

**Steering Committee Meeting
August 19-20, 2014
Bethesda North Marriott Hotel and Conference Center**

General Session: Salon A & B

Meeting Purpose

The purpose of this meeting is to welcome the new Multiple Chronic Condition UH2 Demonstration Projects, provide introductions, an overview of the Collaboratory, understanding of the Core Working Groups, discuss lessons learned, data sharing and current ethics and regulatory issues.

TUESDAY, AUGUST 19, 2014

DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
8:00 - 8:10 a.m.	Welcome Opening remarks	<i>Barry Collier Josephine Briggs Rob Califf</i>	<i>Meeting goals and expectations</i>
8:10 - 8:30 a.m.	Opening Address	<i>Thomas Insel Michael Lauer</i>	<i>To look at innovative thinking about Pragmatic Clinical Trials</i>
8:30 – 8:50 a.m.	Overview of the NIH HCS Research Collaboratory	<i>Josephine Briggs</i>	<i>Learn about the NIH HCS Research Collaboratory</i>
8:50 – 9:00 a.m.	Questions and Answer Session		
9:00 – 9:45 a.m.	Collaboratory Coordinating Center Overview and Goals	<i>Rob Califf</i>	<i>Coordination of the CC How do projects work with the CC Metrics for the Collaboratory Success</i>
9:45 – 10:00 a.m.	Break		

TUESDAY, AUGUST 19, 2014

DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
10:00 – 12:00 a.m.	Introduction to the Core Working Groups <ul style="list-style-type: none"> • Biostatistics and Design • Phenotype, Data Quality and Data Standards • Patient Reported Outcomes • Stakeholder Engagement • Electronic Health Records • Ethics and Regulatory • Healthcare Systems Interactions 	<p style="text-align: center;"><i>Liz DeLong</i></p> <p style="text-align: center;"><i>Ed Hammond</i> <i>Meredith Zozus</i></p> <p style="text-align: center;"><i>Kevin Weinfurt</i></p> <p style="text-align: center;"><i>Sean Tunis</i></p> <p style="text-align: center;"><i>Lesley Curtis</i></p> <p style="text-align: center;"><i>Jeremy Sugarman</i></p> <p style="text-align: center;"><i>Eric Larson</i></p>	<p><i>Provide an introduction on the purpose, goals and deliverables for the Core Group. Provide an update on the progress of deliverables and products; lessons learned, data collected and items in progress</i></p> <p style="text-align: center;"><i>Discussion on potential generalizable knowledge from the Core</i></p> <p><i>Discussion on engagement with the MCC UH2 PIs and expectations</i></p>
12:00 – 1:00 p.m.	Lunch		
1:00 – 2:30 p.m.	Discussion of MCC Demonstration Projects	<p style="text-align: center;"><i>Vincent Mor, PhD</i> <i>Douglas Zatzick, MD</i> <i>Miguel Vazquez, MD</i></p>	<i>Provide an overview of the project followed by Q&A</i>
2:30 – 2:45 p.m.	Break (Move to Breakout Rooms)		
2:45: - 5:45 p.m.	Breakout Session <i>Location: Great Falls, Middlebrook, and Oakley</i>	<i>See breakout schedule</i>	
5:45 -6:00 p.m.	Closing Remarks	<p style="text-align: center;"><i>Barry Collier</i> <i>Josephine Briggs</i> <i>Rob Califf</i></p>	<i>Summarize Day 1</i>
6:00 - 9:00 p.m.	Reception and Dinner <i>Location: Glen Foyer / White Oak B</i>	<p style="text-align: center;"><i>Asba Tasneem</i></p> <p style="text-align: center;"><i>Gina Uhlenbrauck</i></p>	<p style="text-align: center;"><i>Presentations on</i></p> <p style="text-align: center;"><i>SharePoint Demonstration</i></p> <p style="text-align: center;"><i>“The Living Textbook of Pragmatic Clinical Trials”</i></p>

WEDNESDAY, AUGUST 20, 2014

DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
8:00 - 8:15 a.m.	Welcome Opening remarks	<i>Barry Collier</i> <i>Josephine Briggs</i> <i>Rob Califf</i>	<i>Meeting goals and expectations</i> <i>Review from Day 1</i>
8:15 – 9:30 a.m.	Lessons Learned from <ul style="list-style-type: none"> • Pragmatic Trials in Maintenance Hemodialysis: Time to Reduce Mortality in ESRD (TiME) • Collaborative Care for Chronic Pain in Primary Care / Pain Program for Active Coping and Training (PPACT) 	<i>Laura Dember</i> <i>Lynn DeBar</i>	<i>Provide lessons learned during the UH2 and UH3 phases</i>
9:30 – 10:00 a.m.	Governance and Process <ul style="list-style-type: none"> • NIH Collaboratory Data Sharing Policy and Considerations • Publications and Products Process • Data Quality 	<i>Catherine Meyers</i> <i>Rob Califf</i> <i>Meredith Zozus</i>	<i>Review status of governance and processes</i>
10:00 – 10:15 a.m.	Break		
10:15– 11:15 a.m.	Overview of ethics and regulatory issues	<i>Rob Califf</i> <i>Jeremy Sugarman</i>	<i>Provide a review of the ethics and regulatory issues identified from the first group of UH2 projects and lessons learned</i>
11:15 – 11:30 a.m.	CC Bioethics Supplement Update	<i>Jeremy Sugarman</i> <i>Kevin Weinfurt</i>	<i>Provide an update on the activities of the CC Bioethical Supplement project</i>
11:30 – 12:30 p.m.	Lunch		
12:30 - 1:30 p.m.	Panel of Directors	<i>Josephine Briggs (Chair)</i> <i>Richard Hodes</i> <i>Thomas Insel</i> <i>Judith Fradkin</i> <i>Patricia Grady</i>	
1:30 – 1:45 p.m.	Closing remarks/Adjourn	<i>Barry Collier</i> <i>Josephine Briggs</i> <i>Rob Califf</i>	<i>Summarize the meeting</i>