- \* Opportunity: Get to the DTFs to share the work products beyond the CTSA. Encourage submission to JCTR.



To: Steering Committee  
Date Received: 10.19.18 @ 11:08 am  
From Who: **Phil Kern**  
Affiliation: CTSA Affiliation  
Hub/Location: University of Kentucky

**Would you like a response from NCATS: Would like it to be added to the Steering Committee Agenda for discussion.**

Suggestion for: Steering committee

NCATS Response/Notes: PCSS feedback sent to Kathleen Brady. NCATS has reviewed these notes and will add these topics to the November Steering Committee call agenda.

Pod call Oct 10, 2018

Discussed recent SC call of 9/10/18

Information given to pod members re: funding for un-meetings, synergy papers, HEAL RFA.

Taskforce on career development. The formation of the STARWORK taskforce was described with a focus on how to improve the success of KL2 scholars. A survey of KL2 scholars is intended. Pod members agreed that it would be very useful to obtain direct feedback from KL2 scholars about their perceptions, barriers, etc. The definition of “success” has clearly changed over the last 10-20 yr. However, Pod members felt that another survey should be performed targeting CTSA. It would be easy to poll CTSA to obtain basic descriptive information on number of scholars, grant funding, current status, and other typical measures of success. All CTSA have this information, and provide this with every grant renewal, and we could go all the way back to the initiation of the CTSA program. We should mine the data that we have.

Other issues arising.

Peer review of CTSA grants. Everyone has their own story of unreasonable/unfair reviews. Can NCATS establish a standing study section?

Pre-authorization of pilot grant. This was considered a burden, and it was hoped that NCATS could work to “untie” our hands.

Common metrics. When will we see the results of the survey on the common metrics? Many expressed skepticism that the effort put into the common metrics has yielded significant information.





# Lessons Learned

## Outgoing Steering Committee 2016 - 2018 Cohort

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# Steering Committee Nominations 2019 – 2021 Cohort

- Vacancies: 1 Administrator, 4 UL1 PIs
- SC invitations to be sent by December 14<sup>th</sup>
- Announcement to the consortium in January CTSA Program newsletter



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Next Meeting

January 14, 2019  
2:30 – 4:00 ET

