NIH Collaboratory
Regulatory & Ethics Core

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Overview

Pragmatic clinical trials and comparative-effectiveness research that rely on data collected as part of routine clinical care face unique regulatory and ethical challenges.

http://www.rethinkingclinicaltrials.org/cores-and-working-groups/regulatory-ethics/
Overview

The Regulatory/Ethics Core:

1. Identifies areas of regulatory and ethical uncertainty
2. Works with Demonstration Projects to navigate regulatory/ethical complexities affecting PCTs conducted within healthcare systems
3. Develop policies and practices to provide a framework for the ethical conduct of health systems research that is in compliance with relevant regulations

http://www.rethinkingclinicaltrials.org/cores-and-working-groups/regulatory-ethics/
Core Leadership & Support

• Co-Chairs:
  • Jeremy Sugarman (Johns Hopkins)
  • Judith Carrithers (Johns Hopkins)
  • Kevin Weinfurt (Duke)

• NIH Representative:
  • David Wendler (NIH Dept. of Bioethics)

• Project Manager:
  • Tammy Reece (Duke)
Core Members

• Elaine Bergman
• Denise Cifelli
• Gregory Clarke
• Susan Ellenberg
• Sheila Fireman
• Beverly Green
• Adrian Hernandez
• Adeola Jaiyeola
• Lindsay Kindler

• Julie Lima
• Rosemary Madigan
• David Magnus
• Carmit McMullen
• Susan Mitchell
• Miguel Vazquez
• Ben Wilfond
• Doug Zatzick
Key Functions

- Address common areas of concern for PCTs
  - Regulatory issues
  - Minimal risk criteria
  - Informed consent
- Engage with regulatory/ethical oversight bodies
- Conduct empirical research to inform issues
- Examine approaches for streamlining regulatory pathways
- Collaborate with allied groups on CIRB review, quality by design, and more
  - CTTI
  - Sentinel Initiative
  - PCORI
  - HCSRN
Key Functions

- Document lessons learned for other Demonstration Projects
- Distill generalizable learning for broader research community
  - Includes teleconference consults with Demo Project PIs/study teams with input from Core members, other Collaboratory faculty/staff, and NIH and OHRP representatives
  - Minutes/notes from these consults made publicly available via NIH Collaboratory Living Textbook

http://www.rethinkingclinicaltrials.org/demonstration-project-ethics-and-regulatory-documentation/
Core Products & Publications

• Dedicated issue in *Clinical Trials* addressing 11 areas of regulatory/ethical concern for PCTs
  • *Clin Trials*; Oct 2015 12(5)
Core Products & Publications

http://www.rethinkingclinicaltrials.org/cores-and-working-groups/regulatory-ethics/
Grand Rounds Presentations

A Tentative Introduction to the Revised Common Rule for the Protection of Human Subjects
Jeremy Sugarman, MD, MPH, MA
Harvey M. Meyerhoff Professor of Bioethics & Medicine
Berman Institute of Bioethics and Department of Medicine
Johns Hopkins University
Baltimore, Maryland USA

Comparison of Different Approaches for Notification and Authorization in Pragmatic Clinical Research Evaluating Commonly Used Medical Practices
Jeremy Sugarman, MD, MPH, MA
Kevin P. Weinfurt, PhD

DATA MONITORING COMMITTEES FOR PRAGMATIC CLINICAL TRIALS
Susan S. Ellenberg, Ph.D.
University of Pennsylvania
October 16, 2015

Exploring the Ethical and Regulatory Issues in Pragmatic Clinical Trials: Introducing a Special Series in Clinical Trials
Jeremy Sugarman, MD, MPH, MA
Harvey M. Meyerhoff Professor of Bioethics & Medicine
Berman Institute of Bioethics and Department of Medicine
Johns Hopkins University
Baltimore, Maryland

Data and Safety Monitoring in Pragmatic Trials
Greg Simon
Group Health Research Network
Thank You