NIH Collaboratory Rethinking Clinical Trials®
Health Care Systems Research Collaboratory

Steering Committee Meeting
May 9, 2016
Congressional Ballroom, Bethesda Marriott
Pooks Hill Road

May 10, 2016
Lister Hill Auditorium, NIH Campus

Agenda

DAY 1 MONDAY, MAY 9, 2016 *Bethesda Marriott Congressional Ballroom*			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
8:00 – 8:15 a.m.	**Welcome** **Opening Remarks**	*Josephine Briggs* *Richard Hodes* *Lesley Curtis*	*Discussion meeting goals and expectations:* *The purpose of this meeting is to discuss the progress of the Collaboratory, hear updates from the Core Working Groups and Committees, hear updates and lessons learned from the UH3s, discuss data sharing, and discuss sustainability of the Collaboratory and the generalizable knowledge learned.*
8:15 – 8:45 a.m.	**KEYNOTE SPEAKER**	*Michael Lauer*	*Discussion on* • *Perspectives on what should happen outside of the Collaboratory – emphasizing the need for generalizability* • *A 30,000-foot view of clinical trials at NIH and how PCTs fit in*

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8:45 – 9:15 a.m.	**DRN Querying: Use and Sustainability**	*Lesley Curtis* *Rich Platt*	*Discuss planned sustainability and uses of the DRN* *Discussion on improving the development of data sharing resources (e.g., documentation of how data are generated and coded) to improve the quality of analyses. This may align well with the data warehouse model the NIH is currently considering.* *Discussion on the expanding the utility of the DRN for current and future UH2/UH3 studies*
9:15 – 9:30 a.m.	**Data Governance/Data Sharing** • Collaboratory principles for data sharing across the Demonstration Projects (5 min) • Summary of Data Sharing Policy from Working Group (10 min)	*Adrian Hernandez* *Greg Simon*	*Discussion of Collaboratory data sharing principles and policy*

9:30 – 10:45 a.m.	**Continuation: Data Governance/Data Sharing**
	Final data sharing plans will be provided in the packet, to focus the discussion on the obstacles and replication of analyses.
	• Discuss obstacles related to the final data sharing plan
	  ○ Have your research partners expressed concerns about how the data will be shared (enclave, repository, etc.)?
	  ○ How will individual health systems be identified in shared data sets?
	  ○ Are there legal/regulatory obstacles to sharing your data sets?
	• How/Where will you be sharing your results?
	• Can the analysis be replicated using the shared data sets?
		Moderator:
		Adrian Hernandez
		
		Greg Simon
		Susan Huang
		Jerry Jarvik
		Laura Dember
		Lynn DeBar
		Gloria Coronado
			*Discussion of **final** data sharing plans for the first group of UH3s: how and where data will be shared, any foreseen obstacles, and replication of analyses*

10:45 – 11:00 a.m.	**Break**		

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DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
11:00 – 12:00 p.m.	**Continuation: Data Governance/Data Sharing** Data sharing plans will be provided in the packet, to focus the obstacles and implementation of the Collaboratory policy. • What is your current data sharing plan and do you foresee any obstacles? • What information did the IRB require about how the data would be shared beyond the study in order to waive informed consent? • How will you put the policy from the data sharing work group into practice in your study? • What data are you planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)?	*Moderator:* *Adrian Hernandez* *Doug Zatzick* *Vincent Mor* *Miguel Vazquez/ George (Holt) Oliver*	*Discussion about the current data sharing plans for the MCC UH3s, what will be shared, and any foreseen obstacles with current data sharing plans*
12:00 – 12:30 p.m.	**ICD-10 Transition**	*Rachel Richesson*	*Discussion on how the transition of ICD-9 to ICD-10 will affect the Demonstration Projects, and in general, what it means for PCTs*
12:30 – 1:00 p.m.	**Lunch**		
1:00 – 1:45 p.m.	**Unstable Control Group** • Biostatistics and Study Design	*Liz DeLong* *David Murray*	*Discussion on exploring techniques to anticipate changes in the control group. This is a major challenge for PCTs. Approaches such as stepped-wedge design, adaptive interventions/smart design, and adaptive designs are options. Small strategic ancillary studies may help investigators measure mediators without complicating PCT designs.*
1:45 – 2:15 p.m.	**Results Reporting for PCTs**	*Kevin Weinfurt*	*Discussion of what information should be reported in a PCT results publication, including details about the health systems data and analytic methods used*

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2:15 – 2:30 p.m.	**Discussion from the Following Core Groups:** • Stakeholder Engagement • Healthcare Systems Interactions	*Rachael Moloney* *Eric Larson / Leah Tuzzio*	*Discussion on generalizable knowledge created out of the Cores, how it can be utilized, and future work of the Cores* *Provide lessons learned from the Demonstration Projects* *Provide update on Core activities on **sustainability** for the Demonstration Projects*
2:30 – 3:00 p.m.	**Training/Mentoring the Next Generation of Researchers**	*Adrian Hernandez*	*Discuss how to change the next generation of researchers and models to help educate people on PCTs*
3:00 – 3:15 p.m.	**Break**		
3:15 – 4:30 p.m.	**Generalizable Lessons Learned and Sustainability from the Demonstration Projects** **10 min per project** **15 min discussion** • 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 • Lumbar Imaging with Reporting of Epidemiology (LIRE) • Time to Reduce Mortality in End-Stage Renal Disease (TiME) • Suicide Prevention Outreach Trial (SPOT)	*Lynn DeBar* *Gloria Coronado* *Susan Huang* *Jerry Jarvik* *Laura Dember* *Greg Simon*	*Project abstracts in the meeting materials. Presentation to focus on generalizable lessons learned and on how the Demonstration Projects are planning for **sustainability*** ***Updated look at the Barriers Score Card from the first group of UH3 Projects***

DAY 1
MONDAY, MAY 9, 2016

Bethesda Marriott Congressional Ballroom

DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
4:30 – 5:15 p.m.	**Generalizable Lessons Learned and Sustainability from the Demonstration Projects** **10 min per project** **15 min discussion**		*Project abstracts in the meeting materials. Presentation to focus on overall lessons learned from the UH2 planning phase of the study, sustainability for the UH3 implementation phase, and any challenges*
	• A Policy-Relevant U.S. Trauma Care System Pragmatic Trial for PTSD and Comorbidity (Trauma Survivors Outcomes and Support [TSOS])	*Doug Zatzick*	*Identify the issues/challenges utilizing the **Barriers Score Card** from the MCC UH3s* *<u>Additional questions to consider for discussion:</u>* • *Are there **any special considerations** that should be considered when designing a Multiple Chronic Condition PCT?* • *Was the UH2 planning period useful—what did it allow you to do?* • *What worked/didn't work about the UH2 phase?* • *Were the milestones for the UH2 phase appropriate and clear enough?* • *What changes would you recommend about the UH2 phase and transition?* • *How has the Coordinating Center assisted your project?* • *What could the Coordinating Center have done to provide more assistance?* • *Feedback on the UH3 transition process: information letter to PIs, review criteria, submission process, and approval process*
	• Improving Chronic Disease Management with Pieces (ICD-Pieces™)	*Miguel Vazquez*	
	• Pragmatic Trial of Video Education in Nursing Homes (PROVEN)	*Vincent Mor*	
5:15 – 5:45 p.m.	**Living Textbook**	*Kevin Weinfurt* *Jonathan McCall* *Gina Uhlenbrauck* *Karen Staman*	*Discussion about the restructure of the Living Textbook and the **sustainability** of the resource*
5:45 – 6:00 p.m.	**Closing Remarks/Adjourn**	*Josephine Briggs* *Richard Hodes* *Lesley Curtis*	*Summarize the meeting*

DAY 2
TUESDAY, MAY 10, 2016

Ethical and Regulatory Issues of Pragmatic Clinical Trials Workshop
Lister Hill Auditorium, NIH Campus

DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
8:00 – 8:10 a.m.	**Welcome and Introduction**	*Josephine Briggs* *Catherine Meyers* *Wendy Weber*	*Discuss the overall meeting goals and objectives:* *The workshop aims to inform research funders and investigators on progress with navigating ongoing ethical and regulatory challenges for pragmatic clinical trial (PCT) research.* • *Describe the unique challenges PCTs face in the current ethical and regulatory environment* • *Provide strategies to address some of these challenges from ongoing PCTs* • *Identify available and needed resources to assist PCT research funders and investigators to address ethical and regulatory requirements*
8:10 – 8:30 a.m.	**KEYNOTE SPEAKER**	*Jeremy Sugarman*	*Discuss the overall landscape of the ethical and regulatory issues facing PCTs*
8:30 – 10:15 a.m.	**Options for Altered Consent and the Importance of Minimal Risk Determination** • Moderator Summary • Q&A	*Moderator:* *Kevin Weinfurt* *<u>Panel</u>:* *Laura Dember* *Gregory Simon* *John Lantos* *Emma Meagher*	*A moderated discussion using case examples from the Collaboratory to focus on options for altered consent and the importance of minimal risk determination for PCTs*
10:15 – 10:30 a.m.	**Break**		

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DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
10:30 – 12:15 p.m.	**Oversight of Pragmatic Clinical Trials – Institutional Review Boards and Data & Safety Monitoring Boards** • Moderator Summary • Q&A	*Moderator:* *Adrian Hernandez* *Panel:* *Douglas Zatzick* *Pearl O'Rourke* *Susan Ellenberg*	*A moderated discussion using case examples from the Collaboratory to focus on issues in the oversight of PCTs by institutional review boards and data & safety monitoring boards*
12:15 – 1:15 p.m.	**Lunch**		
1:15 – 2:00 p.m.	**Privacy Issues for Pragmatic Clinical Trials** • Moderator Summary • Q&A	*Moderator:* *Valerie Bonham* *Introduction:* *Sarah Greene* *Panel:* *Valery Gordon* *Miguel Vazquez*	*A moderated discussion using case examples from the Collaboratory to focus on the privacy issues for PCTs*
2:00 – 2:45 p.m.	**Vulnerable Populations** • Moderator Summary • Q&A	*Moderator:* *David Wendler* *Panel:* *Susan Huang* *Mary Jane Welch*	*A moderated discussion using case examples from the Collaboratory to focus on issues regarding the inclusion of vulnerable populations in PCTs*
2:45 – 3:00 p.m.	**Break**		
3:00 – 4:00 p.m.	**Expert Panel Q&A**	*Moderator:* *Jeremy Sugarman* *Panel:* *Kevin Weinfurt* *Adrian Hernandez* *Valerie Bonham* *David Wendler*	*Provide an opportunity for Q&A on the ethical and regulatory issues facing PCTs. Focus discussion on the objectives of the meeting:* • *Describe the unique challenges PCTs face in the current ethical and regulatory environment* • *Provide strategies to address some of these challenges from ongoing PCTs* • *Identify available and needed resources to assist PCT research funders and investigators to address ethical and regulatory requirements*
4:00 p.m.	**Concluding Remarks**	*Michael Lauer*	*Summarize the meeting*