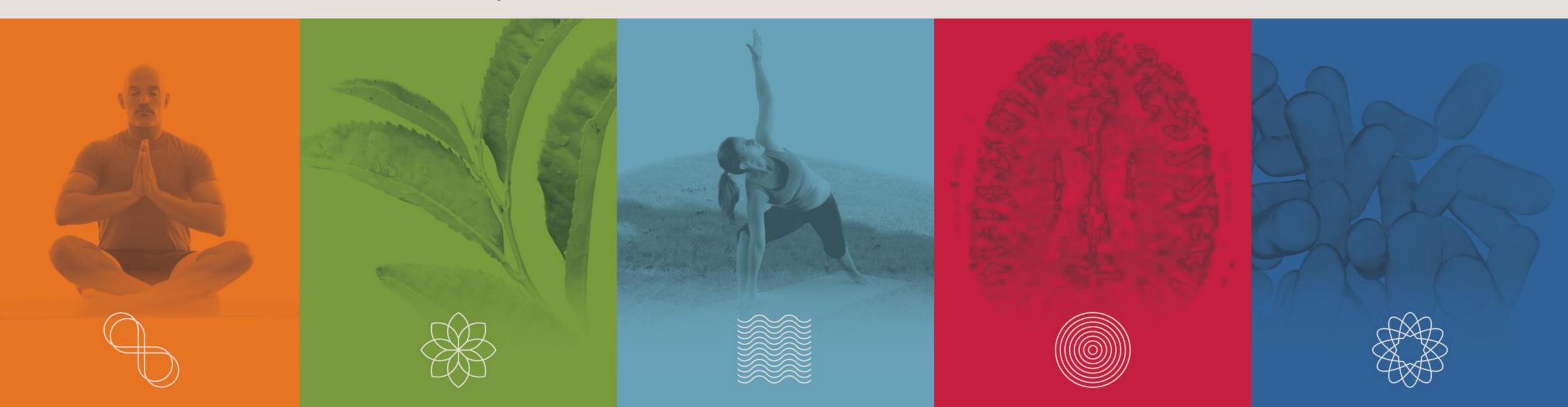
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Complexities in ePCT Bioethics Ecosystem: Have we overcome the challenges?

Wendy Weber ND, PhD, MPH April 22, 2020



VIEWPOINT

Ethics and Regulatory Complexities for Pragmatic Clinical Trials Sugarman and Califf JAMA June 18, 2014 Volume 311, Number 23, 2381-2382

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and Rounds 28. When BCY Participants are Lost 14 Follow art 3 Why Even a Few Carl Mutter An Interview with David Socherty Billington and Wilcondow

Perspective

Ethical and regulatory issues of 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**

Full contents are listed on the back cover

SCT

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Opinion

CLINICAL TRIALS

pragmatic cluster randomized trials in

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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
 - - IRBs
 - DSMBs – Gatekeepers

Increased familiarity with PCTs (in some places)



Challenges still exist

- Data Sharing
- Privacy
- Regulated Products
- Risk Determination

