NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

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.

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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

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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

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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

Opinion

VIEWPOINT

Ethics and Regulatory Complexities for Pragmatic Clinical Trials

Jeremy Sugarman, MD, MPH, MA

Some patients do not receive the best care possible, either because research to support clinical decision making with

Nature of Interventions

Interventions that are the focus of CER and PCTs may

The American Journal of Bioethics, 15(9): 18–33, 2015

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DOI: 10.1080/15265161.2015.1062186

Open Peer Commentaries

Is Shared Decision Making an Appropriate Analytic Frame for Research on Medical Practices?

Jeremy Sugarman, Johns Hopkins University

AJOB EMPIRICAL BIOETHICS
2016, VOL. 7, NO. 2, 71–75
http://dx.doi.org/10.1080/23294515.2016.1152104

Routledge
Taylor & Francis Group

INTRODUCTION

Ethics of research in usual care settings: Data on point

Jeremy Sugarman MD, MPH, MA

Future Medicine

JOURNALS BOOKS ABOUT US CONTACT US

JOURNAL OF COMPARATIVE EFFECTIVENESS RESEARCH, VOL. 5, NO. 5 | RESEARCH ARTICLE

normal

Physicians' perspectives regarding pragmatic clinical trials

Rachel Topazian, Juli Bollinger, Kevin P Weinfurt, Rachel Dvoskin, Debra Mathews, Kathleen Brelsford,

Ethics and Regulatory Challenges and Opportunities in Patient-Centered Comparative Effectiveness Research

Jeremy Sugarman, MD, MPH, MA

Abstract

The Affordable Care Act includes an array of ethics and regulatory approaches to research (including

AJOB EMPIRICAL BIOETHICS
2016, VOL. 7, NO. 2, 76–91
http://dx.doi.org/10.1080/23294515.2015.1117536

ARTICLE

Patients' views concerning research on medical practices: Implications for consent

Kevin P. Weinfurt[a], Juli M. Bollinger[b], Kathleen M. Brelsford[c], Travis J. Crayton[c], Rachel J. Topazian[b], Nancy E. Kass[d], Laura M. Beskow[e], and Jeremy Sugarman[f]

[a]Duke Clinical Research Institute and Department of Psychiatry and Behavioral Sciences, Duke University School of Medicine; [b]Berman Institute of Bioethics, Johns Hopkins University; [c]Duke Clinical Research Institute, Duke University School of Medicine; [d]Berman Institute of Bioethics and Department of Health Policy and Management, Johns Hopkins University; [e]Duke Clinical Research Institute and Department of Medicine, Duke University School of Medicine; [f]Berman Institute of Bioethics, Department of Health Policy and Management, and Department of Medicine, Johns Hopkins University

Comparison of Approaches for Notification and Authorization in Pragmatic Clinical Research Evaluating Commonly Used Medical Practices

Kevin P. Weinfurt, PhD,† Juli M. Bollinger, MS,‡ Kathleen M. Brelsford, MA, MPH, PhD,* Martina Bresciani, BA,* Zachary Lampron, MPH,* Li Lin, MS,* Rachel J. Topazian, BA,‡ and Jeremy Sugarman, MA, MPH, MD‡§‖*

Background: For pragmatic clinical research comparing commonly used treatments, questions exist about if and how to notify participants about it and secure their authorization for participation.

Most respondents (77%–94%) felt that participation in the hypothetical study posed no risks of harm to their health or privacy.

Conclusions: Current attitudes about notification and authorization approaches and difficulties understanding pragmatic clinical re-

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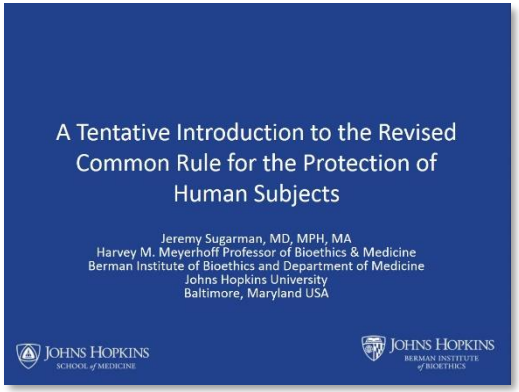
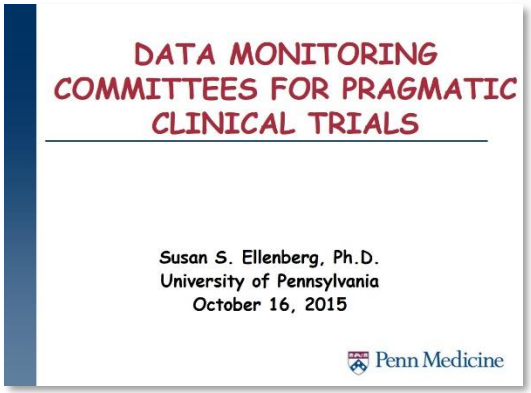
Grand Rounds Presentations





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Thank You