



**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 <i>Rita Roy, MD, Temporary Voting Chairperson, PEAC</i>
10:10 AM	Welcome from FDA Commissioner <i>Robert M. Califf, MD, Commissioner, FDA</i>
10:15 AM	Conflict of Interest Statement <i>Letise Williams, Designated Federal Official, CDRH, FDA</i>
10:20 AM	Welcome and Opening Remarks <i>Michelle Tarver, MD, PhD., CDRH Director, FDA</i>
10:25 AM	Informed Consent (IC) & Key Information: An Overview <i>(Jose) Pablo Morales, MD, Senior Medical Advisor, Office of Clinical Policy, FDA</i>
10:40 AM	Industry Perspective <i>Allison Anderson, MS, Associate Director of Clinical Trials, Boston Scientific</i>
10:50 AM	Academia Perspective <i>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</i>
11:00 AM	Health Care Provider Perspective <i>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</i>



11:10 AM	Patient perspective <i>Greg Merritt, PhD., Founder, Patient is Partner, LLC</i>
11:20 AM	Open Committee Discussion
11:45 AM	BREAK (Webcast Closes)
12:00 PM	Virtual Breakout Session Begins (<i>separate meeting link</i>) (<i>if registered for this session, please join using breakout session link at 11:50am</i>)
12:30 PM	LUNCH
12:55 PM	Webcast Reopens
1:00 PM	Virtual Breakout Summations <i>FDA moderators</i>
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 <i>Temporary Voting Chairperson, PEAC</i>
5:00 PM	Adjourn