U.S. Department of Health & Human Services • National Institutes of Health

National Center for Complementary and Integrative Health

Complexities in ePCT Bioethics Ecosystem:

Have we overcome the challenges?

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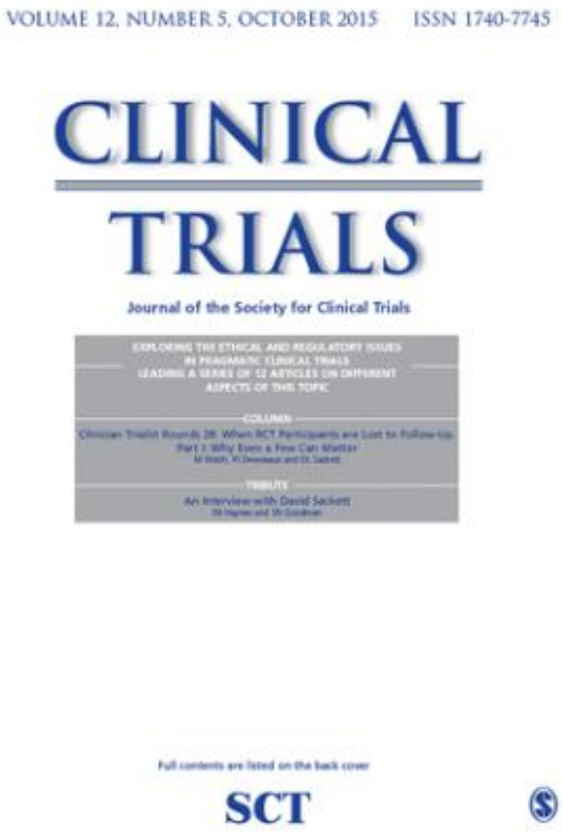
VIEWPOINT

Ethics and Regulatory Complexities for Pragmatic Clinical Trials

Sugarman and Califf JAMA June 18, 2014 Volume 311, Number 23, 2381-2382



Perspective

CLINICAL TRIALS

Clinical Trials
2015, Vol. 12(3) 276–286

DOI: 10.1177/1740774515571140
ctj.sagepub.com
SAGE

Ethical and regulatory issues of pragmatic cluster randomized trials in contemporary health systems

Monique L Anderson[1,2], Robert M Califf[1,2,3] and Jeremy Sugarman[4,5]; for the participants in the NIH Health Care Systems Research Collaboratory Cluster Randomized Trial Workshop

Ten Complexities + 1 more

- **Consent**
- **Risk Determination**
- Nature of Intervention
- **Identifying Research Participants**
- Institutional Review Boards
- Regulated Products
- Research and Quality Improvement
- Vulnerable Subjects
- **Data Monitoring**
- **Gatekeepers**
- Data Sharing/Privacy

Progress

- Set of case examples to address
  - Consent
  - Risk Determination
  - Identifying Research Participants
- Increased familiarity with PCTs (in some places)
  - IRBs
  - DSMBs
  - Gatekeepers

Challenges still exist

- Data Sharing
- Privacy
- Regulated Products
- Risk Determination