NIH Collaboratory Rethinking Clinical Trials™
Health Care Systems Research Collaboratory

# *Preconference Workshop: Essentials of Embedded Pragmatic Clinical Trials*

## AcademyHealth 2019 Annual Research Meeting

## Adjunct Workshop

## Washington, D.C.

## June 1, 2019

| DURATION | AGENDA TOPIC | SPEAKERS | GOALS |
|---|---|---|---|
| 8:00-8:45<br>(45 min) | **What are Embedded Pragmatic Clinical Trials (ePCTs)?** | Catherine Meyers, NIH/NCCIH | • Welcome and introduction of agenda and objectives<br>• Identify key considerations in the design and conduct of ePCTs and how they differ from explanatory trials<br>• Learn about the advantages and disadvantages of ePCTs, and when a pragmatic approach can be used to answer the research question |
| 8:45-9:15<br>(30 min) | **Engaging Stakeholders & Aligning with Health System Partners** | Leah Tuzzio, MPH Kaiser Permanente Washington Health Research Institute | • Describe the breadth of stakeholders to engage as partners and approaches for engaging them through all phases of the study<br>• Understand the real-world priorities and perspectives of health system leaders and how to obtain their support<br>• Highlight challenges of partnering with diverse health systems |
| 9:15-9:45<br>(30 min) | **Measuring Outcomes** | Emily O'Brien, DCRI | • Describe methods for measuring outcomes using data sources such as electronic health records (EHRs) and patient-reported outcomes (PROs) |
| 9:45-10:15<br>(30 min) | **ePCT Design** | David Murray, NIH/Office of Disease Prevention | • Learn about cluster-randomized and stepped-wedge study designs |
| 10:15-10:30<br>(15 min) | **Break** | | |
| 10:30-11:00<br>(30 min) | **ePCT Analysis** | David Murray, NIH/Office of Disease Prevention | • Recognize the analytical challenges and trade-offs of pragmatic study designs, focusing on what PIs need to know |
| 11:00-Noon<br>(60 min) | **ePCTs in Context: Panel Discussion with Collaboratory Demonstration Project PIs** | Moderator: Kevin Weinfurt, DCRI Panel: Susan Huang, ABATE; Vince Mor, PROVEN | • Introduce PIs of 2 ongoing ePCTs to reflect on the morning topics, discussing challenges, solutions, and lessons learned<br>• Q & A with attendees |

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| Noon-1:00<br>(60 min) | **Lunch** | | |
| 1:00-1:30<br>(30 min) | **Pilot & Feasibility Testing** | Wendy Weber, NIH/NICCH | • Identify approaches to evaluating the capabilities of the partner health system and testing key elements of various types of interventions |
| 1:30-2:00<br>(30 min) | **Ethical & Regulatory Oversight Considerations** | Kevin Weinfurt, co-PI, NIH Collaboratory Coordinating Center<br><br>Julie Kaneshiro, OHRP | • Learn about the regulatory and ethical challenges of conducting ePCTs |
| 2:00-2:30<br>(30 min) | **Dissemination & Implementation** | Wynne Norton, NIH/NCI | • Learn methods for designing ePCTs so findings can be easily implemented; build in sustainability from the beginning<br>• Identify considerations for dissemination of study results |
| 2:30-3:30<br>(60 min) | **ePCTs in Context: Panel Discussion with Collaboratory Demonstration Project PIs** | Moderator: Kevin Weinfurt, DCRI Panel: Susan Mitchell, PROVEN; Laura Dember, TiME | • Introduce PIs of 2 ongoing ePCTs to reflect on the afternoon topics, discussing challenges, solutions, and lessons learned<br>• Q & A with attendees |
| 3:30-3:45<br>(15 min) | **Break** | | |
| 3:45-4:45<br>(60 min) | **Assembling an ePCT Team & Writing a Grant Application** | Robin Boineau, NIH/NCCIH<br><br>Marcel Salive, NIH/NIA | • Identify skills needed for a strong study team<br>• Learn how to develop a compelling ePCT application<br>• Tips from Collaboratory PIs |
| 4:45-5:00<br>(15 min) | **Next Steps** | Kevin Weinfurt, DCRI | • Final Q & A<br>• Wrap up including identifying sources for further learning |