Ethical and Regulatory Dimensions of Pragmatic Clinical Trials

A SPECIAL GRAND ROUNDS SERIES

Join us for the NIH Pragmatic Trials Collaboratory’s special Grand Rounds series examining ethical and regulatory challenges in pragmatic clinical trials. Over the past decade, the program’s Ethics and Regulatory Core has worked with investigators to navigate ethical and regulatory complexities associated with research conducted within healthcare systems. With this new series, the Core is bringing together bioethicists, investigators, and regulatory experts to share lessons learned, discuss empirical findings, and explore remaining uncertainties.

KEYNOTE PRESENTATION—BUILDING AN ACADEMIC LEARNING HEALTH SYSTEM: WHY IS IT SO HARD?
September 9, 2022

Moderator: Stephanie Morain, PhD, MPH

Steven Joffe, MD, MPH
Art and Ilene Penn Professor and Chair
Department of Medical Ethics & Health Policy
University of Pennsylvania Perelman School of Medicine
Professor of Pediatrics
University of Pennsylvania Perelman School of Medicine

RESPONDING (OR NOT) TO SIGNALS OF POTENTIAL CLINICAL SIGNIFICANCE IN PRAGMATIC CLINICAL TRIALS
October 14, 2022

Moderator: Stephanie Morain, PhD, MPH

Joseph Ali, JD
Assistant Professor, Dept. of International Health
Johns Hopkins Bloomberg School of Public Health
Core Faculty & Associate Director for Global Programs
Johns Hopkins Berman Institute of Bioethics

Tanya Matthews, PhD
HRPP Director
Kaiser Permanente Washington

Leslie J. Crofford, MD
Wilson Family Chair in Medicine
Professor of Medicine and Pathology, Microbiology & Immunology
Chief, Division of Rheumatology
Vanderbilt University Medical Center
### DATA SHARING AND PRAGMATIC CLINICAL TRIALS: LAW & ETHICS AMIDST A CHANGING POLICY LANDSCAPE

**November 11, 2022**

**Moderator:** Pearl O’Rourke, MD

**Stephanie Morain, PhD, MPH**  
Assistant Professor  
Berman Institute of Bioethics & Johns Hopkins School of Public Health

**Kaye Spector-Bagdady, JD, MBioethics**  
Associate Director, Center for Bioethics & Social Sciences in Medicine  
Assistant Professor of Obstetrics & Gynecology  
University of Michigan Medical School

### THE STEPPED WEDGE CLUSTER RANDOMIZED TRIAL: FRIEND OR FOE?

**December 9, 2022**

**Moderator:** Stephanie Morain, PhD, MPH

**Monica Taljaard, PhD**  
Senior Scientist, Clinical Epidemiology Program  
Ottawa Hospital Research Institute  
Full Professor, Epidemiology and Community Medicine  
University of Ottawa

**David Magnus, PhD**  
Thomas A Raffin Professor of Medicine and Biomedical Ethics  
Professor of Pediatrics, Medicine, and by courtesy of Bioengineering  
Director, Stanford Center for Biomedical Ethics  
Associate Dean for Research  
Stanford Center for Biomedical Ethics

### ETHICAL CONSIDERATIONS WHEN VULNERABLE POPULATIONS ARE SUBJECTS IN PRAGMATIC TRIALS

**January 13, 2023**

**Moderator:** Stephanie Morain, PhD, MPH

**Emily A. Largent, JD, PhD, RN**  
Emanuel & Robert Hart Assistant Professor of Medical Ethics and Health Policy  
Department of Medical Ethics and Health Policy  
University of Pennsylvania Perelman School of Medicine

### INFORMING AND CONSENTING: WHAT ARE THE GOALS?

**February 10, 2023**

**Moderator:** Stephanie Morain, PhD, MPH

**P. Pearl O’Rourke, MD (retired)**  
Harvard Medical School

**David S. Wendler, PhD, MA**  
Senior Researcher  
Head, Section on Research Ethics  
Department of Bioethics  
NIH Clinical Center

**Miguel Vazquez, MD**  
Professor of Internal Medicine  
UT Southwestern Medical Center

**P. Michael Ho, MD, PhD**  
Professor of Medicine  
University of Colorado School of Medicine