



**U.S. Food and Drug Administration (FDA)  
Center for Devices and Radiological Health (CDRH)  
Patient Engagement Advisory Committee (PEAC) Meeting  
FDA Virtual Meeting**

**Discuss and make recommendations on the topic “Patient-Centered Informed Consent in  
Clinical Study of FDA-Regulated Medical Products ”**

**AGENDA**

**October 30, 2024  
10:00 AM – 5:00 PM ET**

---

- 10:00 AM **Patient Engagement Advisory Committee (PEAC) Call to Order**  
*Rita Roy, MD, Temporary Voting Chairperson, PEAC*
- 10:10 AM **Welcome from FDA Commissioner**  
*Robert M. Califf, MD, Commissioner, FDA*
- 10:15 AM **Conflict of Interest Statement**  
*Letise Williams, Designated Federal Official, CDRH, FDA*
- 10:20 AM **Welcome and Opening Remarks**  
*Michelle Tarver, MD, PhD., CDRH Director, FDA*
- 10:25 AM **Informed Consent (IC) & Key Information: An Overview**  
*(Jose) Pablo Morales, MD, Senior Medical Advisor, Office of Clinical Policy, FDA*
- 10:40 AM **Industry Perspective**  
*Allison Anderson, MS, Associate Director of Clinical Trials, Boston Scientific*
- 10:50 AM **Academia Perspective**  
*Nancy E. Kass, ScD, Phoebe R. Berman Professor of Bioethics and Public Health  
Berman Institute of Bioethics and Bloomberg School of Public Health  
Johns Hopkins University*
- 11:00 AM **Health Care Provider Perspective**  
*Neal Dickert, MD, PhD., Associate Professor, Thomas R. Williams Professor of  
Medicine, Emory University School of Medicine, Division of Cardiology, ECCRI  
Co-Director, Emory Health Services Research Center, Emory University Rollins  
School of Public Health*



- 11:10 AM **Patient perspective**  
*Greg Merritt, PhD., Founder, Patient is Partner, LLC*
- 11:20 AM **Open Committee Discussion**
- 11:45 AM **BREAK (Webcast Closes)**
- 12:00 PM **Virtual Breakout Session Begins** *(separate meeting link)*  
*(if registered for this session, please join using breakout session link at 11:50am)*
- 12:30 PM **LUNCH**
- 12:55 PM **Webcast Reopens**
- 1:00 PM **Virtual Breakout Summations**  
*FDA moderators*
- 2:00 PM **Open Public Hearing**
- 3:00 PM **Open Committee Discussion**
- 3:30 PM **BREAK**
- 3:40 PM **Committee Discussion of FDA Questions**
- 4:55 PM **Closing Remarks**  
*Temporary Voting Chairperson, PEAC*
- 5:00 PM **Adjourn**