

## 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

**Leslie J. Crofford, MD**

Wilson Family Chair in Medicine  
Professor of Medicine and Pathology, Microbiology & Immunology  
Chief, Division of Rheumatology  
Vanderbilt University Medical Center

**Tanya Matthews, PhD**

HRPP Director  
Kaiser Permanente Washington

## 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

### Kayte 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