Then, Now and the Future: Ethics and Regulatory Challenges in Pragmatic Clinical Trials

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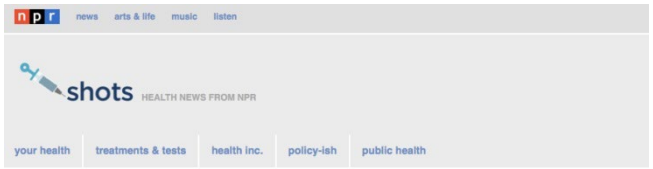
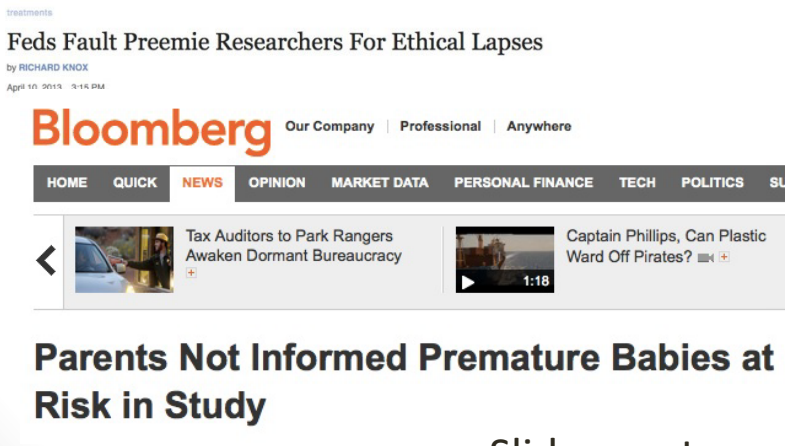
Background Conditions

- There is a broad moral claim to obtain evidence to improve clinical practice since most decisions are now made without reliable evidence to know which choices optimize health
- Technology permits conducting large scale research and cohort finding for rare diseases and special populations, often with minimal incremental risks and burdens and less cost

An Ethics Framework for a Learning Health Care System: *A Departure from Traditional Research Ethics and Clinical Ethics*

BY RUTH R. FADEN, NANCY E. KASS, STEVEN N. GOODMAN, PETER PRONOVOST, SEAN TUNIS, AND TOM L. BEAUCHAMP





Rethinking Clinical Trials

Slide courtesy of Steven Joffe, MD, MPH

March 2013

Major Areas of Controversy

- Consent
- Risks and benefits
- Standard of care

Alternative Bioethical Views


The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

The OHRP and SUPPORT


The NEW ENGLAND JOURNAL of MEDICINE

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June 2013

The OHRP and SUPPORT — Another View

Ethics and Regulatory Issues in the Collaboratory

- Multi-stakeholder conversations at the planning stage convened by the Ethics & Regulatory Core
  - Investigators and research teams
  - Sponsors
  - IRBs
  - Regulators
- Minutes reviewed and posted
- Updates following project implementation

  https://rethinkingclinicaltrials.org/demonstration-project-ethics-and-regulatory-documentation/

Public Hearing

HHS.gov
U.S. Department of Health & Human Services

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Public Meeting August 28, 2013

Public Meeting Transcript

A transcript for the meeting has been posted. View transcript here or in PDF format (PDF – 940 KB). OHRP staff created this transcript from the video captions by correcting transcription errors and identifying the speakers. The caption text accompanying each video is unedited.

August 26, 2013 – Full Meeting Agenda

A full agenda for the August 28, 2013 public meeting has been added to the docket, and is available at this page of the docket.

August 21, 2013 - Information on viewing the August 28, 2013 HHS Public Meeting on Protections of Human Subjects and Research Studying Standard of Care Interventions

For those who cannot attend the August 28, 2013 HHS Public Meeting on the Protections of Human Subjects and Research Studying Standard of Care Interventions, HHS is providing an option to view the public meeting via live streaming technology. To view the HHS public meeting live on August 28, 2013, go to the HHS live streaming site at: www.HHS.gov/live, then hit the"Click to Play" arrow.

On August 16, 2013, HHS added to the docket a basic agenda for the meeting. The basic agenda is available in PDF or Microsoft Word format at this page of the docket.

In a Federal Register notice on June 26, 2013 (PDF - 107 KB) , HHS announced a public meeting to be held on August 28, 2013, to seek public input and comment on how certain provisions of the Federal policy for the protection of human subjects should be applied to research studying one or more interventions which are used as standard of care treatment in the non-research context.

http://www.hhs.gov/ohrp/newsroom/rfc/Public%20Meeting%20August%2028,%202013/aug28public.html

IOM/NAM Workshop

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JAMA®

The Journal of the American Medical Association

Sugarman J, Califf RM. Ethics and regulatory complexities for pragmatic clinical trials. *JAMA* 2014; 311: 2381-2382.

Anderson M, Califf R, Sugarman J, for the NIH Health Care Systems Research Collaboratory Cluster Randomized Trial Workshop. Ethical and regulatory issues of pragmatic cluster randomized trials in contemporary health systems. *Clin Trials* 2015; 12: 276-286.

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CLINICAL TRIALS

Journal of the Society for Clinical Trials

EXPLORING THE ETHICAL AND REGULATORY ISSUES IN PRAGMATIC CLINICAL TRIALS LEADING A SERIES OF 12 ARTICLES ON DIFFERENT ASPECTS OF THIS TOPIC

COLUMN

Clinician Trialist Rounds 28: When RCT Participants are Lost to Follow-Up. Part I: Why Even a Few Can Matter
M Walsh, PJ Devereaux and DL Sackett

TRIBUTE

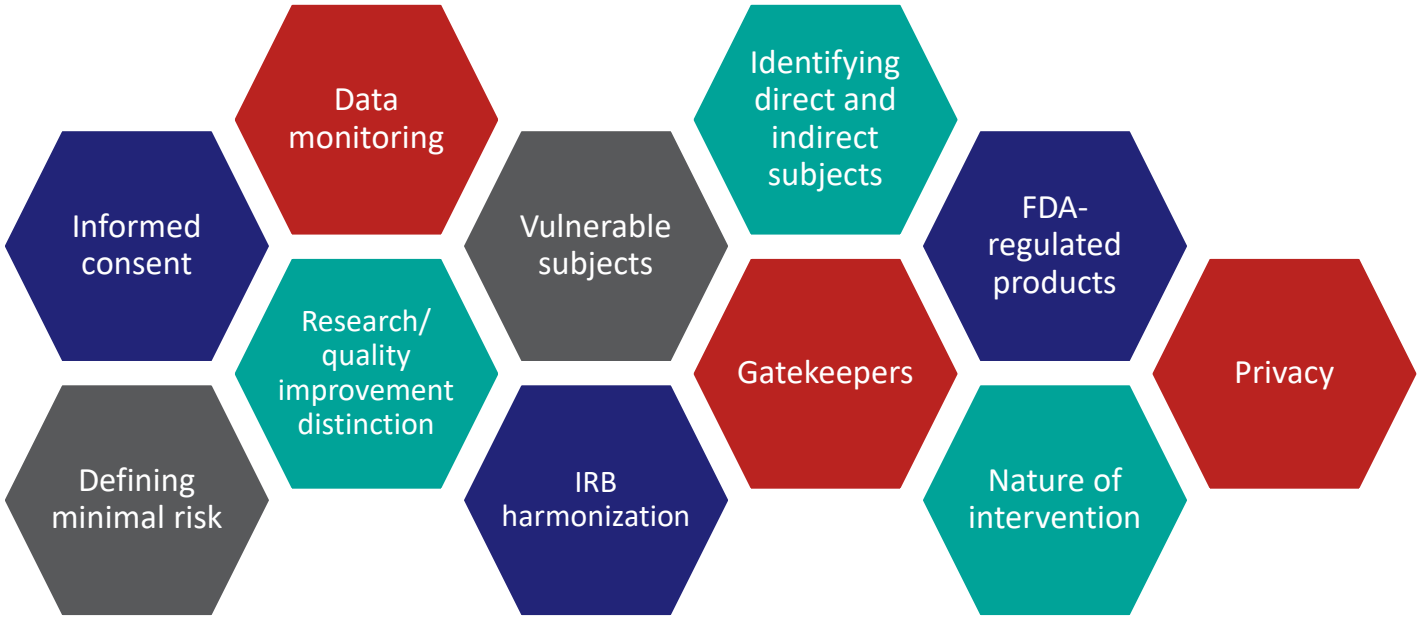
An Interview with David Sackett
RB Haynes and SN Goodman

Full contents are listed on the back cover

SCT

Clinical Trials Special Series

Guest Editors: Jeremy Sugarman and Robert Califf



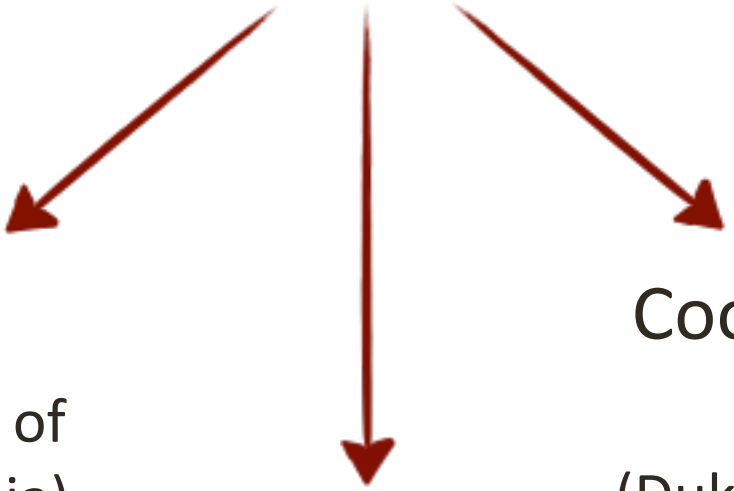
http://ctj.sagepub.com/content/early/recent

NIH Ethics Supplements

CTSA

(University of Washington & Stanford)

NIH Collaboratory



TiME

(University of Pennsylvania)

ABATE

(University of California - Irving)

Coordinating Center

(Duke & Hopkins)

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

INTRODUCTION

Ethics of research in usual care settings: Data on point

Jeremy Sugarman MD, MPH, MA

Signals from Early Empirical Research

- At least a substantial minority of people want to be meaningfully engaged in research decision-making
  - Regardless of risk
  - Regardless of health care norms
- It is unclear if the nature of these activities were clearly understood and their best interests were not compromised
- Since requiring traditional written consent may compromise some research this issue must be better understood

Subsequent Issues

- Standards for data monitoring
  - Points to consider
  - Sample charter
- Incidental findings/PCT collateral findings
- Payments and incentives

https://rethinkingclinicaltrials.org/cores-and-working-groups/regulatory-ethics/

Now and on the Horizon

- Ethics in research design
  - Stepped wedge
  - Implementation science
- Responding to PRO signals
- Disclosure and authorization alternatives
  - Opting out
  - Broad notification
- Clinicians obligations to participate
- Data sharing

Concluding Comments

- Addressing the ethical and regulatory challenges of PCTs is surprisingly complex
- The well-rehearsed habit of 'adding protections' in research ethics *may not* be actually be providing needed protections and may inadvertently stymie important research efforts
- Additional data and deliberation should help inform the development of appropriate policies and procedures