

CTSA Program Steering Committee Webinar

Monday, August 14, 2017
2:30 – 4:00 (EDT)

Agenda

2:30	Welcome	Kathleen Brady and Petra Kaufmann, Co-Chairs
2:30 – 2:35	Introduction of New SC member: Martin Zand (CLIC)	Kathleen Brady and Petra Kaufmann
2:35 – 2:45	Program Meeting Feedback	Christopher Austin and Petra Kaufmann
2:45 – 2:50	Common Metrics Update: Accrual Pilot	Sundeep Khosla and Redonna Chandler
2:50 – 3:00	Trial Innovation Network Update	Petra Kaufmann
3:00 – 3:02	Pod Exercise Survey Feedback	Erica Rosemond
3:02 – 3:20	Opioid Project Discussion	Kathleen Brady, Christopher Austin, and Redonna Chandler
3:20 – 4:00	Open Floor Discussion on <ul style="list-style-type: none">• Training• Governance Document	Moderated by: Kathleen Brady and Petra Kaufmann



Welcome New Steering Committee Member, Martin Zand (CLIC)!

Program Meeting Feedback

Christopher Austin (NCATS)
Petra Kaufmann (NCATS)

Fall CTSA Program Meeting Feedback

- Request for PI only discussion time
 - Morning session will be PI only
 - NCATS Update
 - Facilitated Discussion
 - Determining if Space Available for Breakouts for U PIs and K/T PIs
 - NCATS will work with Steering Committee and PIs to shape morning session
 - More information may be requested to ensure productive session
- Top 3 Topical Areas for Other Sessions
 - Informatics
 - Clinical Research
 - Collaborative Innovation Awards



Common Metrics Update: Accrual Pilot

Sundeep Khosla (Mayo Clinic)

Redonna Chandler (NCATS)

Trial Innovation Network

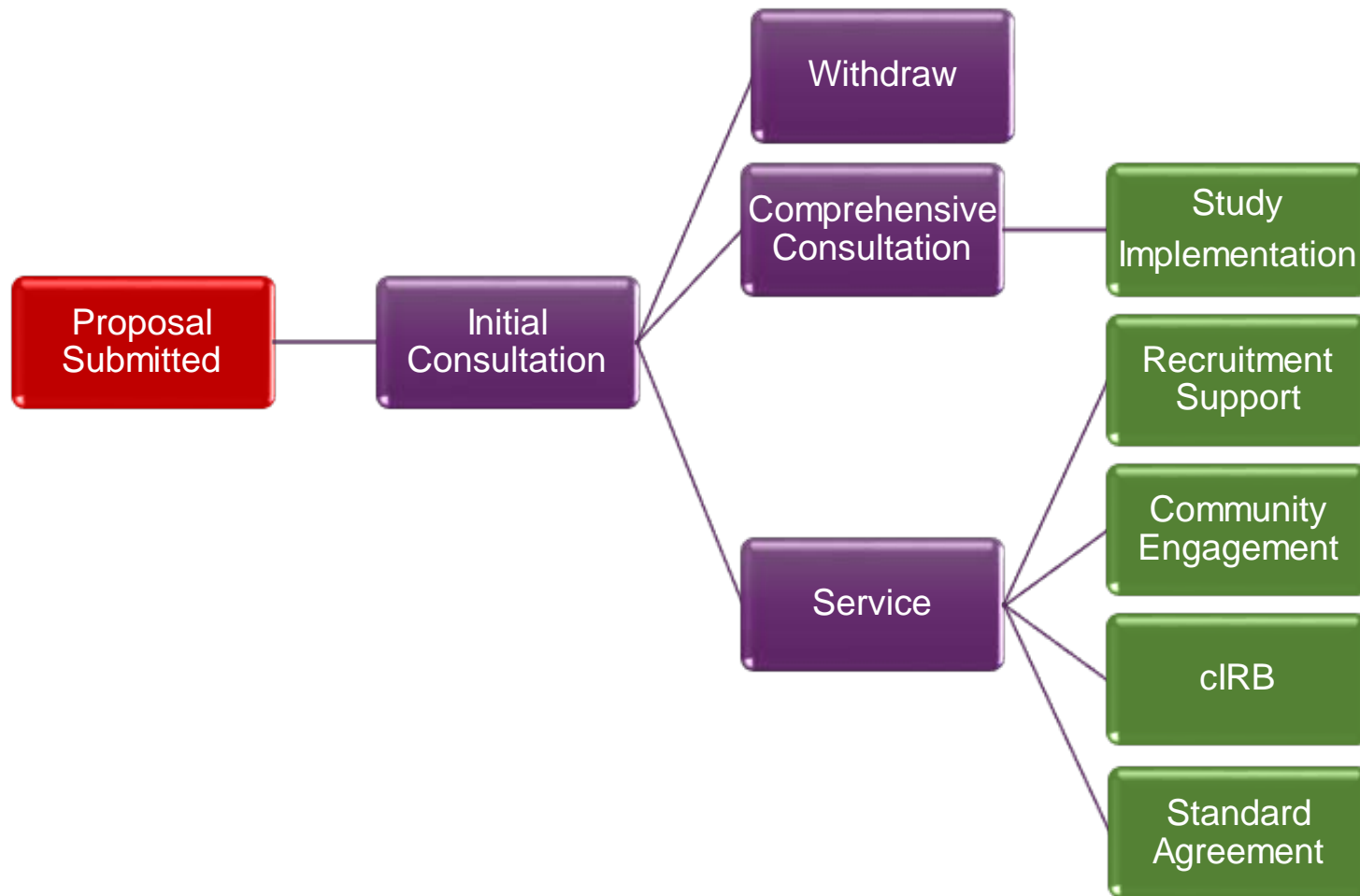
Operational Innovation, Excellence, and Collaboration

Petra Kaufmann

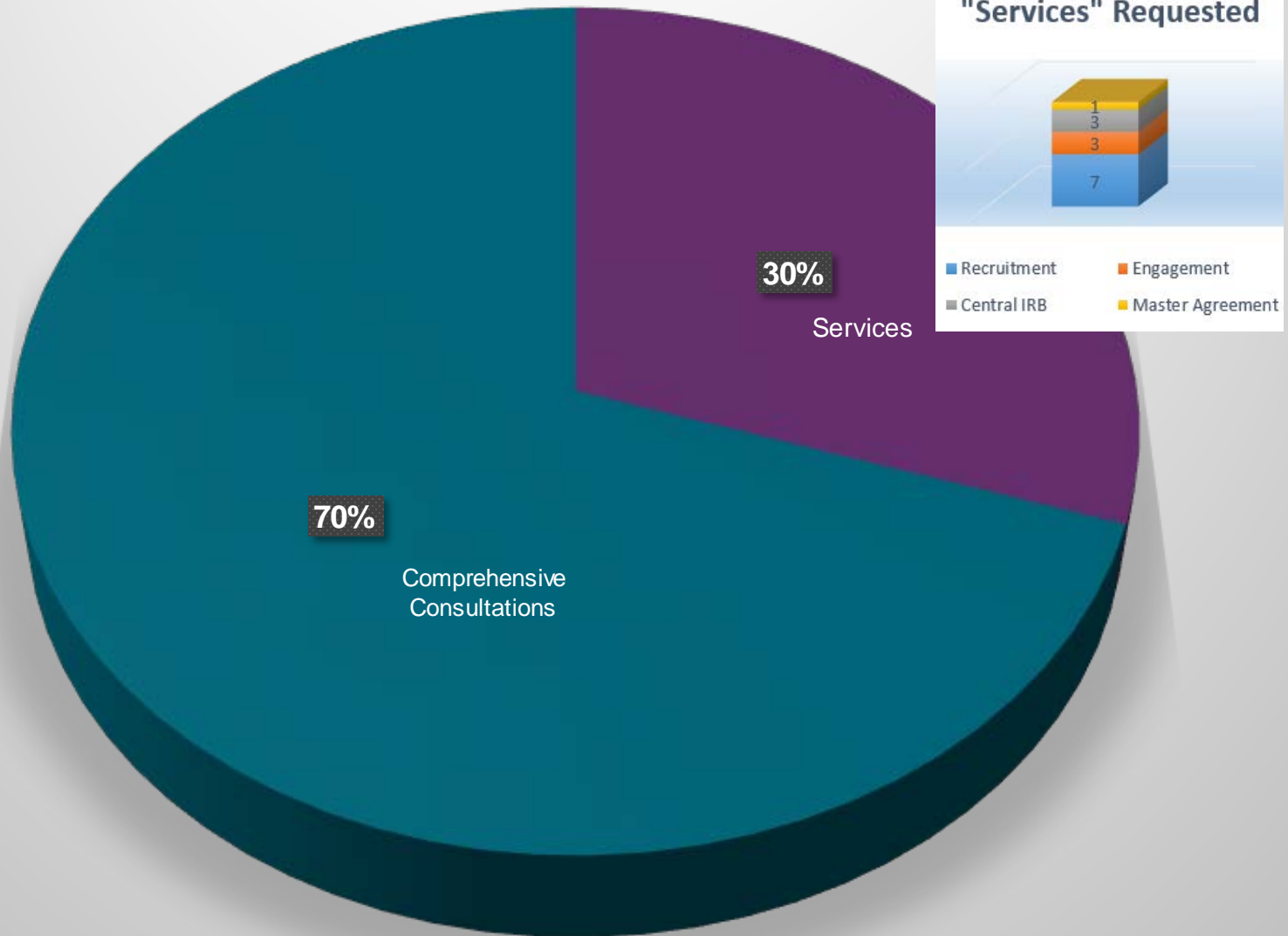
Director, Division of Clinical Innovation

August 14, 2017

Trial Innovation Network Pathway for Proposal Requests

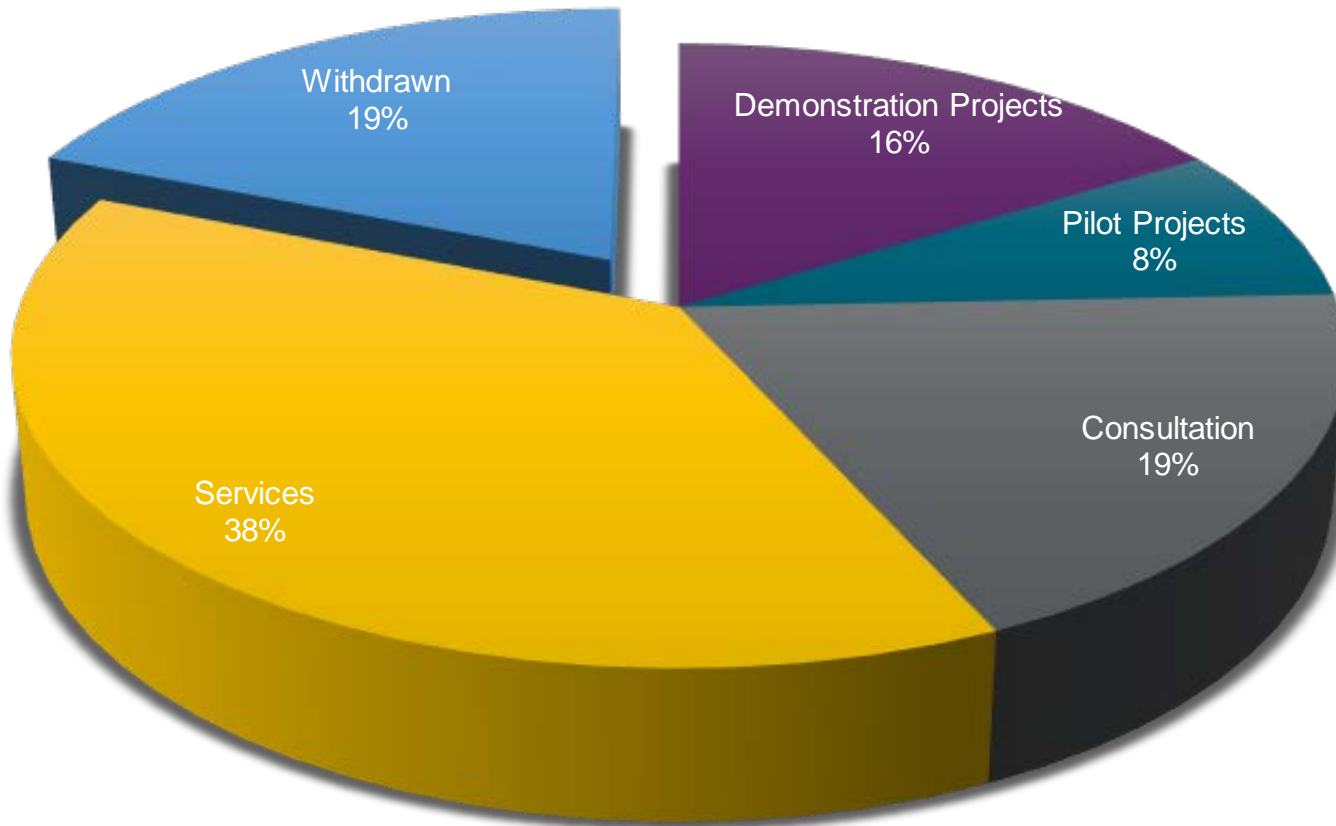


Trial Innovation Network Support Distribution



National Center
for Advancing
Translational Sciences

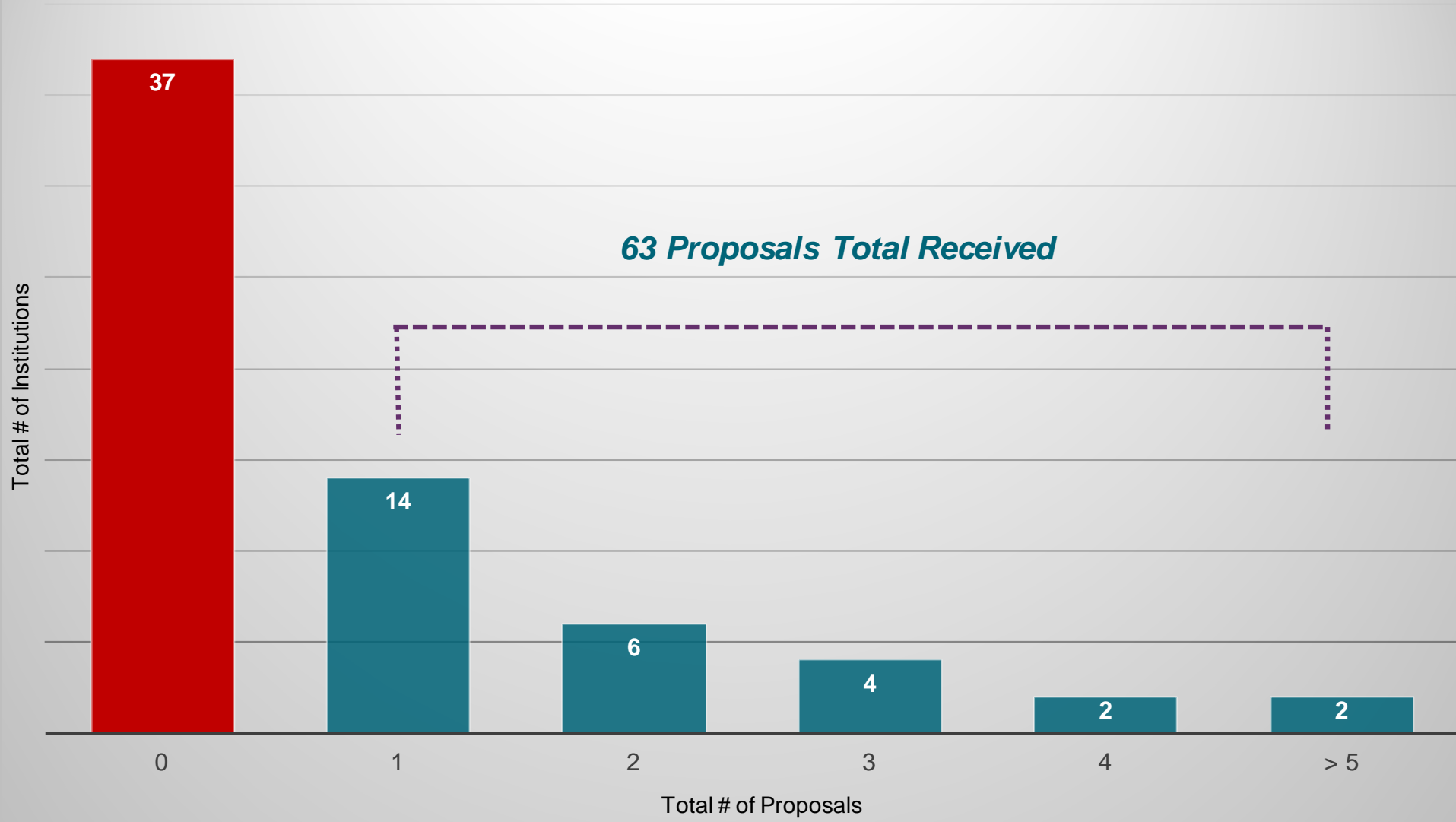
Where are we now?



■ Demonstration Projects ■ Pilot Projects ■ Consultation ■ Services ■ Withdrawn



Network Proposal Submission Summary



Protocol Review Committee

Purpose and Scope

- The Trial Innovation Network Protocol Review Committee (PRC) will evaluate clinical research protocols submitted to the network to assess the scientific merit of the proposed study, the risk profile and participant safety to promote safe and high quality scientific research within the Network.
- The PRC will review proposals that are approved by the Proposal Assessment Team (PAT) that have not undergone scientific/peer review.
- Membership of the PRC includes a chair, medical experts, scientists, and other clinical research or trial experts



How Do You Fit in This Puzzle?



The PRC will be in need of member support from the CTSA community, particularly:

- **Content Experts:** As needed, scientific, medical reviewers and operations experts will prepare their reviews prior to the meeting and present those reviews during the meeting.
- **Statistician:** The statistician will review the study design, including endpoints, statistical plans, and power calculations.

A formal request will be generated and issued from the Trial Innovation Network. In the mean time, we are asking that you begin pondering possible nominees.





Interested Pls can visit <https://trialinnovationnetwork.org/> for more information.



Feedback on Policy and Procedures for Surveys

Erica Rosemond (NCATS)

Erica.Rosemond@nih.gov

Link to Data Collected: <https://docs.google.com/spreadsheets/d/1vXqp5zZVR5bcFJHLJ7bS-aKjfDmiltw02HpOsgmfsOk/edit?usp=sharing>

Replaced following terms in shared document:

DCI = DIVISION; CTSA = PROGRAM; NCATS = IC; C4 = COORDINATING CENTER; Removed all identifiers = NAME

Survey Policy and Procedures – Highlights of Feedback

52 responses received:

- Require a clear rationale for surveys that are tied to an action by NCATS, coordinating center, workgroup or hub; state how data will be used; clear that the survey was vetted
- Vetting:
 - Careful vetting (beta testing); need assessment (can you receive this info any other way? Key informant interviews?)
 - Vetting by SC, DCI Leadership and/or coordinating center prior to release
 - Need rigorous design: incorporate social scientists and methodology centers, combined need for content experts and survey experts
- Limit the number:
 - Target the surveys (not just to the PIs), combine related surveys, create strategic priority areas for surveys
- Utilize the coordinating center for:
 - Managing all surveys: track requests, archive surveys and results (reduce redundancy and disseminate results); make survey info searchable (survey and individual questions, topics, key words – metadata, code surveys)
- Utilize the Evaluators Group for:
 - Creating a resource of best practices and templates for surveys
- Other: allow opt out without consequence, responders share in publication, route surveys via administrators, request notification for certain topics



Feedback on Governance for the CTSA Program

Erica Rosemond (NCATS)

Erica.Rosemond@nih.gov

Link to Data Collected: https://docs.google.com/spreadsheets/d/13thH7zzghZBCNRlgBlbqPSHtAScJa2M4_A8Wy8uoc88/edit?usp=sharing

Replaced following terms in shared document:

DCI = DIVISION; CTSA = PROGRAM; NCATS = IC; Removed all identifiers = NAME or IC DIRECTOR

Governance for the CTSA Program – Highlights of Feedback

53 responses received with call for:

- Enhancing the roles and responsibilities for the Steering Committee, suggestion for additional types of members on the SC (non-PI level who are more actively engaged in work – for Steering Committee and other Committees)
- Description of how decisions are made
- Clarity on how are priorities are established in the DTFs
- Enhanced clarity of the role in several activities (Common Metrics Initiative, TIN, Coordinating Centers)
- Enhanced communication and dissemination of information
 - Via effective use of PODS (suggest SOP to be developed)
 - Via annual or semi-annual reporting from the SC and DTFs to the hubs
- Definition of membership within the CTSA Program (hubs that are in NCE)
- Mechanisms for conflict resolution within activities
- Greater flexibility for activities within the hubs (not one-size fits all approach)
- Enhanced inclusion of the Administrators
- Revision of Figure 1
 - Reconfiguration (inverted); include PODs, expansion of detail in some sections (DTFs, Common Metrics, Coordinating Centers), separate reporting/communication from activities, include other activities



Opioid Research Discussion

Kathleen Brady (Medical University of South Carolina)
Christopher Austin (NCATS)
Redonna Chandler (NCATS)

Opioid Research

- Reviewing ideas from pods and investigators
- Trial Innovation Network examining capacity for CTSA Program to reach into:
 - Rural settings
 - FQHCs, State/County Health Departments
 - IDeA States
 - Indian Health Service
 - Veterans Affairs
- Planning webinar to prioritize ways CTSA Program could participate in opioid research
 - Include key CTSA Program Investigators, Addiction Scientists, Nora Volkow, and NCATS staff



Open Floor Discussion

- Training
 - Goals of K and T programs
 - Numbers and duration
 - Early vs later, pre- vs post-doc
 - Perspectives on cost sharing

- Governance Document

- Topics from the floor