

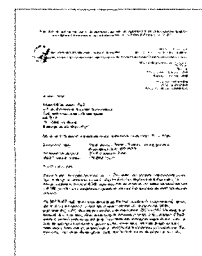
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- I am a member of Merck KGaA's Bioethics Advisory Panel and Stem Cell Research Oversight Committee; and a member of IQVIA's (formerly Quintiles) Ethics Advisory Panel
- I co-chair the Ethics and Regulatory Core for the NIH Health Care Systems Research Collaboratory and co-lead the Ethics and Regulatory Task Force for PCORNet
- I receive(d) salary/grant support through Johns Hopkins University for this work
- The views expressed here are my own and do not necessarily reflect the views of the sponsors, the Collaboratory or PCORNet

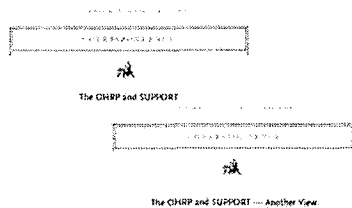
- Given the brevity of this talk, my hope is to simply sketch some of the major ethical issues related to PCTs and LHSs
- I have selected prominent examples to illustrate particular points and trigger discussion; it would be inappropriate to consider this to represent a comprehensive review



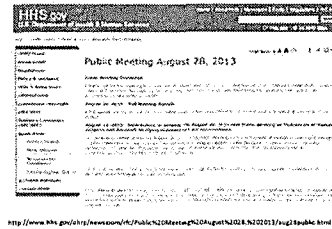
Hastings Cent Rep 2013 Jan/Feb:S16



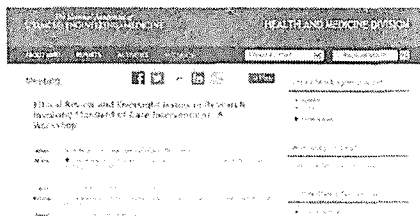
Alternative Bioethical Views



Public Hearing



IOM/NAM Workshop



Major Areas of Controversy

- Consent
- Risks and benefits
- Standard of care

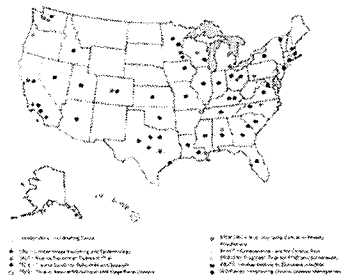
Background Conditions

- 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

NIH Health Care Systems Research
Collaboratory

- Pragmatic trial design
- Electronic health record as core data collection instrument
- At least 2 integrated health systems collaborating
- 10 demonstration projects + 5 new projects approved for a planning phase

NIH Health Care Systems Research
Collaboratory



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



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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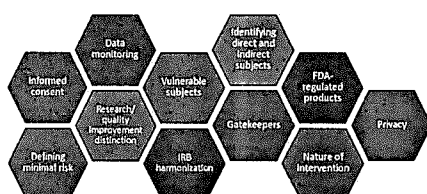


SCF

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Clinical Trials Special Series

Guest Editors: Jeremy Sugarman and Robert Califf



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

已知：在△ABC中，AB=AC，∠BAC=90°
 D为BC的中点，E、F分别为AB、AC上的点
 且AE=CF，连接DE、DF、EF。求证：△DEF是等腰直角三角形。

INTRODUCTION

Ethics of research in usual care settings: Data on point

Jeremy Sugarman MD, MPH, MA

Signals from 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

Emerging Issues

- Standards for data monitoring
- Patients in 'non-traditional' roles
- Incidental findings

Concluding Comments

- There is an array of ethical and regulatory challenges for PCTs and CER
- Substantial empirical and conceptual attention directed at these issues is needed before the possibility of achieving a learning health system can be realized
- To be most meaningful, these efforts should be grounded in actual experiences