



NIH Collaboratory

Health Care Systems Research Collaboratory

Ethics and Regulatory

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Rethinking Clinical Trials



Personnel

Core Leaders

- Robert Califf, MD (Regulatory)
- Jeremy Sugarman, MD, MPH, MA (Ethics)

Core Members

- Ross McKinney, MD
- James Sabin, MD
- Kevin Weinfurt, PhD

Working Group Members

- Monique Anderson, MD
- Laura Beskow, MPH, PhD
- Denise Cifelli, MS
- Susan Ellenberg, PhD
- Sheila Fireman, MA, JD
- Kathryn James, PA, MPH
- Rebecca Kaganov, BA
- Lindsay Kindler, PhD, RN, CNS
- Rosemary Madigan, RN, MS, MPH
- Dave Wendler, MA, PhD

Administrative Support

- Tammy Reece, MS



Particular Research Ethics Expertise

- Quality of consent
- Research design
- Conflicts of interest
- Boundary issues
- Empirical approaches



Activities

- Advice and consultation
- Extensive interactions with NIH and OHRP regarding each UH2
 - Case studies posted on www.nihcollaboratory.org
- Workshop on Cluster Randomized Trials
 - Manuscript submitted
- Empirical ethics supplements
- Top topics in pragmatic clinical trials
 - Series of papers for *Clinical Trials* planned
- Disseminating information about our experiences
 - Sugarman J, Califf RM. *JAMA* 2014; 311: 2381-2382
 - “Living Textbook”: Rethinking Clinical Trials