

CTSA Clinical & Translational Science Awards Program

CTSA Program Steering Committee meeting
December 11, 2017, 2:30-4:00pm
Webinar

Steering Committee Attendees:

Christopher Austin	Robert Clark	Melissa Haendel	Harry Shamoon
Kathleen Brady	Dan Cooper	Sundeep Khosla	Susan Smyth
Ebony Bouleware	Dan Ford	Tim Murphy	Joel Tsevat
David Center	Alan Green	Reza Shaker	Martin Zand

NCATS Attendees:

Penny Burgoon	Samantha Jonson	Pamela McInnes	Erica Rosemond
Redonna Chandler	Mike Kurilla	Mary Purucker	Steve Siedel

Session	Summary Discussion	Action Item
Consent Workgroup Presentation & Discussion (Brady, Jerome)	<p>A task force work group formed in February to examine issues confronted by CTSA Program hubs around broad consent. Focused on 3 domains:</p> <ul style="list-style-type: none"> • Participant contact • Clinical data sharing • Bio-specimens <p>Survey results reflected:</p> <ul style="list-style-type: none"> • Variability regarding Broad Consent policy responses across Institutions • Opt-in vs Opt-out Models: opt-out preferred for participant contact and data-sharing • Lack of alignment with broad consent practices and Common Rule • Institutions could improve researcher knowledge about evolving capacity to access data <p>Discussion of valuable next steps for Consortium to move forward and address results</p> <ul style="list-style-type: none"> • Opt-in vs Opt-out <ul style="list-style-type: none"> ○ Discrepancy between CTSA Program hubs for opt-in and opt-out policy based on both legal constraints and best practices ○ Where less legal barriers exist, option to assemble a consensus examining how/why this can be done and alignment with Common Rule ○ Opt-in would require additional education ○ What metrics are utilized to measure success of the policies; what are those metrics? ○ Which one better facilitates research and supports autonomy? 	<p>Targeted areas CTSA Program hubs can improve</p> <p>Determine best practices for institutions to facilitate processes for researcher access to data</p>
NCATS Update	<p>NCATS updates will be recurring on meetings going forward. Christopher Austin provided an overview of the federal budget process.</p> <p>For any questions, please contact NCATS or your Program Officer.</p>	<p>SC to explore communication mechanisms to inform hubs</p>
Steering Committee Membership updates	<p>Thank you to departing Steering Committee members:</p> <p>Robert Clark – UT Health Science Center</p> <p>Sundeep Khosla – Mayo Clinic</p> <p>Harry Shamoon – Einstein-Montefiore</p>	

	<p>Welcome new Steering Committee members: Barry Collier – Rockefeller University Bradley Evanoff – Washington University of St. Louis Phil Kern – University of Kentucky</p>	
New DCI Staff Members	<p>Michael Gregory Kurilla – Director, Division of Clinical Innovation Valery Gordon – Trial Innovation Network, Program Director Pablo Cure – Program Officer Jane Atkinson – Director, Trial Innovation Network</p>	
<p>Discussion and Decisions of SC Structure (Brady)</p>	<p>Discussion on the value and importance of SC and PI calls and meeting frequency to disseminate ideas</p> <p>Discussion to articulate role of committee to accurately reflect functionality</p> <p>NCATS asking for input regarding K and T PI representation on PI calls</p> <ul style="list-style-type: none"> Should these call remain monthly? <p>Pod structure, function and frequency-</p> <ul style="list-style-type: none"> Would setting an agenda be more effective? Utilize Pods as task oriented? <p>Discussion on viable communication mechanisms from SC to PIs and Pods</p>	<p>SC calls to remain Executive sessions -</p> <p>PI Calls to remain monthly</p> <p>K, T, Co-PIs, and Multiple PIs to be included on PI calls</p> <p>Mobilize SC members to gather feedback from pods about the usefulness of the pod structure</p> <p>Create small ad-hoc group to focus on proposed communication model; will be an agenda item for January's call</p>