Ethical & Regulatory Issues of Pragmatic Clinical Trials Workshop

May 10, 2016
**Ethical & Regulatory Issues of Pragmatic Clinical Trials Workshop**

**May 10, 2016, Lister Hill Auditorium, 8:00 a.m. – 4:30 p.m.**

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8:00 a.m. – 8:10 a.m.  **Welcome and Introduction**  
*Catherine M. Meyers, M.D., F.A.H.A.*  
Director, Office of Clinical and Regulatory Affairs  
National Center for Complementary and Integrative Health  
National Institutes of Health, HHS  

*Wendy Weber, N.D., Ph.D., M.P.H.*  
Chief, Clinical Research Branch, Division of Extramural Research  
National Center for Complementary and Integrative Health  
National Institutes of Health, HHS

8:10 a.m. – 8:30 a.m.  **Keynote Speaker**  
*Jeremy Sugarman, M.D., M.P.H., M.A.*  
Harvey M. Meyerhoff Professor of Bioethics and Medicine  
Johns Hopkins Berman Institute of Bioethics

8:30 a.m. – 10:00 a.m.  **Panel 1: Options for Altered Consent and the Importance of Minimal Risk Determination**  
*Moderator: Kevin P. Weinfurt, Ph.D.*  
Professor in Psychiatry and Behavioral Sciences  
Duke University School of Medicine  
Co-Director, Program for Empirical Bioethics  
Duke Clinical Research Institute

*Laura M. Dember, M.D.,*  
Professor of Medicine, University of Pennsylvania, School of Medicine

*Gregory E. Simon, M.D., M.P.H.,*  
Senior Scientific Investigator, Group Health Research Institute, Group Health Cooperative

*John D. Lantos, M.D.,*  
Director of Pediatric Bioethics, University of Missouri-Kansas City School of Medicine

*Emma Meagher, M.D.,*  
Senior Associate Dean for Clinical Research, University of Pennsylvania

10:00 a.m. – 10:15 a.m.  **Moderator Summary**  
**Q&A**

10:15 a.m. – 10:30 a.m.  **Break**
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<th>Time</th>
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| 10:30 a.m. – 12:00 p.m. | **Panel 2**: Oversight of Pragmatic Clinical Trials – Institutional Review Boards and Data and Safety Monitoring Boards | **Moderator**: Adrian F. Hernandez, M.D., M.H.S., F.A.H.A.  
Professor of Medicine  
Duke University School of Medicine  
Director, Outcomes and Health Services Research  
Faculty Associate Director  
Duke Clinical Research Institute |
| 12:00 p.m. – 12:15 p.m. | Moderator Summary  
Q&A |  
Douglas F. Zatzick, M.D., Professor and Vice Chair for Health Services, University of Washington School of Medicine, Harborview Medical Center  
P. Pearl O'Rourke, M.D., Director, Human Research Affairs, Partners HealthCare Systems  
Susan S. Ellenberg, Ph.D., Professor of Biostatistics and Epidemiology, University of Pennsylvania Perelman School of Medicine |
| 12:15 p.m. – 1:15 p.m. | Lunch |  
Valerie Bonham, J.D., Senior Attorney  
Office of the General Counsel  
Public Health Division  
National Institutes of Health, HHS |
| 1:15 p.m. – 1:45 p.m. | **Panel 3**: Privacy Issues for Pragmatic Clinical Trials | **Moderator**: Valerie Bonham, J.D.  
Senior Attorney  
Office of the General Counsel  
Public Health Division  
National Institutes of Health, HHS  
Sarah M. Greene, M.P.H., Executive Director, Health Care Systems Research Network  
Valery Gordon, Ph.D., M.P.H., Director, Clinical Research Policy, Office of Science Policy, National Institutes of Health, HHS  
Miguel Vazquez, M.D., Medical Director of Kidney Transplantation, Professor, Internal Medicine, University of Texas Southwestern Medical Center |
| 1:45 p.m. – 2:00 p.m. | Moderator Summary  
Q&A |  
David Wendler, Ph.D., Senior Researcher  
NIH Clinical Center  
National Institutes of Health, HHS |
| 2:00 p.m. – 2:30 p.m. | **Panel 4**: Vulnerable Populations | **Moderator**: David Wendler, Ph.D.  
Senior Researcher  
NIH Clinical Center  
National Institutes of Health, HHS  
Susan S. Huang, M.D., M.P.H., Professor, Infectious Disease, Medical Director, Epidemiology and Infection Prevention, School of Medicine, University of California, Irvine  
Mary Jane Welch, D.N.P., A.P.R.N., B.C., C.I.P., Assistant Professor, Community Systems and Mental Health Nursing, Director, Human Subjects’ Protection, College of Nursing, Rush University Medical Center |
2:30 p.m. – 2:45 p.m.  **Moderator Summary**

**Q&A**

2:45 p.m. – 3:00 p.m.  **Break**

3:00 p.m. – 4:00 p.m.  **Panel 5: Expert Panel Q&A**  
**Moderator:** Jeremy Sugarman, M.D., M.P.H., M.A.  
Harvey M. Meyerhoff Professor of Bioethics and Medicine  
Johns Hopkins Berman Institute of Bioethics  

Kevin P. Weinfurt, Ph.D., Professor in Psychiatry and Behavioral Sciences, Duke University School of Medicine, Co-Director, Program for Empirical Bioethics, Duke Clinical Research Institute  

Adrian F. Hernandez, M.D., M.H.S., F.A.H.A., Professor of Medicine, Duke University School of Medicine, Director, Outcomes and Health Services Research, Faculty Associate Director, Duke Clinical Research Institute  

Valerie Bonham, J.D., Senior Attorney, Office of the General Counsel, Public Health Division, National Institutes of Health, HHS  

David Wendler, Ph.D., Senior Researcher, NIH Clinical Center, National Institutes of Health, HHS  

4:00 p.m. – 4:30 p.m.  **Concluding Remarks**  
**Michael S. Lauer, M.D., F.A.C.C., F.A.H.A.**  
Deputy Director for Extramural Research  
Office of the Director  
National Institutes of Health, HHS  

This Workshop was inspired by a series of articles in the October 2015 special issue of *Clinical Trials*  
http://ctj.sagepub.com/content/12/5.toc