Ethics and Regulatory Core

Co-Chairs:

- Jeremy Sugarman, MD, MPH, MA
- Pearl O'Rourke, MD
- Stephanie Morain, PhD, MPH



Mission

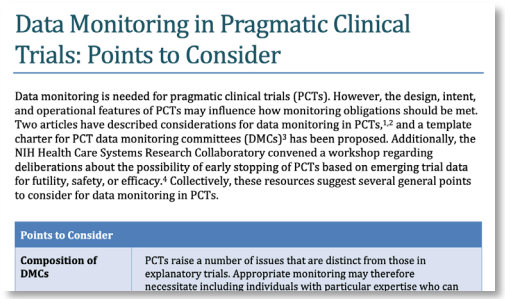
- Identify areas of regulatory and ethical uncertainty for ePCTs
- Help trials navigate regulatory and ethical issues
- Provide a framework for ethical, compliant conduct of ePCTs

Meeting Schedule
Quarterly
Monthly Check-Ins

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

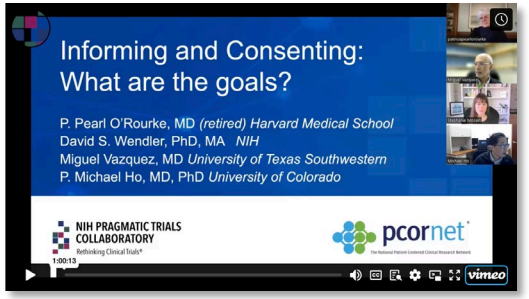
Ethics and Regulatory Core: Key Resources

- 8 Living Textbook chapters
- Foundational scholarship on ethics and regulatory issues in ePCTs
- Data monitoring resources
  - Committee charter template
  - Points to Consider for ePCTs
- Documentation of ethics and regulatory consultations with NIH Collaboratory Trials
- Workshop on ethical and regulatory dimensions of ePCTs (recording available)
- Empirical research to understand stakeholder perspectives on ePCTs


Data Monitoring in Pragmatic Clinical Trials: Points to Consider

Data monitoring is needed for pragmatic clinical trials (PCTs). However, the design, intent, and operational features of PCTs may influence how monitoring obligations should be met. Two articles have described considerations for data monitoring in PCTs,[1,2] and a template charter for PCT data monitoring committees (DMCs)[3] has been proposed. Additionally, the NIH Health Care Systems Research Collaboratory convened a workshop regarding deliberations about the possibility of early stopping of PCTs based on emerging trial data for futility, safety, or efficacy.[4] Collectively, these resources suggest several general points to consider for data monitoring in PCTs.

Points to Consider	
Composition of DMCs	PCTs raise a number of issues that are distinct from those in explanatory trials. Appropriate monitoring may therefore necessitate including individuals with particular expertise who can



Think Pragmatically: Investigators' Obligations to Patient-Subjects When Research is Embedded in Care

Stephanie Morain [1], Emily Largent [2]

Ethics and Regulatory Documentation

BEST-ICU Ethics Regulatory Follow-up

Chat 4 Heart Health Ethics Regulatory Follow-up

RAMP Ethics and Regulatory Discussion

MOMs Ethics and Regulatory Discussion

Ethics and Regulatory Core: Contributions to Trials

- Worked with trials to:
  - Navigate regulatory hurdles
  - Provide guidance and clarity on ethical considerations
  - Design appropriate methods for consent or notification
  - Facilitate discussions with regulatory bodies
  - Inform data monitoring plans
- Collaborated with trials on lessons learned publications

Consultation in first 3 months

"Having adjusted our strategy prior to IRB submission based on input from the Core was likely a major reason the IRB review went so smoothly."
—PIs of the IMPACt-LBP trial

"The Core provided expertise and a kind of gravitas for us to go in a direction for consent waiver we knew we wanted to go."
—PIs of the NOHARM trial

"It was amazing how helpful Jeremy Sugarman and others were."
—Lynn Debar, Co-PI of BackInAction