Grand Rounds Special Series:
Ethics and Regulatory Issues in Pragmatic Clinical Trials

Grand Rounds is a weekly webinar hosted by the NIH Health Care Systems Research Collaboratory and PCORnet. Starting in September 2015, one Grand Rounds per month will feature a topic from the *Clinical Trials* 12-article special issue on ethical and regulatory challenges in pragmatic clinical trials. Each session will include a presentation by the author(s) followed by time for discussion. For details and archived presentations, visit [https://www.nihcollaboratory.org/Pages/Grand-Rounds-Hub.aspx](https://www.nihcollaboratory.org/Pages/Grand-Rounds-Hub.aspx).

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| 9/25/2015  | Ethical and Regulatory Issues in Pragmatic Clinical Trials: Introducing a Special Series in Clinical Trials  
Jeremy Sugarman – Johns Hopkins |
| 10/16/2015 | Data Monitoring Committees for Pragmatic Clinical Trials  
Susan Ellenberg – University of Pennsylvania |
| 11/20/2015 | Gatekeepers for Pragmatic Clinical Trials  
Danielle M. Whicher – PCORI |
| 12/18/2015 | The Ethics and Regulatory Landscape of Including Vulnerable Populations in Pragmatic Clinical Trials  
Mary Jane Welch – Rush University |
| 1/15/2016  | Harmonization and Streamlining of Research Oversight for Pragmatic Clinical Trials  
Pearl O’Rourke – Massachusetts General  
John Lantos – Children’s Mercy Hospital |
| 2/19/2016  | Harms, Benefits, and the Nature of Interventions in Pragmatic Clinical Trials  
Joe Ali – Johns Hopkins |
| 3/18/2016  | Ethical Responsibilities Toward Indirect and Collateral Participants in Pragmatic Clinical Trials  
Jaye Bea Smalley – PCORI |
| 4/15/2016  | Considerations in the Evaluation and Determination of Minimal Risk in Pragmatic Clinical Trials  
John Lantos – Children’s Mercy Hospital |
| 5/20/2016  | Use of Altered Informed Consent in Pragmatic Clinical Trials  
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| 6/17/2016  | Oversight on the Borderline: Quality Improvement and Pragmatic Research  
John Finkelstein – Boston Children’s |
| 7/15/2016  | The Food and Drug Administration and Pragmatic Clinical Trials of Marketed Medical Products  
Monique Anderson – Duke University |
| 8/19/2016  | Privacy and Confidentiality in Pragmatic Clinical Trials  
Deven McGraw – HHS OCR  
Alan Rubel – University of Wisconsin |