

FY23 Research Matters

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Date and Time	Location	Title	Presenter(s)	Presentation Slides	Recording Link
September 20, 2022 Noon to 1 p.m.	MS Teams Live	FDA Inspection Prep – 3 Part Miniseries <i>Part 1 - Preparing for the audit</i> AAHRPP Prep	QA/Monitoring Office Meyad Baghezza	<ul style="list-style-type: none"> • Welcome • CT.gov and SI Support Updates • FDA Inspection - Part 1 • AAHRPP Prep 	Session Recording
October 18, 2022 Noon to 1 p.m.	MS Teams Live	FDA Inspection Prep – 3 Part Miniseries <i>Part 2 - During the audit</i> Not-for-Cause Monitoring Visits	QA/Monitoring Office	<ul style="list-style-type: none"> • Welcome and Announcements • CT.gov and SI Support Updates • FDA Inspection - Part 2 • Not-for-Cause Monitoring Visits 	Session Recording
November 15, 2022 Noon to 1 p.m.	MS Teams Live	FDA Inspection Prep – 3 Part Miniseries <i>Part 3 - After the audit</i> Retrospective Chart Reviews	QA/Monitoring Office Meyad Baghezza	<ul style="list-style-type: none"> • Welcome and Announcements • CT.gov and SI Support Updates • FDA Inspection - Part 3 • Retrospective Chart Reviews 	Session Recording
December 20, 2022 Noon to 1 p.m.	MS Teams Live	CANCELED			
January 17, 2023 Noon to 1 p.m.	MS Teams Live	State of the HRPP NIH Data Sharing Policy	Rhonda Oilepo	<ul style="list-style-type: none"> • Welcome and Announcements • HRPP Updates • CT.gov and SI Support Updates • State of the HRPP 	Session Recording

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Date and Time	Location	Title	Presenter(s)	Presentation Slides	Recording Link
February 21, 2023 Noon to 1 p.m.	MS Teams Live	Reliance and sIRB	Hend Nadim Brendan Paulman	<ul style="list-style-type: none"> Welcome and Announcements CT.gov and SI Support Updates Overview of sIRB and Reliance Processes 	Session Recording
March 21, 2023 Noon to 1 p.m.	MS Teams Live	SI Support – 6 Part Miniseries <i>Part 1 – Preparing for an IND/IDE</i> Electronic Consent and Record Keeping	Rasija Nambiar, Raj Varadarajan, and Eriko Iwatate Tara Garcia	<ul style="list-style-type: none"> Welcome and Announcements Part 1 – Preparing for an IND/IDE Electronic Consent and Record Keeping 	Session Recording
April 18, 2023 Noon to 1 p.m.	MS Teams Live	SI Support – 6 Part Miniseries <i>Part 2 – Initial IND/IDE submissions</i> Recruitment & Compensation	Rasija Nambiar and Raj Varadarajan Stephanie Francisco	<ul style="list-style-type: none"> Welcome and Announcements Part 2 - Submitting Initial IND/IDE Recruitment and Compensation 	Session Recording
May 16, 2023 Noon to 1 p.m.	MS Teams Live	SI Support – 6 Part Miniseries <i>Part 3 – Modifications to IND/IDE</i> Social Media Tools	Rasija Nambiar and Raj Varadarajan Satish Veerla	<ul style="list-style-type: none"> Welcome and Announcements Part 3 - Modifications to IND/IDE Social Media in Research 	Session Recording

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June 20, 2023 Noon to 1 p.m.	MS Teams Live	SI Support – 6 Part Miniseries <i>Part 4 – Safety (Incident) Reports</i> Protocol Deviations & Noncompliance	Rasija Nambiar, Raj Varadarajan, and Eriko Iwatate Meyad Bird	<ul style="list-style-type: none"> • Welcome and Announcements • Part 4 - Safety Reports for IND/IDE • Protocol Deviations & Noncompliance 	Session Recording
July 18, 2023 Noon to 1 p.m.	MS Teams Live	SI Support – 6 Part Miniseries <i>Part 5 – Annual Reports</i> UPIRSOs	Rasija Nambiar, Raj Varadarajan, and Eriko Iwatate Erik Soliz	<ul style="list-style-type: none"> • Welcome and Announcements • Part 5 - Annual Reports • Unanticipated Problems Involving Risk to Subjects or Others • IRB Updates 	Session Recording
August 15, 2023 Noon to 1 p.m.	MS Teams Live	SI Support – 6 Part Miniseries <i>Part 6 – Ending IND/IDE</i> Waivers of Consent & HIPAA Authorization	Rasija Nambiar, Raj Varadarajan, and Eriko Iwatate Heather Klug	<ul style="list-style-type: none"> • Welcome and Announcements • Performance Review Process Overview • Part 6 - Final Report • Waivers of Consent and HIPAA Authorization 	Session Recording