Complexities in ePCT Bioethics Ecosystem: Have we overcome the challenges?

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

Monique L Anderson¹,², Robert M Califf¹,²,³ and Jeremy Sugarman⁴,⁵; 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