CTSA Clinical & Translational Science Awards Program

CTSA Program Steering Committee meeting
January 8, 2018, 2:30-4:00pm
Webinar

Steering Committee Attendees:

Christopher Austin	Robert Clark	Alan Green	Tim Murphy
Kathleen Brady	Barry Coller	Phil Kern	Reza Shaker
Ebony Bouleware	Bradley Evanoff	Donald Lloyd-Jones	Susan Smith
David Center	Dan Ford	George Mashour	Joel Tsevat

NCATS Attendees:

Mike Kurilla	Patricia Jones	Samantha Jonson	Erica Rosemond

Session	Summary Discussion	Action Item
Introduction of New Steering Committee Members (Coller, Evanoff, Kern)	Barry Coller- Rockefeller University • Functions as Physician in Chief at Rockefeller University Hospital, Vice President for Medical Affairs and serves as PI of CTSA Program hub Bradley Evanoff- Washington University, St Louis • Director of Division of General Medicine, practicing Internist, co-directed CTSA Program hub since 2007 inception and became director in 2010. He also serves on the Common Metrics committee Philip Kern- University of Kentucky • He serves as Associate Provost, practicing Endocrinologist and has been PI of CTSA Program hub since 2009	

NCATS Update (Austin)	NCATS updates will be recurring on meetings going forward. Christopher Austin provided an overview of the federal budget process. For any questions, please contact NCATS or your Program Officer.
	
	Senator Roy Blunt, head Appropriations Committee in the Senate, visited NCATS in late December. Goal of visit:
	• Inform Congress of other NCATS supported programs and initiatives in addition to the CTSA program
	• Generate enthusiasm about potential Biomedical Research to impact medical needs
	
	Key Dates:
	• NCATS Council and Cures Acceleration Network Review Board, January 11th, 8:30-3:00 PM ET
	• CTSI Program PI Town Hall Webinar, January 24th, 2-3:00 PM ET
	  ○ Open Forum format with Q & A from the floor
	  ○ Potential to occur regularly; could replace PI calls contingent on feedback
		Inform Congress about other components of NCATS
		
		SC to explore if Forum model will advance communication and programmatic goals for PIs

Clinicaltrials.Gov Presentation and Discussion (Reyes, White)	Clinical trials group evolved from a working group within the CTSA program to focus on Clinical Trials. After the release of the IOM report and streamlining committees, the group sustained a working relationship.	

	Highlights of presentation: • Institutional designated responsible party liable for daily fine and institution is at risk for losing all NIH funding ○ Not all institutions elect PIs as responsible party • Results must be reported within one year of completion of study, irrespective of publications and independent of IRB and federal guidelines enforced by NIH • Compliance response rates increased with inclusion of PI on email notices • Registering Investigators prior to patient enrollment could prevent noncompliance Discussion topics regarding Results Report Taskforce: • Support for FTE Biostatistician justified within certain institutions • Reporting could assist with reducing institutional risk and enhance quality of research • Potential for Clinicaltrials.gov to craft a "2.0" version to accommodate evolving demands • Tools embedded in IRB application to be disseminated to taskforce members at institutions to capture studies triggering FDAAA or NIH policy requirements • Behavioral Study designs can vary and education required due to delayed exposure • Registration could affect faculty whom do not associate themselves as clinical trial scientists • Cohesion of the CTSA Program and compliance group would be beneficial	Mobilize PIs and Study Coordinators to be proactive in meeting regulatory requirements? Schedule CT.gov presentation for consortium presentation.
Consent Workgroup Update (Brady)	Identified next steps: • Identifying resources for training clinical staff • Working with Collaboration & Engagement DTF in developing toolkit to support stakeholder engagement	Requesting ideas from SC around significant next steps
Opioid Workgroup Update (Brady)	Taskforce focusing on Opioid issue and response of CTSA Program hubs • Looking to develop a white paper by conducting a landscape analysis by identifying available networks at CTSA Program hubs • G. Mashour project: extension of best practices for surgeons for Opioid prescription • A. Green/K. Brady project: -data query of the phenotype of people admitted to EDs with Opioid overdose NIDA expressed interest in co-funding a portion of Collaboration Innovation Award (CCIA) Meeting between NIH and NIDA to discuss explicit needs not being met that the consortium could address.	List of potential projects will be posted to CLIC website Solicit CTSA Program Hub participation in projects
Communications Working Group update (Brady)	Taskforce mission: • To develop an efficient comprehensive multi-modal, multi-directional plan with synchronous and asynchronous components to optimize communication among NCATS, SC and PI group	Will post assembled Pod survey results on CLIC website