CTSA Program Steering Committee

Monday, January 8, 2018
2:30 – 4:00 (EDT)
## Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:30</td>
<td>Welcome</td>
<td>Kathleen Brady, Christopher P. Austin</td>
</tr>
<tr>
<td>2:32 – 2:45</td>
<td>Introduction of New Steering Committee Members (2x min each)</td>
<td>New Members</td>
</tr>
<tr>
<td></td>
<td>• Barry Coller (Rockefeller University)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Bradley Evanoff (Washington University of St. Louis)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Phil Kern (University of Kentucky)</td>
<td></td>
</tr>
<tr>
<td>2:45 – 3:00</td>
<td>NCATS Update</td>
<td>Christopher P. Austin</td>
</tr>
<tr>
<td></td>
<td>• Continuing Resolution Update</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Senator Roy Blunt’s (MO) Visit to NCATS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Jan 24(^{th}) CTSA Program PI Call Town Hall</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Jan 11(^{th}) NCATS Council</td>
<td></td>
</tr>
</tbody>
</table>
| 3:00 – 3:30 | Clinicaltrials.Gov Presentation and Discussion                         | Anthony Keyes<br><i>Johns Hopkins University</i> 
Sarah White<br><i>Partners Healthcare</i> |
| 3:30 – 3:35 | Consent Workgroup Update                                              | Kathleen Brady                                                |
|         | • Consent Workgroup presented their work last month. See slides from that presentation [here](#) |                                                               |
| 3:35 – 3:50 | Opioid Workgroup Update                                               | Kathleen Brady                                                |
| 3:50 – 3:55 | Communications Workgroup Update                                       | Kathleen Brady                                                |
| 3:55 – 4:00 | Topics from the floor                                                  | All                                                           |
Welcome 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
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
    • 1st CR – Ran through Dec 8
    • 2nd CR – Ran through Dec 22
    • 3rd CR – Runs through Jan 19
Senator Roy Blunt’s Visit to NCATS

Touring NIH’s @ncats_nih_gov today w/ @RoyBlunt. This robot arm has utterly changed how we screen compound libraries for potential treatments. It would take a human 12 years to do what this robot can do in 1 week: bit.ly/2oTtJju
Important Dates

• NCATS Council and Cures Acceleration Network Review Board
  • Jan. 11, 8:30 – 3 PM ET
  • CTSA Program updates feature Steering Committee rotations and October 25 – 27 CTSA Program Meetings
  • CTSA Program PIs on Council
    • Harry Selker (Tufts University)
    • Anantha Shekhar (Indiana University)
    • Eric Topol (Scripps University)
  • Watch live here: https://videocast.nih.gov/summary.asp?live=26930&bhcp=1

• CTSA Program PI Town Hall Webinar
  • Jan. 24, 2 – 3 PM ET
  • A RedCap survey will be distributed to the consortium this week
  • In the meantime, send your ideas to Samantha.Jonson@nih.gov
ClinicalTrials.Gov Presentation

Anthony Keyes
Johns Hopkins University

Sarah White
Partners Healthcare
Clinicaltrials.gov Program

Presentation to CTSA

January 8, 2018

Anthony Keyes, MBA, PMP
Program Manager, Clinical Research Projects
Institute for Clinical and Translational Services (ICTR)

Prince Nuamah, MD
Clinical Research Compliance Specialist
ICTR

Nidhi Atri, MD
Clinical Research Compliance Specialist
ICTR
Registration and Reporting Requirements

Why Register and Report?

– Commitment to research participants
– Scientific validity/transparency
– Ethical standards
– Responsible stewardship of federal funds
– Help IRB assess value of new studies
– Required by law (FDAAA)
– Required for journal publication (ICMJE)
– Required by NCI
– Required for CMS
– Required by WHO
– Bill and Melinda Gates and several other foundations
Key Components of the Final Rule

– NIH now requires submission of full protocol and statistical analysis plan at the same time as submission of results information.
  • This includes any study with a Primary Completion Date on or after January 18th, 2017.
  • Limited redaction opportunities in the required format
– Allowance for direct cost to be included in grants ($2,000 line item per study)
Penalties Outlined in the Final Rule

• Under FDAAA an organization can be fined $11,569 per study/per day with late results
  – https://www.federalregister.gov/documents/2017/02/03/2017-02300/annual-civil-monetary-penalties-inflation-adjustment

• NIH can withhold funding to organizations that are out of compliance
  – Francis Collins, NIH Director, published a viewpoint in JAMA with the following quote, “In addition, NIH will withhold clinical trial funding to grantee institutions if the agency is unable to verify adequate registration and results reporting from all trials funded at that institution.”
Deadline for Updating Record

- Within 30 calendar days
  - Study start date
  - Overall recruitment status
  - Individual site status
  - Intervention name(s)
  - IRB status
  - Primary and/or Study Completion Date
  - Contact Information

Update Requirements

When to update a study in-process?

• While Study is In-Process:
  – The record must be updated within 30 days of a change to:
    • Recruitment Status -
      - Not yet recruiting
      - Recruiting
      - Enrolling by invitation
      - Active, not recruiting
      - Completed
      - Suspended
      - Terminated (Halted Prematurely)
      - Withdrawn (No Participants Enrolled)
  – Record Verification Date must be updated at least every 12 months, even if no changes to the study
  – Need to update ends when the study is completed/terminated and results are entered, approved and posted

Update Requirements

When to respond to comments?

• Registration and while Study is In-Process:
  – Must respond to PRS comments to correct errors, deficiencies and/or inconsistencies within 15 calendar days*

• Results reporting:
  – Must respond to PRS comments to correct errors, deficiencies and/or inconsistencies within 25 calendar days*

*Per NIH Final Rule released 09/16/16
When to submit Basic Results?

• No later than 12 months after (Primary) Completion Date.

• **Primary Completion Date** **FDAAA** [Required for records first released on or after December 1, 2008]
  – Date that the final subject was examined or recvd an intervention for purposes of final data collection for the primary outcome, whether the trial concluded per protocol or was terminated.
  – Must keep this field accurate in clinicaltrials.gov since it’s how NIH determines the timeliness of basic results reporting

• **Study Completion Date**
  – Final date on which data was (or is expected to be) collected.

Source: [https://prsinfo.clinicaltrials.gov/definitions.html#PrimaryCompletionDate](https://prsinfo.clinicaltrials.gov/definitions.html#PrimaryCompletionDate)
Practical Application

How long will it take to..

• Register a Trial?
  – ClinicalTrials.gov estimates up to 10 hours

• Submit Basic Results?
  – ClinicalTrials.gov estimates up to 50 hours
  – Highly variable based on study specifics
  – Tables cannot be copy/pasted from publication
  – May need statistical assistance
  – ClinicalTrials.gov will assist if needed
Protocol Information Review Process

<table>
<thead>
<tr>
<th>PI/Study Team</th>
<th>PRS Administrator reviews record for completeness and adherence to policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>JHU ClinicalTrials.gov Program</td>
<td>Errors in the record?</td>
</tr>
<tr>
<td></td>
<td>Yes → PRS Administrator sends comments to “Record Owner”</td>
</tr>
<tr>
<td></td>
<td>No → PRS Administrator marks record as “Approved” and then “Released”</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ClinicalTrials.gov</th>
<th>PRS Reviewer reviews record for completeness and adherence to policy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Errors in the record?</td>
</tr>
<tr>
<td></td>
<td>Yes → PRS Reviewer sends comments to “Record Owner” and PRS Administrator</td>
</tr>
<tr>
<td></td>
<td>No → NCT Number assigned</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Public</th>
<th>2-5 days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Record available to the public for information and recruitment</td>
</tr>
</tbody>
</table>
Clinicaltrials.gov Program Highlights

• **Staffing**
  – 2.5 FTEs, soon increasing to 3.5.

• **For the PI/Study team, assistance with...**
  – Registration
    • Account creation and maintenance
    • Initial registration
      – Required for Applicable Clinical Trials
      – NEW*: required for any clinical trial receiving *full or partial NIH funding*
    • PRS reviewer comments (now time-limited to 15 calendar days*)
    • Update reminders (required every 12 months regardless of changes)
    • Changes to PI/Study team (including when a PI leaves)
    • Per policy, the Sponsor, JHU is the responsible party. This enables us to provide internal review for all studies before they are submitted
Communication Process for Noncompliant Studies

1.) The Program maintains a detailed database of all studies.

2.) The Program will inform the PI, central contact, and record owner via e-mail #1 when a study needs attention.

3.) If no response to the initial communication, a follow-up e-mail #2 will be sent with carbon copies to both Division/Department Director and Assistant Administrator.

4.) At this point, if no action has been made, e-mail #3 will be sent with carbon copy to Dr. Daniel Ford.
Clinicaltrials.gov Program Highlights

• For the PI/Study team, assistance with...
  – Results Reporting
    • Results reporting reminders (due 12 months after *primary completion date*)
    • Assistance with results reporting
    • Assistance with PRS reviewer comments (now time-limited to 25 calendar days**)
    • Changes to PI/Study team (including when a PI leaves)
    • Direct services at $50 per hour (optional)
    • 1 hour of statistical support provided free of charge

* Final data collection date for primary outcome measure.

**Per NIH Final Rule released 09/16/16
Internal Collaborations

IRB

• Updated Clinical Trials section of the application to create uniformity
• Program staff have “View only” access to all records in eIRB2 and archives
• Updated *Johns Hopkins School of Medicine Organization Policy on Registration of Clinical Trials* to be in accordance with the FDA Final Rule
• Pulled paper records from off-site storage to enable results reporting for older studies (JHM Policy is to retain records for at least 7 years)
• Created ability to run reports for changes in PI, studies which have been terminated, and studies which are identified as Clinical Trials, but have no NCT registration number

1/8/2018
Internal Collaborations

CRMS

• Generated a list of all studies that have begun enrollment but do not have an NCT number in neither eIRB nor CRMS
  – Any internal system which tracks actual participant enrollment can be used to ensure FDA and ICMJE guidelines and regulations are followed

• Receiving weekly reports for these studies and assisting PIs with compliance
Increasing Compliance – Decreasing Liability

Results Expected and Results Late in Johns Hopkins University SOM PRS Account

Average days in review (initial submission to public release) = 74
Challenges

- High turnover among research staff
- Older records
- Lack of awareness of ethical and legal implications
- Lack of internal monitoring prior to program launch
- Lack of communication and formal exit procedures for PIs and study team members leaving the institution
- Competing academic, research, & clinical responsibilities among PIs
- Data stewardship (especially when PIs leave)
- Lack of training and/or statistical knowledge
- Lack of incentive
- Lack of perceived value
Regulatory Bodies

- Per FDAAA, the Responsible Party for an Applicable Clinical Trial must submit required clinical trial information through the Protocol Registration and Reporting System (PRS) no later than 21 days after enrollment of the first participant.
- Per FDAAA, results reporting must be no later than one year after primary completion date.
- Potential monetary penalty of $11,569 for noncompliance per day, per study.
- As of January 2017 requires registration and results reporting for all clinical trials receiving funding.
- Can withhold grant funding for investigators and institutions that are noncompliant.
Trials that meet the clinical trial definition of The International Committee of Medical Journal Editors (ICMJE) that the investigator may wish to publish, must register the study on ClinicalTrials.gov prior to enrollment of the first participant.

Qualifying clinical trials which will render claims for items and services to the Center for Medicare and Medicaid Services (CMS). The National Clinical Trial (NCT) number must be included on claims for items and services provided in clinical trials that are qualified for coverage.

Signatories to the May 18, 2017 WHO, International Clinical Trials Registry Platform (ICTRP) such as the Bill and Melinda Gates foundation requires registration and results reporting of our grantees.
Select References

- ACT Wizard: http://grants.nih.gov/clinicaltrials_fdAAA/docs/Flow_chart-ACT_only.pdf
- Clinicaltrials.gov history: https://www.clinicaltrials.gov/ct2/about-site/history
- Clinicaltrials.gov homepage: https://www.clinicaltrials.gov/
- Clinicaltrials.gov FAQ: https://clinicaltrials.gov/ct2/manage-recs/faq
- FDA Guidance on Form FDA 3674: http://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm
- HHS takes steps to provide more information about clinical trials to the public: https://www.nih.gov/news-events/news-releases/hhs-takes-steps-provide-more-information-about-clinical-trials-public
Select References – Final Rule

- Federal Register Notice: HHS Final Rule
- Federal Register Vol. 81, No 183, September 21, 2016
- Federal Register Notice: NIH Policy
- Summary Table: HHS Final Rule and NIH Policy
- Summary of Changes: HHS Final Rule and NIH Policy
- JAMA: Toward a New Era of Trust and Transparency in Clinical Trials
- NEJM: The Final Rule for US Clinical Trial Registration and Results Information Submission
- NIH Director’s Blog: Clinical Trials – Sharing of Data and Living Up to Our End of the Bargain
- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
Select Publications

- Gopal AD, Desai NR, Tse T, Ross JS. Reporting of noninferiority trials in ClinicalTrials.gov and corresponding publications. JAMA. 2015 Mar 17;313(11):1163-
Clinical Trials Registration and Results Reporting Taskforce

Sarah White, MPH
swhite12@partners.org
Director, Quality Improvement Program – Partners Healthcare
Chair, National Clinical Trials Registration and Results Reporting Taskforce
1/8/18
Clinical Trials Registration and Results Reporting Taskforce

- **Membership**: Academic medical centers, universities, hospitals
  - Started as taskforce of the NCATS CTSA consortium; currently receive support from Harvard Catalyst (WebEx line, admin support)
  - Taskforce members are institutional resources responsible for oversight and administration of ClinicalTrials.gov registration and results reporting (100+ attendees on monthly calls)

- **Focus**: Domestic clinical trials registration and results reporting requirements

- **Objectives**:
  - Identify best practices
  - Develop tools for regulatory support and investigators
  - Serve as a communication forum
Clinical Trials Registration and Results Reporting Taskforce

Examples of our work:

- Template presentation slides (registration & results reporting)
- Template questions to identify Applicable Clinical Trials and trials triggering NIH policy (in eIRB application)
- Administration and oversight benchmark survey
- Guidance on how to manage relocation of the Responsible Party
- Sample job descriptions
- Manual of considerations for protocol redaction prior to posting
- Forum for feedback to ClinicalTrials.gov staff
# Taskforce – Member Institutions

<table>
<thead>
<tr>
<th>Institution</th>
<th>Institution</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Association of American Medical Colleges (AAMC)</td>
<td>Mayo Clinic</td>
<td>University of Kansas Medical Center</td>
</tr>
<tr>
<td>Beaumont Health</td>
<td>Medical University of South Carolina</td>
<td>University of Kentucky</td>
</tr>
<tr>
<td>Beth Israel Deaconess Medical Center</td>
<td>Miami Children’s Research Institute</td>
<td>University of Miami</td>
</tr>
<tr>
<td>Boston Children’s Hospital</td>
<td>Moffit Cancer Center and Research Institute</td>
<td>University of Michigan</td>
</tr>
<tr>
<td>Brigham and Women’s Hospital</td>
<td>Nationwide Children’s Hospital</td>
<td>University of Michigan, Comprehensive Cancer Center</td>
</tr>
<tr>
<td>Boston Medical Center</td>
<td>New York University School of Medicine</td>
<td>University of North Carolina, Chapel Hill</td>
</tr>
<tr>
<td>Boston University Medical Campus</td>
<td>New York University Langone Medical Center</td>
<td>University of Oklahoma Health Sciences Center</td>
</tr>
<tr>
<td>Broward Health</td>
<td>Northwestern University</td>
<td>University of Pennsylvania</td>
</tr>
<tr>
<td>Brown University</td>
<td>Ohio State University</td>
<td>University of Pittsburgh</td>
</tr>
<tr>
<td>Cambridge Health Alliance</td>
<td>Ohio State Cancer Center</td>
<td>University of Pittsburgh Cancer Institute</td>
</tr>
<tr>
<td>Cancer Treatment Center’s of America</td>
<td>Oregon Health and Science University</td>
<td>University of Rochester</td>
</tr>
<tr>
<td>Cedars-Sinai Medical Center</td>
<td>Palmetto Health</td>
<td>University of South Florida</td>
</tr>
<tr>
<td>Children’s Hospital of Philadelphia</td>
<td>Partners Healthcare</td>
<td>University of Texas Health Science Center at Houston</td>
</tr>
<tr>
<td>Children’s National Health System</td>
<td>Pennsylvania State University College of Medicine</td>
<td>University of Texas Medical Branch, Galveston</td>
</tr>
<tr>
<td>Children's Mercy Kansas City</td>
<td>Radford University</td>
<td>University of Texas Health Science Center at San Antonio</td>
</tr>
<tr>
<td>Cleveland Clinic</td>
<td>Rockefeller University</td>
<td>University of Texas Southwestern</td>
</tr>
<tr>
<td>Columbia University Medical Center</td>
<td>Roger Williams Medical Center</td>
<td>University of Texas MD Anderson</td>
</tr>
<tr>
<td>Dana Farber Cancer Center</td>
<td>Rutgers, The State University of New Jersey</td>
<td>University of Utah</td>
</tr>
<tr>
<td>Dartmouth Medical Center</td>
<td>Stanford University</td>
<td>University of Vermont, Lamer College of Medicine</td>
</tr>
<tr>
<td>Duke University</td>
<td>State University of New York, College of Optometry</td>
<td>University of Virginia</td>
</tr>
<tr>
<td>Emory University</td>
<td>Texas Tech University Health Sciences at El Paso</td>
<td>University of Wisconsin-Madison</td>
</tr>
<tr>
<td>Fred Hutchinson Cancer Center</td>
<td>University of Arkansas for Medical Sciences</td>
<td>US Department of Veteran Affairs</td>
</tr>
<tr>
<td>Georgetown University</td>
<td>University of California, Davis</td>
<td>Vanderbilt University</td>
</tr>
<tr>
<td>Hackensack Meridian Health</td>
<td>University of California, Irvine</td>
<td>Virginia Commonwealth University</td>
</tr>
<tr>
<td>Harvard Catalyst</td>
<td>University of California, Los Angeles</td>
<td>Wake Forest School of Medicine</td>
</tr>
<tr>
<td>Harvard Longwood Medical Area Schools</td>
<td>University of California, San Francisco</td>
<td>Weill Cornell Medical College</td>
</tr>
<tr>
<td>Houston Methodist Research Institute</td>
<td>University of Cincinnati</td>
<td>Winship Cancer Institute of Emory University</td>
</tr>
<tr>
<td>Icahn School of Medicine, at Mount Sinai</td>
<td>University of Colorado, Anschutz Medical Campus</td>
<td>Yale University</td>
</tr>
<tr>
<td>Indiana University</td>
<td>University of Colorado, Denver</td>
<td>University of Illinois at Chicago</td>
</tr>
<tr>
<td>Johns Hopkins University School of Medicine</td>
<td>University of Connecticut Health Center</td>
<td>University of Iowa</td>
</tr>
<tr>
<td>Massachusetts Eye and Ear Infirmary</td>
<td>University of Florida</td>
<td>University of Iowa</td>
</tr>
<tr>
<td>Massachusetts General Hospital</td>
<td>University of Illinois at Chicago</td>
<td>University of Iowa</td>
</tr>
<tr>
<td>Massachusetts General Hospital Cancer Center</td>
<td>University of Iowa</td>
<td>University of Iowa</td>
</tr>
</tbody>
</table>
Special Project:
Increasing compliance with clinical trial reporting requirements at academic medical centers

*Led by:* Dr. Evan Mayo-Wilson, Johns Hopkins Bloomberg School of Public Health

**Collaborators:**
- JHU-CERSI
- JHU-Institute for Clinical and Translational Research
- Yale University
- Partners Healthcare
- Harvard Catalyst
- National Clinical Trials Registration and Results Reporting Taskforce

**Funding:** U.S. Food and Drug Administration (FDA), National Center for Research Resources and the National Center for Advancing Translational Sciences
Survey of PRS administrators

How do academic organizations support research transparency?

1. Policies and procedures
2. Staff
3. Material resources (e.g., electronic management systems)

- Survey took place November 2016 to March 2017
- 783 accounts on ClinicalTrials.gov
  - “Active”
  - “University/Organization”
  - In the U.S.
- 366 (47%) participants partially or fully completed the survey
- Of ~50,000 records, participants are responsible for over 40,000 (>80%)
Results

- ~40% of organizations have policies regarding registration and results reporting
- 18% use computer software to manage their records (2 connect directly with ClinicalTrials.gov)
- PIs are normally responsible for determining whether trials must be registered and reported
- Some PRS administrators:
  - Provide training
  - Enter results
  - Notify PIs about problems with records
- Large organizations more likely to have a policy and resources compared with small organizations
Current study aims (qualitative study)

- Highlight challenges for registration and results reporting
- Identify ways some organizations have overcome those challenges
- Share tools that help academic organizations register and report trials
  - Policies, checklists, manuals of procedures
  - Slides, websites, and other training materials
  - Database templates, programs, code
Current study Interview questions

(1) How do you decide and monitor whether trials are registered and reported?

(2) What resources are used to support trial registration and results reporting?

(3) What has been most influential in helping you and your organization register and report clinical trials?

(4) What are some of the challenges you and your colleagues had to overcome? Were you able to overcome them?

(5) What advice would you give colleagues at other organizations that want to increase their levels of registration and reporting?
If you or your colleagues are willing to be interviewed, contact

Dr. Evan Mayo-Wilson
evan.mayo-wilson@jhu.edu

We want to hear from many stakeholders, including:

- Organization leaders / policymakers
- IRB staff
- PRS administrators
- Investigators
- Other people you suggest!
Prioritize Public & Community Awareness of Research Opportunities & potential of Return of Value

Trials Today at researchmatch.org

19,444 recruiting studies registered on ClinicalTrials.gov looking for volunteers
3,486 sponsors organizations looking for volunteers
2,416 medical conditions

To end disease tomorrow, begin with Trials Today.

Thousands of organizations across the country are looking for people like you to take part in research studies. Whether you are looking for treatment, or want to help out with research that will improve treatment, diagnosis, and prevention, there are studies that need you!

We know figuring out where to start can be the hardest part about finding research studies you might like to join. That’s why we’ve made it easier for you to find the information you need. We made a quick way to search the thousands of studies available on ClinicalTrials.gov. By answering a few short questions, we can help you find a list of studies that may interest you.
Consent Workgroup Update

Kathleen Brady
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.
Opioid Workgroup Update

Kathleen Brady
Pod Feedback Survey

From: CLIC Communications [mailto:clic@CLIC-CTSA.ORG]
Sent: Thursday, January 4, 2018 12:17 PM
To: CTSA_PI_LIST@LIST.NIH.GOV
Subject: Response Required: CTSA Program Steering Committee Pod Feedback

Dear CTSA Program PIs,

The CTSA Program Steering Committee (SC) is gathering data on the effectiveness of the pods as a mechanism for communication of SC activities. Like everything we do, the pod structure was an experiment, and may not be the most efficient or effective mechanism of communication (and now in 2018, certainly not the most technologically savvy!). Among other issues, there is considerable variability in the way the pods function, leading to potential differences in the information various PIs receive. We’ve heard your concerns and feedback in anecdotal form, and in order to determine what changes if any to make, we need more systematic data — hence this questionnaire.

As a reminder: The pods were created to facilitate bidirectional communication among members of our large and distributed network, ensuring that all CTSA Program PIs would be informed of discussion points and action items from executive session SC calls, and conversely that all PIs would have a mechanism to raise issues for the SC to consider.

We request that you complete this very brief (but important!) survey on or before Thursday, Jan 11, 2018. CLIC will post aggregate data from this questionnaire onto the CLIC website and will not use any direct quotes or include any identifiable information. Further, CLIC will act as an honest broker and will not provide NCATS with any identifiable information from this survey.

Pod participants should complete the following questionnaire: http://j.mp/2CgdCIH

Thank you for your time and we look forward to hearing from you!

CLIC

Please contact us at clic@clic-ctsa.org with any questions.
Thank you!

Next Call: Feb. 12, 2018 2:30 – 4:00 ET
<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:30</td>
<td>Welcome</td>
<td>Kathleen Brady, Christopher P. Austin</td>
</tr>
<tr>
<td>2:32 – 2:45</td>
<td>Introduction of New Steering Committee Members (2x min each)</td>
<td>New Members</td>
</tr>
<tr>
<td></td>
<td>- Barry Coller (Rockefeller University)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Bradley Evanoff (Washington University of St. Louis)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Phil Kern (University of Kentucky)</td>
<td></td>
</tr>
<tr>
<td>2:45 – 3:00</td>
<td>NCATS Update</td>
<td>Christopher P. Austin</td>
</tr>
<tr>
<td></td>
<td>- Continuing Resolution Update</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Senator Roy Blunt’s (MO) Visit to NCATS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Jan 24th CTSA Program PI Call Town Hall</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Jan 11th NCATS Council</td>
<td></td>
</tr>
<tr>
<td>3:00 – 3:30</td>
<td>Clinicaltrials.Gov Presentation and Discussion</td>
<td>Anthony Keyes&lt;br&gt; <em>Johns Hopkins University</em>&lt;br&gt; Sarah White&lt;br&gt; <em>Partners Healthcare</em></td>
</tr>
<tr>
<td>3:30 – 3:35</td>
<td>Consent Workgroup Update</td>
<td>Kathleen Brady</td>
</tr>
<tr>
<td></td>
<td>- Consent Workgroup presented their work last month. See slides from that presentation <a href="#">here</a>.</td>
<td></td>
</tr>
<tr>
<td>3:35 – 3:50</td>
<td>Opioid Workgroup Update</td>
<td>Kathleen Brady</td>
</tr>
<tr>
<td>3:50 – 3:55</td>
<td>Communications Workgroup Update</td>
<td>Kathleen Brady</td>
</tr>
<tr>
<td>3:55 – 4:00</td>
<td>Topics from the floor</td>
<td>All</td>
</tr>
</tbody>
</table>