NIH Collaboratory Rethinking Clinical Trials™
Health Care Systems Research Collaboratory

Steering Committee Meeting
February 24-25, 2014
DoubleTree by Hilton
Bethesda-Washington, DC

Meeting Purpose

The purpose of this meeting is to celebrate the progress that has been made over the first year, discuss lessons learned, hear updates from the Core Working Groups and Committees, and plan for the implementation phase for the UH3s as well as the onboarding of the new UH2s.

MONDAY, FEBRUARY 24, 2014			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
8:00 - 8:15 a.m.	**Welcome** **Opening remarks**	*Barry Coller* *Josephine Briggs* *Rob Califf*	*Meeting goals and expectations* *New UH2's* *Lessons learned from Collaboratory*
8:15 - 10:30 a.m.	1. Ethics Speaker	*Nancy Kass*	*Discussion on what we will need to have in place, going forward, to be able to do more comparative effectiveness work, practical challenges faced in the ethics/regulatory space*
	2. NIH work on ethics	*Kathy Hudson*	*Discussion on deliverables, state of activity, consensus on what needs to be addressed moving forward*
	3. Report on ethics supplements • Coordinating Center • TiME Ethics Supplement • ABATE Infection Project Ethics Supplement • CTSA project	*Jeremy Sugarman & Kevin Weinfurt* *Laura Dember* *Julie Lankiewicz* *David Magnus* *Ben Wilfond*	*Update on the activities and implementation of the various Bioethical Supplement projects* *Coordinating across supplements*
	4. Overview of ethics and regulatory issues	*Rob Califf & Jeremy Sugarman*	*Provide a review of the ethics and regulatory issues*
10:30 - 10:45 a.m.	**Break**		

MONDAY, FEBRUARY 24, 2014			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
10:45 - 11:45 a.m.	PCORnet/CTSA/Collaboratory	*Rachael Fleurence (PCORI)* *Gordon Bernard (Vanderbilt-C4)* *Elaine Collier (NIH)* *Josephine Briggs & Catherine Meyers*	*Learn about the PCORnet program and Methods workshop*
11:45 - 12:30 p.m.	DRN Network Querying Capabilities/Investigator and NIH initiative use of the DRN	*Richard Platt*	*Discuss current and planned capabilities and uses*
12:30 - 1:00 p.m.	**Lunch**		
1:00 - 3:15 p.m.	Data Governance/Data sharing and DRN • NIH Standards and NIH Data Sharing Model (BioLINCC) (30 mins) • Principles for data sharing across the demonstration projects (15 mins) • Table 1 Discussion (15 mins) • Summary of Data Sharing Policy from Working Group (15 mins) • UH3 Data Sharing Proposals/Plan (1hour) each project 20 mins	*Catherine Meyers, and Sean Coady* *Rob Califf* *Rachel Richesson* *Greg Simon* *Ken Kleinman* *Jerry Jarvik* *Laura Dember*	*Overall discussion of data sharing, final sharing plan, how it will be shared and where it will be shared* *Learn about the NIH Standard for data sharing and BioLINCC data sharing* *Table 1 project update and strategies for completion* *<u>Discussion topics by the projects</u>* • *What data could be shared* • *What data you are planning to share from the projects (individual level data, group level data, specific variables/outcomes, etc.)* • *Original data sharing plan and obstacles*
3:15 - 3:35 p.m.	**Break**		

MONDAY, FEBRUARY 24, 2014			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
3:35 - 5:00 p.m.	Continuation: Data Governance/Data sharing and DRN • UH3 Data Sharing Proposals/Plan (40 mins) each project 20 mins • Discussion about 3 questions (30 mins) 1. Do we accept the recommendation that all trials be expected to create and release public use dataset (unsupervised data archive model)? 2. Will there be ongoing NIH support for a centralized unsupervised data archive? 3. Will there be ongoing NIH support for a data enclave or more supervised data archive?	*Lynn DeBar* *Gloria Coronado* *Greg Simon*	*<u>Discussion topics by the projects</u>* • *What data could be shared* • *What data you are planning to share from the projects (individual level data, group level data, specific variables/outcomes, etc.)* • *Original data sharing plan and obstacles*
5:00 - 5:30 p.m.	**Closing Remarks**	*Rob Califf* *Barry Coller* *Josephine Briggs*	*Summarize Day 1*
5:30 - 9:00 p.m.	**Reception and Dinner**	*Asba Tasneem* *Jonathan McCall*	*Presentations on* *SharePoint Updates* *"The Living Textbook of Pragmatic Clinical Trials"*

TUESDAY, FEBRUARY 25, 2014			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
8:00 - 8:10 a.m.	**Welcome** **Opening remarks**	*Barry Coller* *Josephine Briggs* *Rob Califf*	Meeting goals and expectations
8:10 - 9:30 a.m.	Lessons Learned from Core Work Group • Coordinating Center • Biostatistics and Design • Phenotype, Data Quality and Data Standards • Patient Reported Outcomes • Stakeholder Engagement	*Rob Califf* *Yuliya Lokhnygina* *Rachel Richesson* *Kevin Weinfurt* *Sean Tunis*	*What was learned from the UH2s and what can be applied to the new group of UH2s* *Provide update on the progress of deliverables and products; lessons learned, data collected, and items working on next* *Discussion on potential generalizable knowledge* *Discussion on writing projects and engagement with the PIs*
9:30 - 9:50 a.m.	**Break**		
9:50 - 11:00 a.m.	Lessons Learned from Core Work Group • Electronic Health Records • Ethics and Regulatory • Healthcare Systems Interactions	*Jeffery Brown* *Lesley Curtis* *Jeremy Sugarman* *Eric Larson*	*Provide update on the progress of deliverables and products; lessons learned, data collected and items working on next* *Discussion on potential generalizable knowledge* *Discussion on writing projects and engagement with the PIs*
11:00 - 11:45 a.m.	**Lunch**		

TUESDAY, FEBRUARY 25, 2014			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
11:45 - 2:15 p.m.	Lessons Learned from the Demonstration Projects • Decreasing Bioburden to Reduce Healthcare-Associated Infections and Readmissions – Active Bathing to Eliminate Infection (ABATE) Project • Strategies and Opportunities to Stop Colon Cancer in Priority Populations • A Pragmatic Trial of Lumbar Image Reporting with Epidemiology (LIRE) • Collaborative Care for Chronic Pain in Primary Care • Pragmatic Trials in Maintenance Hemodialysis: Time to Reduce Mortality in ESRD (TiME) • Pragmatic trial of population-based programs to prevent suicide attempt	*Discussion Lead by Eric Larson* *Ed Septimus* *Gloria Coronado* *Jerry Jarvik* *Lynn DeBar* *Laura Dember* *Greg Simon*	***Projects provide a 1-2 minute update followed by discussion*** *Overall learn about the lessons learned from Year 1, ongoing transition issues, sustainability for the UH3s and the challenges* *<u>Questions to consider for discussion</u>* • *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 & 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 PI's, Review Criteria, Submission Process and Approval Process* *Discuss and identify metrics to be collected during the implementation phase*
2:15 - 3:00 p.m.	Work Groups for upcoming UH2s - Pragmatic Clinical Trials Focusing on Multiple Chronic Conditions (MCC)	*Rob Califf* *Catherine Meyers*	*Determine if there needs to be any changes with the working groups for new UH2s* • *Do we have the right combination of WGs* • *Do we need additional WGs for MCC trials* • *Did we have the right level of study team engagement in the WG's and was it helpful to individual projects*
3:00 p.m.	**Closing remarks/Adjourn**	*Barry Coller* *Rob Califf* *Josephine Briggs*	