

Steering Committee Meeting
May 23, 2017
Congressional Ballroom, Bethesda Marriott
Pooks Hill Road

May 24, 2017
Lister Hill Auditorium, NIH Campus

Agenda

<p style="text-align: center;">DAY 1 TUESDAY, MAY 23, 2016</p> <p style="text-align: center;"><i>Bethesda Marriott Congressional Ballroom</i></p>			
DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
8:00 – 8:15 am	<p>Welcome</p> <p>Opening Remarks</p>	<p><i>Josephine Briggs</i></p> <p><i>Richard Hodes</i></p> <p><i>Lesley Curtis</i></p>	<p><i>Discuss meeting goals and expectations:</i></p> <p><i>Day 1: Celebrate the Collaboratory's progress; receive updates from the Core Working Groups; hear about the top barriers/challenges and lessons learned from the UH3s; and engage in in-depth discussion of data sharing issues from the Collaboratory</i></p> <p><i>Day 2: Intensive workshop to broaden knowledge about dissemination, implementation, and sustainability of PCT findings</i></p>
8:15 – 9:15 am	KEYNOTE SPEAKER	<i>Rob Califf</i>	<i>Discuss 21st century evidence generation and the top 3 things that the Collaboratory should tackle next</i>

DAY 1
TUESDAY, MAY 23, 2016

Bethesda Marriott Congressional Ballroom

DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
9:15 – 10:15 am	<p>Top Barriers/Challenges and Recent Generalizable Lessons Learned</p> <p style="text-align: center;">10 min per project</p> <ul style="list-style-type: none"> • A Policy-Relevant U.S. Trauma Care System Pragmatic Trial for PTSD and Comorbidity (Trauma Survivors Outcomes and Support [TSOS]) • Improving Chronic Disease Management with Pieces (ICD-Pieces™) • Pragmatic Trial of Video Education in Nursing Homes (PROVEN) • Collaborative Care for Chronic Pain in Primary Care (PPACT) • Strategies and Opportunities to Stop Colon Cancer in Priority Populations (STOP CRC) • Active Bathing to Eliminate (ABATE) Infection 	<p style="text-align: center;"><i>Doug Zatzick</i></p> <p style="text-align: center;"><i>Miguel Vazquez</i></p> <p style="text-align: center;"><i>Vincent Mor</i></p> <p style="text-align: center;"><i>Lynn DeBar</i></p> <p style="text-align: center;"><i>Gloria Coronado</i></p> <p style="text-align: center;"><i>Susan Huang</i></p>	<p><i>Project abstracts and updated barrier scorecards are in the packet</i></p> <p><u><i>Each UH3 demonstration project presentation will identify the following:</i></u></p> <ol style="list-style-type: none"> <i>1. The current top barriers/challenges</i> <i>2. A recent generalizable lesson learned</i>
10:15 – 10:45 am	Break		
10:45 – 11:15 am	<p><i>Continued:</i></p> <p>Top Barriers/Challenges and Recent Generalizable Lessons Learned</p> <p style="text-align: center;">10 min per project</p> <ul style="list-style-type: none"> • Suicide Prevention Outreach Trial (SPOT) • Lumbar Imaging with Reporting of Epidemiology (LIRE) • Time to Reduce Mortality in End-Stage Renal Disease (TIME) 	<p style="text-align: center;"><i>Greg Simon</i></p> <p style="text-align: center;"><i>Jerry Jarvik</i></p> <p style="text-align: center;"><i>Laura Dember</i></p>	<p><i>Project abstracts and updated barrier scorecards are in the packet</i></p> <p><u><i>Each UH3 demonstration project presentation will identify the following:</i></u></p> <ol style="list-style-type: none"> <i>1. The current top barriers/challenges</i> <i>2. A recent generalizable lesson learned</i>
11:15 – 12:00 pm	<p>Revised Common Rule</p> <ul style="list-style-type: none"> • Overview of the Revised Common Rule • Potential Impact of the Revised Common Rule 	<p style="text-align: center;"><i>Julie Kaneshiro</i></p> <p style="text-align: center;"><i>Valery Gordon</i></p>	<p><i>Discuss the main changes included in the revised Common Rule</i></p> <p><i>Discuss the impact of the newly released Common Rule from the NIH's perspective</i></p>
12:00 – 1:30 pm	Lunch		

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DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
1:30 – 1:45 pm	NIH and Other Requirements for ClinicalTrials.gov Reporting	<i>Deborah Zarin</i>	<i>Discuss data sharing from the NIH's perspective</i>
1:45 – 2:00 pm	Vision of Data Sharing from the Collaboratory <ul style="list-style-type: none"> • Collaboratory principles for data sharing across the Demonstration Projects 	<i>Adrian Hernandez</i>	<i>Discuss Collaboratory data sharing principles and policy</i>
2:00 – 3:00 pm	Data Governance/Data Sharing <ul style="list-style-type: none"> • Potential model of data sharing for the Collaboratory (10 min) • Panel 1: How could data from these trials inform quality of care, and what are the associated considerations? (20 min) • Panel 2: What can NIH and other Federal bodies do to incentivize and support data sharing? (30 min) <p>* <u>Final data sharing plans are provided in the packet</u></p>	<p><i>Josie Briggs</i> <i>Rich Platt</i></p> <p><u>Moderator</u> <i>Adrian Hernandez</i></p> <p><u>Panel</u> <i>Miguel Vazquez</i> <i>Laura Dember</i> <i>Jerry Jarvik</i> <i>Susan Huang</i></p> <p><u>Moderator</u> <i>Kevin Weinfurt</i></p> <p><u>Panel</u> <i>Doug Zatzick</i> <i>Greg Simon</i> <i>Bev Green</i></p>	<p><i>Discuss a possible data sharing model for the Collaboratory to adopt</i></p> <p><i>Panel discussion of identified questions from the UH3 projects to provide insight on the topic and any issues/barriers incurred and resolutions</i></p>
3:00 – 3:30 pm	Break		

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DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
3:30 – 4:30 pm	<p><i>Continued:</i> Data Governance/Data Sharing</p> <ul style="list-style-type: none"> • Panel 3: What are special challenges and strategies for sharing data beyond health systems data, such as Medicare and provider data? (30 min) • Panel 4: How might these projects respond to emerging directions for sharing data and tools? (30 min): <ul style="list-style-type: none"> • Journal requests replication of the primary outcome by an independent statistician as a condition of publication • Sponsoring IC creates an enclave and requests that individual-level data be turned over to NIH. Requests to use the data will be vetted by NIH and require IRB approvals. • Institutions request workflows and tools be developed to support integration of the intervention with the EHR; or code that was used to identify eligible participants from EHR or identify whether the primary outcome was met based on EHR data. • PIs will respond to the following questions: <ol style="list-style-type: none"> 1. What are the considerations given existing data sharing plans? 2. How might you respond? <p>* <u>Final data sharing plans are provided in the packet,</u></p>	<p style="text-align: center;"><u>Moderator</u> <i>Lesley Curtis</i></p> <p style="text-align: center;"><u>Panel</u> <i>Vincent Mor</i> <i>Gloria Coronado</i> <i>Lynn DeBar</i></p> <p style="text-align: center;"><u>Moderators</u> <i>Wendy Weber</i> <i>Lesley Curtis</i></p> <p style="text-align: center;"><u>Panel</u> <i>Vincent Mor</i> <i>Susan Huang</i> <i>Gloria Coronado</i> <i>Jerry Jarvik</i> <i>Miguel Vazquez</i> <i>Greg Simon</i></p>	<p style="text-align: center;"><i>Panel discussion of identified questions from the UH3 projects to provide insight on the topic and any issues/barriers incurred and resolutions</i></p>
4:30 – 4:45 pm	Living Textbook	<p style="text-align: center;"><i>Kevin Weinfurt</i> <i>Jonathan McCall</i> <i>Gina Uhlenbrauck</i> <i>Karen Staman</i> <i>Liz Wing</i></p>	<p style="text-align: center;"><i>Rollout of the revamped Living Textbook and sustainability of the resource</i></p>
4:45 – 5:00 pm	Closing Remarks/Adjourn	<p style="text-align: center;"><i>Josephine Briggs</i> <i>Richard Hodes</i> <i>Lesley Curtis</i></p>	<p style="text-align: center;"><i>Summarize the meeting</i></p>
5:00 - 7:00 pm	<p>Reception</p> <p>Location: Hart/Dirksen/Russell Rooms</p> <p>Directly across from the Main Ballroom</p>	<p style="text-align: center;"><i>Collaboratory Trivia</i> <i>Timeline slides</i></p>	

DAY 2
WEDNESDAY, MAY 24, 2017

**PRAGMATIC CLINICAL TRIALS - UNIQUE OPPORTUNITIES FOR DISSEMINATING, IMPLEMENTING & SUSTAINING
EVIDENCE-BASED PRACTICES INTO CLINICAL CARE**

LISTER HILL AUDITORIUM, NIH CAMPUS

DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
8:00 – 8:10 am	Welcome and Introduction	<i>Josephine Briggs Richard Hodes Catherine Meyers Wendy Weber</i>	<i>Discuss the overall goals and objectives of the workshop: To explore challenges and strategies for the dissemination, implementation, and sustainability of pragmatic clinical trial findings. Pragmatic trials are distinct from more traditional clinical trials, as they are designed to assess the impact of interventions delivered in usual or real-world conditions. Moreover, performing pragmatic trials within fully integrated health systems facilitates large-scale, efficient trials that leverage existing infrastructure to answer important clinical questions. Pragmatic clinical trials can also bridge the critical gap between clinical evidence, practice, and policy in health systems.</i>
8:10 – 8:40 am	KEYNOTE SPEAKER	<i>David Chambers</i>	<i>Orient the audience to the definitions and descriptions of dissemination, implementation, de-implementation, and sustainability of research in health systems. Review why it's important to think about these issues from the start (i.e., choosing analysis questions), throughout, and beyond (the work does not end at the primary publication).</i>

DAY 2
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*PRAGMATIC CLINICAL TRIALS - UNIQUE OPPORTUNITIES FOR DISSEMINATING, IMPLEMENTING & SUSTAINING
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LISTER HILL AUDITORIUM, NIH CAMPUS

DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
8:40 – 10:15 am	<p>Setting the Stage for Dissemination and Implementation</p> <ul style="list-style-type: none"> • Moderator Summary • Q&A 	<p><u>Moderator</u> David Chambers</p> <p><u>Panel</u> Susan Huang Doug Zatzick Gloria Coronado</p>	<p><i>This moderated panel will present PCTs as case examples to respond to these topics:</i></p> <p><i>How do researchers prepare and assess context before conducting a PCT so they and their system partners know how to accommodate the intervention?</i></p> <p><i>How do lessons learned from prior trials extend to other clinical settings and other therapeutic areas?</i></p> <p><i>Identify similar/generalizable issues as well as unique issues.</i></p> <p><i>How do health systems determine when to implement?</i></p> <p><i>What are the organizational, state, or national policy motivators to set the stage for successful/efficient dissemination and implementation?</i></p>
10:15 – 10:30 am	Break		
10:30 – 12:00 pm	<p>Health System Engagement: Partnership, Relationships, and Transparency</p> <ul style="list-style-type: none"> • Moderator Summary • Q&A 	<p><u>Moderator</u> Eric Larson</p> <p><u>Panel</u> Miguel Vazquez John Warner Lynn DeBar Andrew Bertagnolli Vincent Mor Kevin Hook</p>	<p><i>This moderated panel will include dyads of academic researchers and health system partners to present PCTs as case examples to describe engagement/sustainment of a relationship between systems and researchers over the life of the project.</i></p> <p><i>The goal is to provide a general understanding of health systems and their dynamic context.</i></p> <p><i>Panelists will address the need for transparency with implementation, barriers, staff/leadership turnover, data sharing, how researchers and health systems can work together to sustain enduring relationships, the unique qualities of partnership, and the lessons that can be applied to other institutions.</i></p>
12:00 – 12:45 pm	Lunch		

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DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
12:45 – 1:30 pm	Swimming with the Sharks: Translation of Pragmatic Trial Results	<p><u>Moderator</u> Lesley Curtis</p> <p><u>Panel</u> Greg Simon Susan Mullaney Ed Septimus Matt Hough</p>	<i>This session involves interactive role playing between a PCT researcher and a panel of health system leaders. The researcher must be able to convince the leaders that the results of his PCT should be implemented in their health system as standard of care. The goal is to illustrate how to be persuasive while also addressing questions and concerns from the health system leaders.</i>
1:30 – 3:00 pm	Designing for Sustainability <ul style="list-style-type: none"> • Moderator Summary • Q&A 	<p><u>Moderator</u> Amy Kilbourne</p> <p><u>Panel</u> Laura Dember Jerry Jarvik Patrick Luetmer Greg Simon</p>	<i>This moderated panel will present PCTs as case examples to respond to these topics: Planning for sustainability; how to implement the intervention and determine if the intervention is sustainable; and policy levers that should be taken into account at the beginning of a PCT</i>
3:00 – 3:15 pm	Break		
3:15 – 4:15 pm	Stakeholder Reactions Panel Discussion	<p><u>Moderator</u> Catherine Meyers</p> <p><u>Panel</u> Kevin Hook Amy Kilbourne Susan Mullaney John Warner</p>	<i>Panelists will address targeted questions about PCTs conducted in health systems. They will reflect on what they learned from the workshop discussions about dissemination, implementation, and sustainability, and provide suggestions on maximizing partnerships between researchers and health systems.</i>
4:15 – 4:30 pm	Concluding Remarks	David Chambers Eric Larson	<i>Summarize and close the meeting</i>