

Overcoming Administrative Burden in Pragmatic Research

Moderator:

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**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Panelist

- **Karen Hartman, MSN**
Mayo Clinic
- **Geeta Swamy, MD**
Duke University
- **P. Pearl O'Rourke, MD**
Co-Lead: Ethics and Regulatory Core
Partners Health Care System (retired)
- **Keith A. Marsolo, PhD**
Co-Lead: Electronic Health Records Core
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- **Michael G. Kurilla, MD, PhD**
National Center for Advancing
Translational Sciences
- **Miguel Vazquez, MD**
PI: ICD-Pieces
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- **P. Michael Ho, MD**
Co-PI: Nudge & Chat 4 Heart Health
University of Colorado

Session Goals

- Understand key issues related to administrative start-up, contracting, IRB review, and data access and data sharing
- Discuss ways to simplify administrative processes
- Understand single IRBs and how they can support efforts to simplify
- Understand key issues with data use agreements
- Hear investigator perspectives from actual pragmatic trials

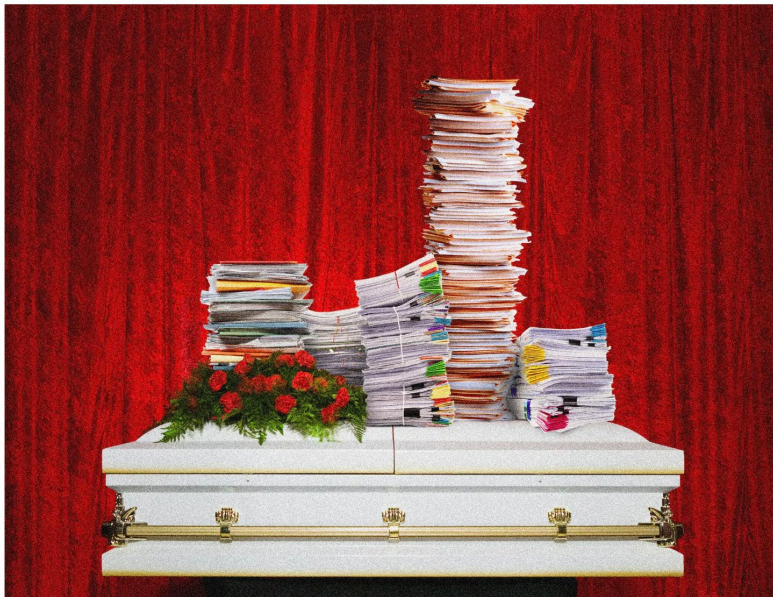
Efficiency & Effectiveness: Untying Our Gordian Knot

The New York Times

OPINION
DAVID BROOKS

Death by a Thousand Paper Cuts

Jan. 18, 2024



Case Examples Used:
Healthcare, Education, Academia & Corporations

“It’s not only that growing bureaucracies cost a lot of money; they also enervate American society. They redistribute power from workers to rule makers, and in so doing sap initiative, discretion, creativity and drive.”

17% of GDP

\$2000/American

“...time tax. If you’ve ever fought a health care, corporate or university bureaucracy, you quickly realize you don’t have the time for it, so you give up.”



2023 Image Created by AFH via DALL-E/ OPEN-AI

Questions to Consider

- What did you do to streamline contracting, IRB review, and data use access? What are the roles of institutions? NIH?
- How does a single IRB work, and how can this process help streamline trial startup? What is central contracting and how does it work?
- What administrative steps can be done in advance?
- What do health systems with rapid trial startup times do differently?
- How have pragmatic researchers overcome administrative barriers?