NCATS Improving Health Through Smarter Science

CTSA Program Steering Committee

Monday, December 11, 2017
2:30 – 4:00 (EDT)

CTSA Clinical & Translational Science Awards Program

National Center for Advancing Translational Sciences

Agenda

2:30	Welcome • Thank you to outgoing SC members	Kathleen Brady, Christopher P. Austin
2:30 – 2:45	Consent Workgroup Presentation and Discussion	Kathleen Brady, Becky Jerome
2:45– 3:00	Steering Committee Membership Update NCATS Update	Kathleen Brady Christopher P. Austin
3:00 – 4:00	Discussion and Decisions of SC Structure • SC/PI Meetings: o What frequency o Who attends o Soliciting feedback from PIs o How will changes be communicated to PIs • Pods: o Do they stay or go o If stay, what is frequency, how get all SC members committed to having them o If they go, what replaces them for PI's to get information from SC/NCATS	Discussion moderated by: Kathleen Brady

Consent Workgroup Presentation and Discussion

Kathleen Brady and Rebecca Jerome

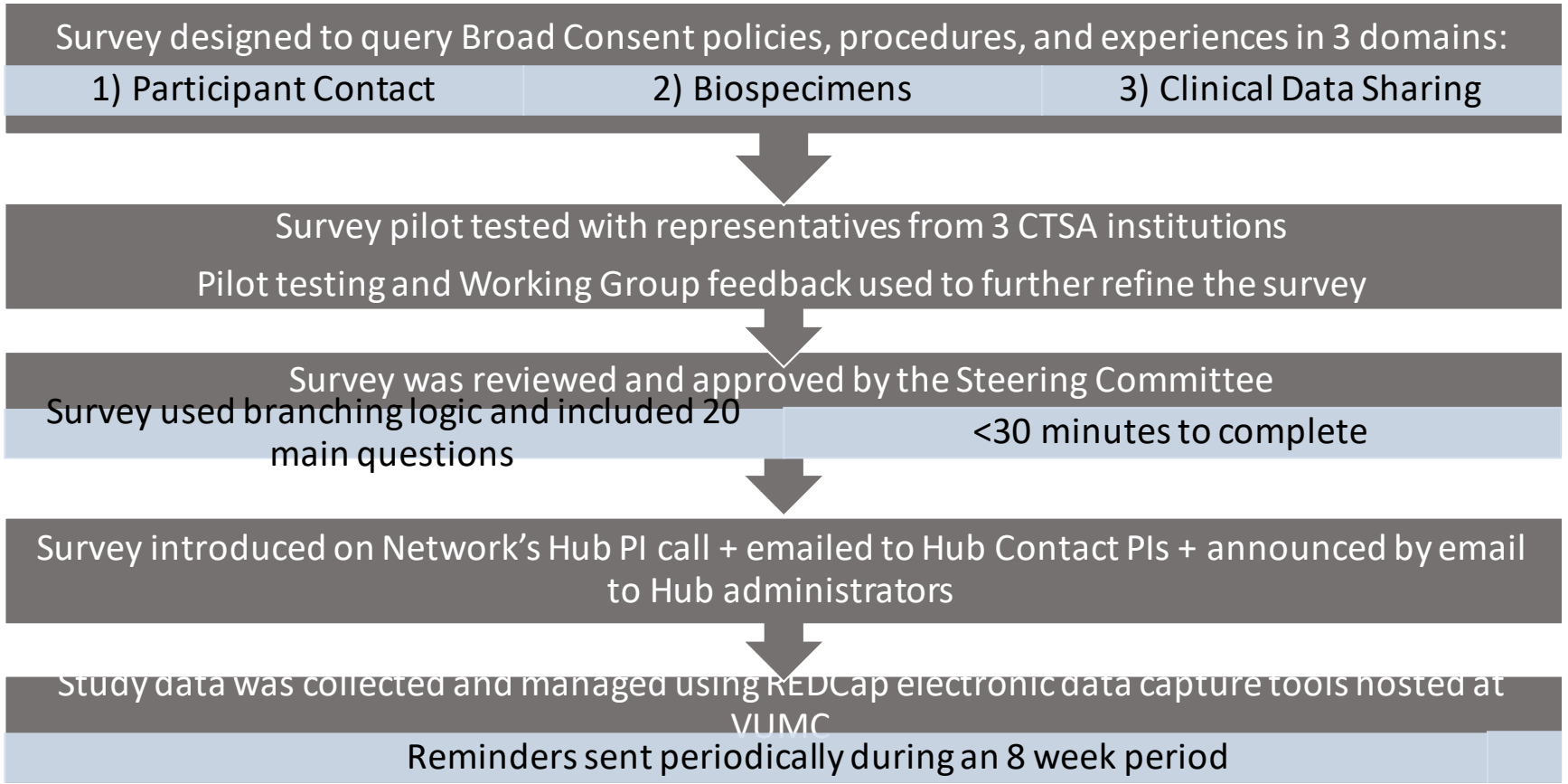
Broad Consent Working Group

Summary Update – December, 2017

Methods, Results and Potential Next Actions

Methods

CTSA Network Survey: Methods



Results

Results

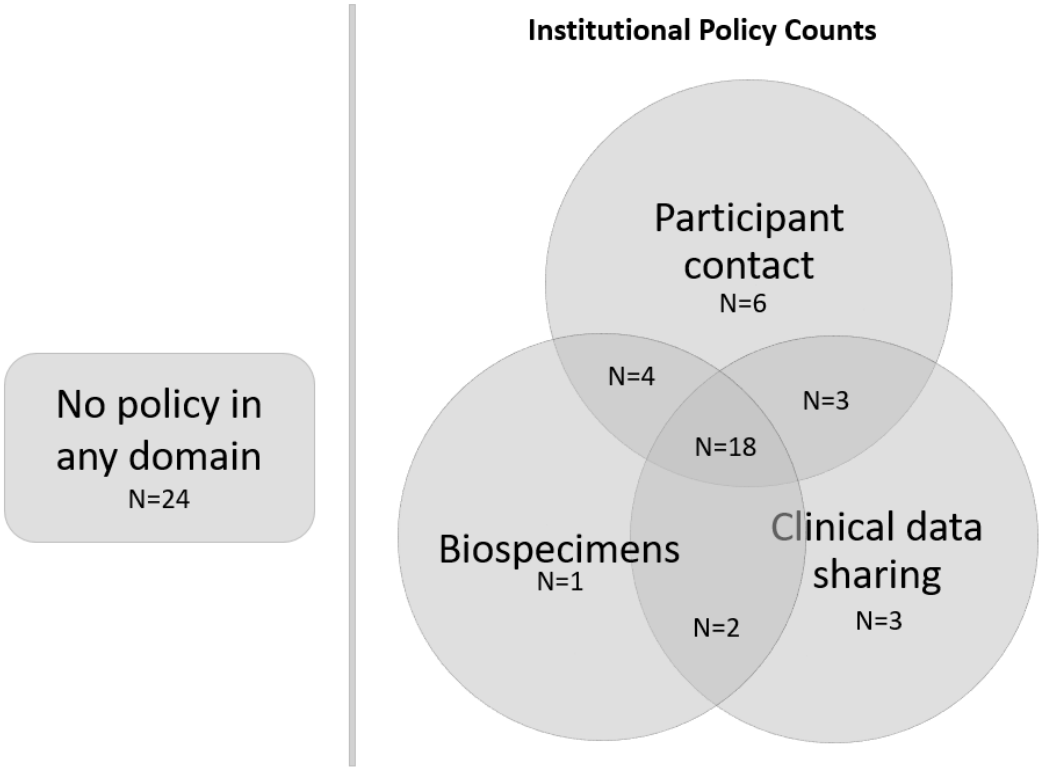
- 61 CTSA institutional Hubs (100%) responded to the survey over an invitation period of eight weeks
- CTSA Hubs were approximately equal in self-reporting as public- (N=31) or privately-funded (N=30) institution
- 37 Hubs responded ‘Yes’, ‘In-Progress’ or ‘Other’ to having a formal institutional policy for at least one of the three domains that constitute Broad Consent for this study

Results: Broad Consent Formal Policy Status

	Participant Contact	Biospecimens	Clinical Data Sharing
Yes	17	13	16
In Progress	13	10	8
Other*	1	2	2
No	30	36	35

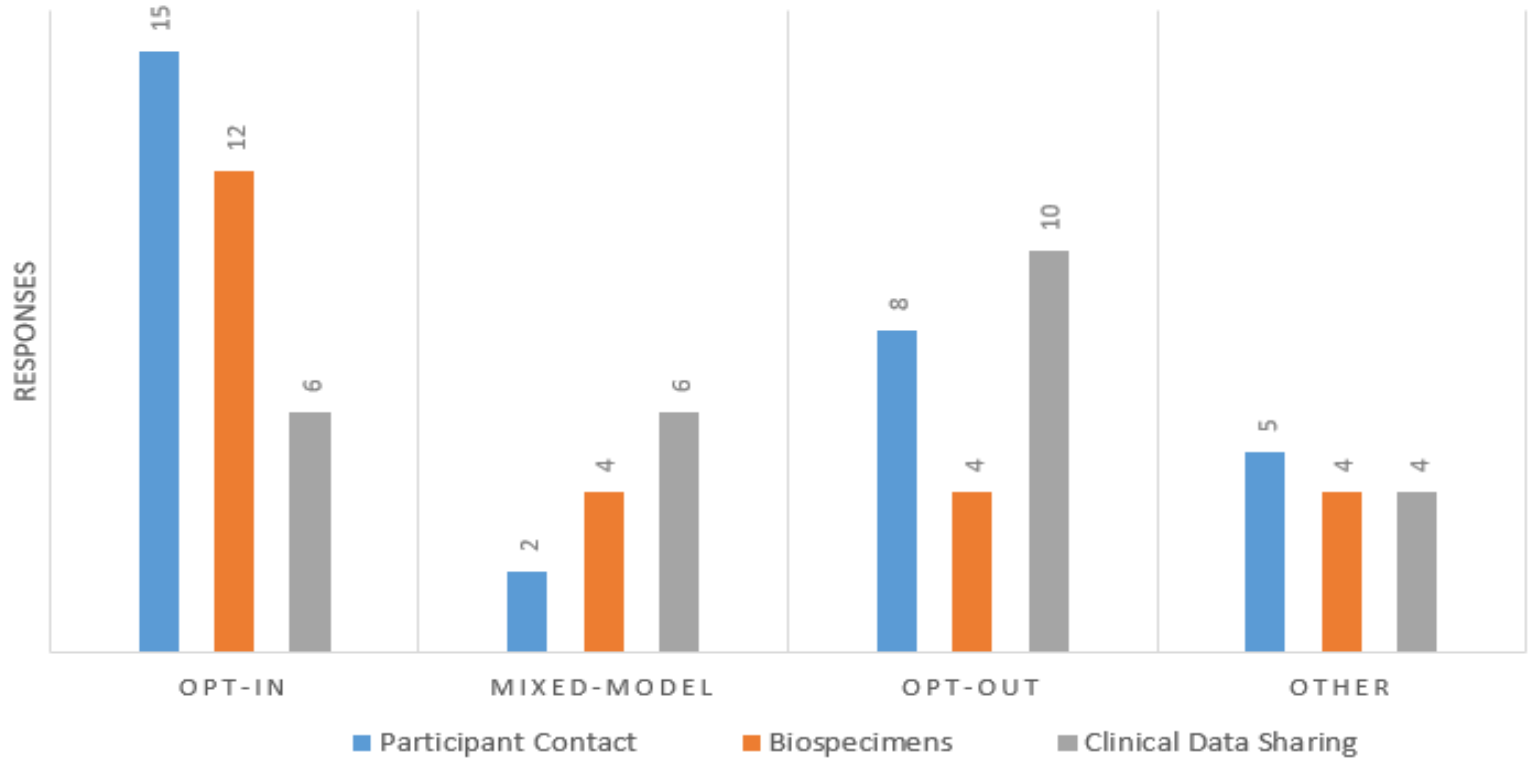
Qualitative assessment of 'Other' responses generally suggested that the Hub's guidance/practice ***derives not from direct engagement with broad consent but from an appropriation of practices associated with individual research studies (e.g., including within the informed consent document an option to grant the researchers permission to contact the signee regarding future research).

Overlap in domain-focused broad consent activities across the Hubs



Note: response counted as a “yes” if an institution answered Yes, In Progress or Other

Opt-in versus Opt-out Models



Provisions for Identified versus De-Identified Data

Response	Biospecimens (n=25 Hubs)	Clinical Data Sharing (n=26 Hubs)
De-identified storage/sharing only	10 (40%)	6 (23%)
Identified and de-identified storage/sharing allowed	12 (48%)	16 (62%)
'Other' or no response	3 (12%)	3 (12%)

Systems Utilization

Domain	Electronic Health Record	Patient Portal	Clinical Trial Management System (CTMS)	Billing System	Other
Participant Contact (N=31)	71%	58%	23%	0	29%
Biospecimens (N=25)	52%	32%	20%	0	40%
Clinical Data Sharing (N=26)	77%	19%	23%	0	27%

Alignment Between Broad Consent Practices and the Common Rule

Response	Participant Contact (N)	Biospecimens (N)	Clinical Data Sharing (N)
Very Closely	5	11	5
Somewhat Closely	7	5	4
Not Very Closely	3	3	3
Not Sure	11	5	9
No Response	5	1	5

Alignment Between Broad Consent Policy and Practice

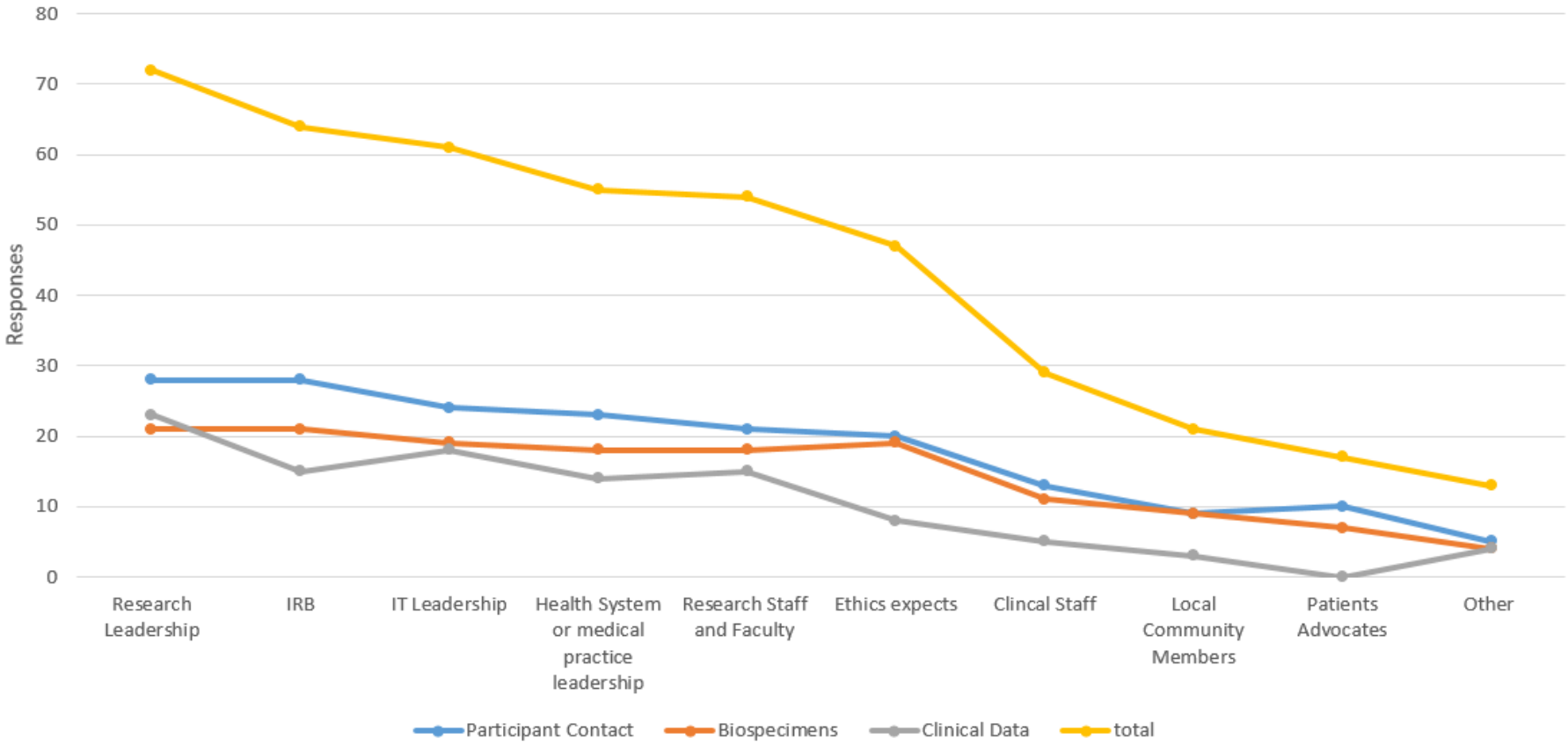
- Hubs with broad consent were asked to rate alignment between policy and practice at their institution, ranging from 0 (Policy Not Yet Implemented) to 100 (Matches Policy Very Closely)

- Alignment ratings for the 3 broad consent domains included:
  - Participant contact: median = 86.5, range 51-100
  - Biospecimens: median = 76.5, range 1-100
  - Clinical data sharing: median 89.5, range 0-100

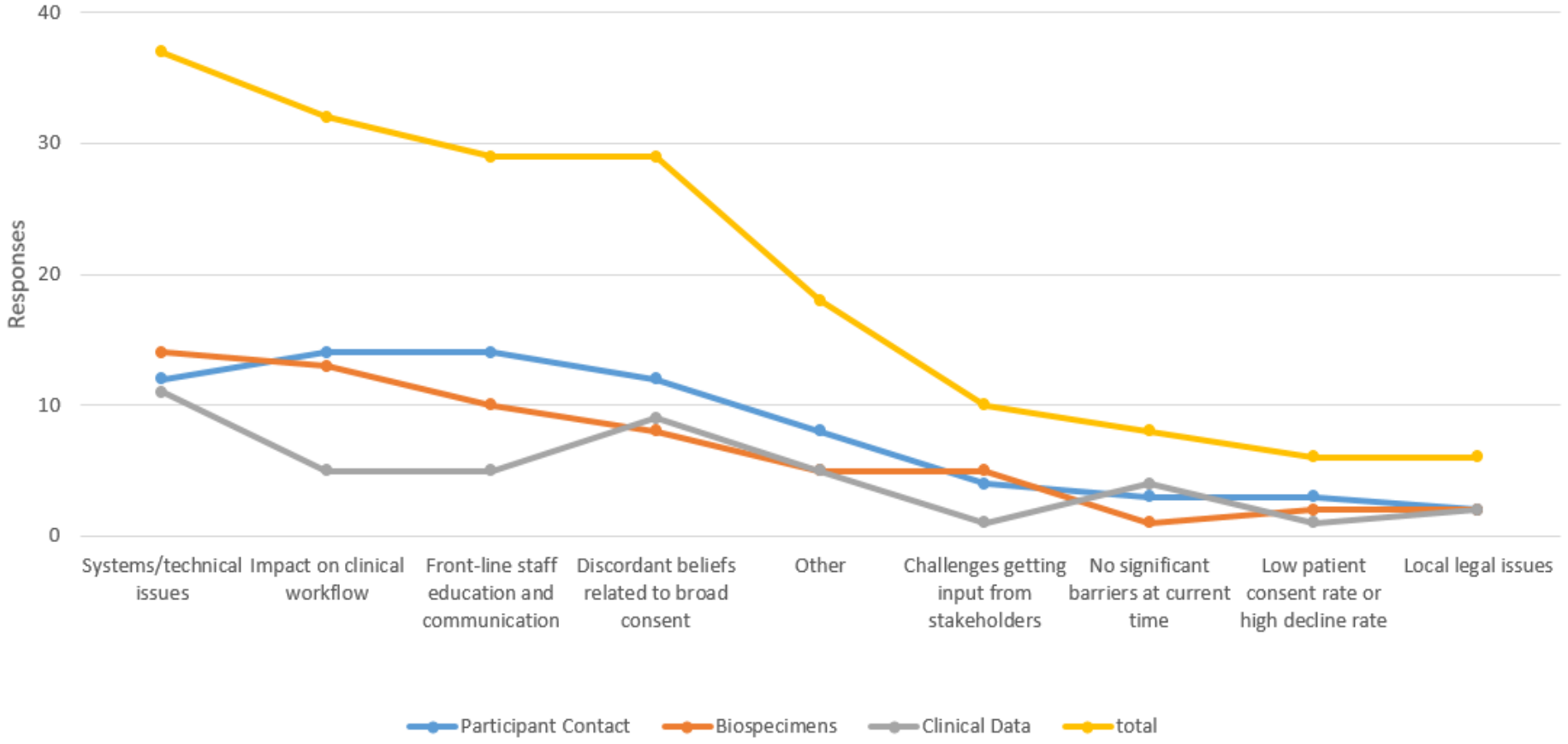
Path for Researcher Access to Data

- Hubs were also asked to rate the clarity of their institution's process for researcher access to data, ranging from 0 (not very clear or well understood path) to 100 (very clear and well understood path)
- Hubs rated this process at a median of 51.5 (range 0-100)
- Accompanying qualitative data indicated institutions could improve researcher knowledge about their evolving capacity to access data.

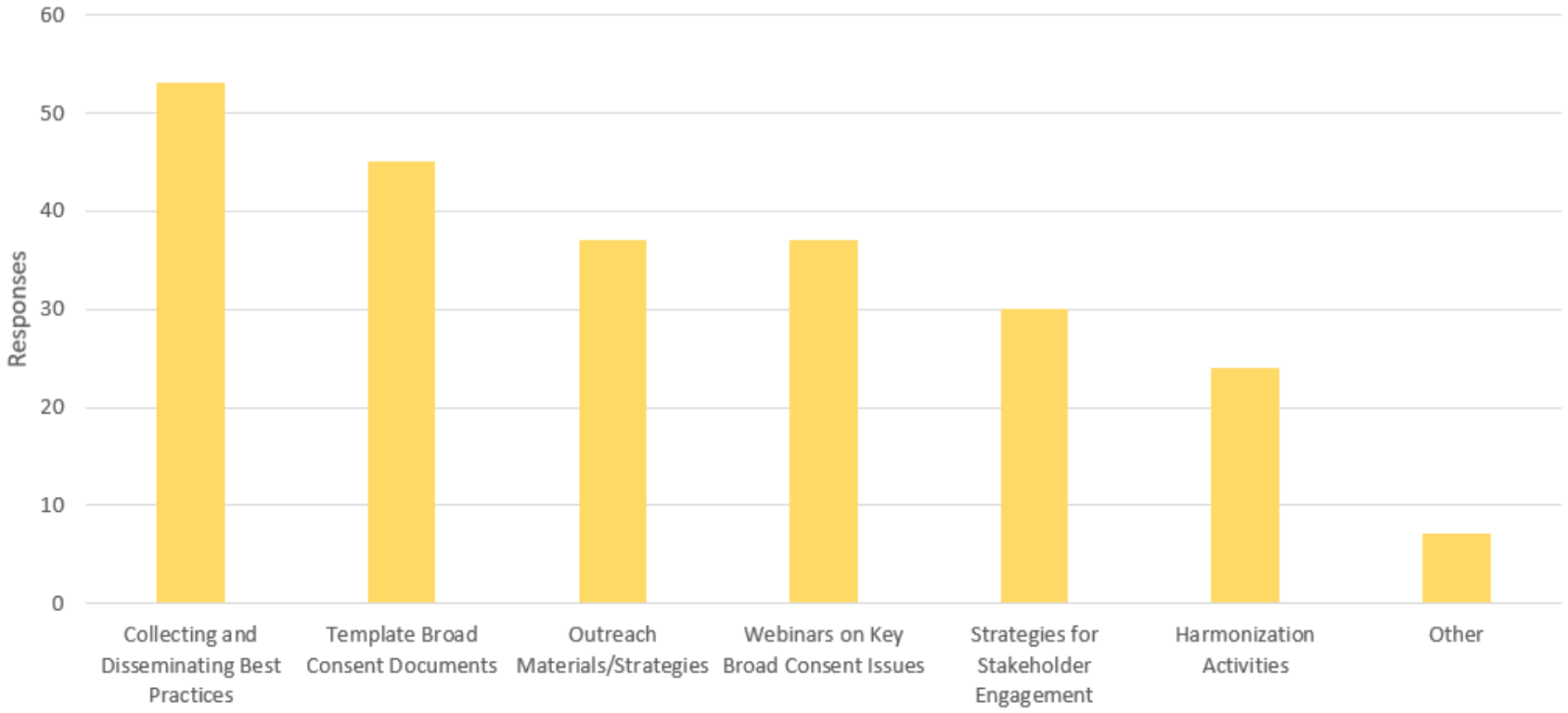
Key informants and/or drivers of broad consent policies and practices



Key barriers for implementation of broad consent policies and practices



Areas in which the CTSA Network could help facilitate broad consent policies and/or implementation



Potential Next Actions

IDEAS FOR FUTURE NETWORK INITIATIVES

Near term activities

- Peer reviewed article on process and survey landscape analysis conducted by Working Group
- Present highlights on CTSA PI call
- TIN webinar discussing results + Q&A
- Adapting existing broad consent examples to a template form for use at different institutions: considering using policies submitted during survey as foundation
- TIN webinar with ~2 institutions with success in broad consent to share their process and lessons learned + Q&A
- In parallel with approaching Common Rule changes, conversations with OHRP and FDA on next steps and guidance, including opportunities for CTSA sites to share specific questions to help inform these discussions
- Identify resources and trainings for clinic staff to consent potential participants.

Longer term activities

- Decision algorithm for when it makes sense/doesn't make sense for an institution to adopt broad consent
- Materials to support patient understanding of what broad consent means and entails
  - PSA type content
  - Informed consent issues; engagement issues e.g. presenting opt-in in a way that sets participant up to be receptive when they are called for a future opportunity
- Toolkit/materials/approach to support stakeholder engagement, with components targeted at different kinds of stakeholders e.g. patients, IT leadership, legal, etc.
- Funding development and evaluation activities related to broad consent e.g. developing, piloting, evaluating novel consent processes, approaches for stakeholder engagement, return of results strategies, etc.

Acknowledgements

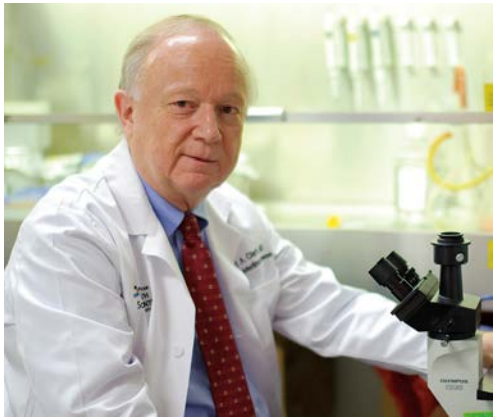
Vanderbilt University: administered and analyzed survey

Participating CTSA Hub Sites included: Albert Einstein College of Medicine, Boston University Medical Campus, Case Western Reserve University, Children's National Medical Center, Columbia University, Dartmouth University, Duke University, Emory University, Georgetown University, Harvard Medical School, Icahn School of Medicine at Mount Sinai, Indiana University-Purdue University at Indianapolis, Johns Hopkins University, Mayo Clinic, Medical College of Wisconsin, Medical University of South Carolina, New York University School of Medicine, Northwestern University, Oregon Health Sciences University, Pennsylvania State University, Rockefeller University, Scripps University, Stanford University, SUNY Buffalo, The Ohio State University, Tufts University, University of Alabama Birmingham, University of California Davis, University of California Irvine, University of California Los Angeles, University of California San Diego, University of California San Francisco, University of Chicago, University of Cincinnati, University of Colorado Denver, University of Florida, University of Illinois at Chicago, University of Kansas Medical Center, University of Kentucky, University of Massachusetts Med School Worcester, University of Miami, University of Michigan, University of Minnesota, University of New Mexico, University of North Carolina Chapel Hill, University of Pennsylvania, University of Pittsburgh, University of Rochester, University of Southern California, University of Texas Health Science Center Houston, University of Texas Health Science Center San Antonio, University of Texas Med Br Galveston, University of Texas Southwestern, University of Utah, University of Washington, University of Wisconsin-Madison, Vanderbilt University, Wake Forrest, Washington University, Weill Cornell Medical Center, Yale University

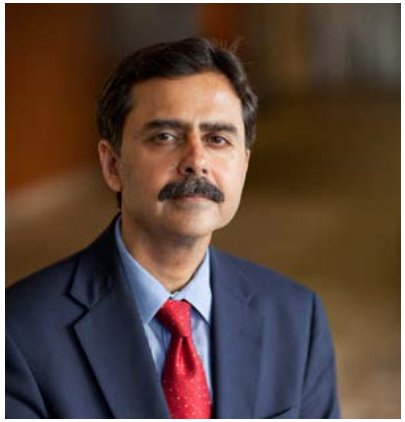
Steering Committee Membership Update

Kathleen Brady

Thank you!



Robert Clark, M.D.
UT Health Science Center



Sundeep Khosla, M.D.
Mayo Clinic

Harry Shamoon, M.D.
Einstein-Montefiore

Invitations Sent to New Steering Committee Members

Barry Coller, M.D.
Rockefeller University

Bradley Evanoff, M.D., M.P.H.
Washington University of St. Louis

Phil Kern, M.D.
University of Kentucky

NCATS Update

Christopher P. Austin

New DCI Staff Members

Michael Gregory Kurilla, M.D., Ph.D.
Director, Division of Clinical Innovation
Start: December 10

Jane Atkinson, D.D.S.
Director, Trial Innovation Network
Start: December 10

Pablo Cure, M.D., M.P.H.
Program Officer
Start: November 29

Valery Gordon, Ph.D., M.P.H.
Trial Innovation Network, Program Director
Start: November 13

FY 2018 Budget

- FY2018 President's Budget request: May 23, 2017
  - NIH: $25.9 billion (reduction of $5.8 billion)
- FY2018 Appropriation bills
  - House and Senate Appropriations committees each passed a Labor, HHS, and Education bill
  - Neither bill was voted on by the full chamber
- FY2018 began October 1, 2017
  - Operating since Oct 1 under a Continuing Resolution (CR), which extends government funding at FY2017 level
  - CR – Runs through Dec 22

Discussion and Decisions of SC Structure

- SC/PI Meetings:
  - What frequency
  - Who attends
  - Soliciting feedback from PIs
  - How will changes be communicated to PIs

- Pods:
  - Do they stay or go
  - If stay, what is frequency, how get all SC members committed to having them
  - If they go, what replaces them for PI's to get information from SC/NCATS

Happy Holidays!

Next Call: January 8, 2018 2:30 – 4:00 ET