Ethics and innovative trial design

Steven Joffe, MD, MPH

Chief, Division of Medical Ethics; Emmanuel and Robert Hart Professor of Medical Ethics and Health Policy, Perelman School of Medicine; Professor of Pediatrics, The Children’s Hospital of Philadelphia

Traditionally, clinical trials have progressed through a linear sequence from phase 1 (safety, pharmacokinetics, and dosing) to phase 2 (preliminary efficacy) to phase 3 (definitive efficacy). However, factors including a desire to speed times to approval and the need to conduct trials in smaller biomarker-defined patient subgroups have led to a profusion of innovative trial designs. Examples of trial design innovation include seamless designs, basket trials, umbrella trials. Just as these trials offer both methodological advantages and limitations, they also offer both advantages and disadvantages with respect to key elements of ethical research such as favorable benefit-risk balance and informed consent.

Monday, March 4
Austrian Auditorium, Clinical Research Building
415 Curie Boulevard, University of Pennsylvania
12–1 P.M

Lunch will be provided for attendees

Information: Mary Pham, Mary.Pham@pennmedicine.upenn.edu
medicaleticshealthpolicy.med.upenn.edu/events