

2022 Northeastern University Research Enterprise Services

Human research protection program educational retreat

Agenda

In-person: Virtual:	Curry Student Center #440 – space is limited, please register early Zoom information and link will be shared with attendees after registration		
Day 1: Monday, November 14, 2022 All times in EST.			
10:00 - 10:15	AM Welcome & Kickoff		
10:15 – 11:15	 AM Overview of the Human Research Protection Program & IRB Definition of "human subjects research" What is under the purview of the IRB? Risk categories & review types Roles & responsibilities 		
11:15 - 11:20	AM Break		
11:20 - 12:10	 PM What is eligible for exemption? Exempt categories Common Rule change impacting exempt research Required elements for submitting an exempt protocol Modifying an approved exempt protocol 		
12:10 - 1:00	M Lunch		
1:00 PM - 2:0	 Expedited Review Expedited categories Common Rule change impacting Expedited research Required elements for submitting an Expedited protocol Modifying an approved Expedited protocol When is renewal required for Expedited protocols? 		
2:15 – 3:15 P	7 Criteria for Approved IRB Protocols		
3:15 – 4:00 P	 Running an IRB Meeting When is full board review required? How and what should members prepare? 		

• What needs to be discussed?

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In-person:Curry Student Center #348 – space is limited, please register earlyVirtual:Zoom information and link will be shared with attendees after registration

D	ay 2: Tuesday, November 15, 2022 All times in EST.
10:00 – 10:45 AM	 Preparing and documenting IRB Review Meeting agendas & minutes What needs to be retained in a protocol file? Reporting & metrics
10:45 – 11:00 AM	Break
11:00 AM – 12:00 PM	Dealing with the unexpected • Unanticipated events • Protocol deviations • Audit preparation
12:00 – 1:00 PM	Lunch
1:00 – 2:00 PM	 Informed Consent Waiver of consent Waiver of documentation Assent forms & process Non-English consent documents
2:00 – 3:00 PM	Vulnerable Populations and Other Considerations for IRB Review
3:00 – 4:00 PM	Decreasing burden, increasing efficiency, and working with what we have

**Schedule is subject to change, but finalized by Friday, November 11, 2022.