

# IRBMED SEMINAR SERIES



## A Comprehensive Look at Monitoring and Auditing of Human Participant Research

Zoom Webinar • May 04, 2021 • 10:00 am – 12:00 pm

### AGENDA

<b>Welcome &amp; Introduction</b>	<b>Judy Birk, J.D.</b> <i>Director, IRBMED</i>	10:00-10:05
<b>DSMBs, DSMPs, Audits &amp; Monitoring</b>	<b>Corey Zolondek, Ph.D.</b> <i>Assistant Director, IRBMED</i>	10:05-10:20
<b>FDA Inspections as a Form of Audit</b>	<b>Melanie Chladny, MPA</b> <i>Senior Regulatory Specialist, UMMS Office of Regulatory Affairs</i>	10:20-10:50
<b>Sponsor-Investigator Monitoring Requirements</b>	<b>Amanda Phelps</b> <i>Quality Initiatives and Monitoring Manager MICHR, Clinical Research Management</i>	10:50-11:20
<b>IRB Requirements for Reporting Monitoring Outcomes</b>	<b>Cameron Shultz, PhD</b> <i>Senior Research Compliance Specialist, IRBMED</i>	11:20-11:45
<b>Questions and Answers</b>		11:45 -12:00

