

## **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	<ul> <li>AM Overview of the Human Research Protection Program &amp; IRB</li> <li>Definition of "human subjects research"</li> <li>What is under the purview of the IRB?</li> <li>Risk categories &amp; review types</li> <li>Roles &amp; responsibilities</li> </ul>		
11:15 - 11:20	AM Break		
11:20 - 12:10	<ul> <li>PM What is eligible for exemption?</li> <li>Exempt categories</li> <li>Common Rule change impacting exempt research</li> <li>Required elements for submitting an exempt protocol</li> <li>Modifying an approved exempt protocol</li> </ul>		
12:10 - 1:00	M Lunch		
1:00 PM - 2:0	<ul> <li>Expedited Review</li> <li>Expedited categories</li> <li>Common Rule change impacting Expedited research</li> <li>Required elements for submitting an Expedited protocol</li> <li>Modifying an approved Expedited protocol</li> <li>When is renewal required for Expedited protocols?</li> </ul>		
2:15 – 3:15 P	7 Criteria for Approved IRB Protocols		
3:15 – 4:00 P	<ul> <li>Running an IRB Meeting</li> <li>When is full board review required?</li> <li>How and what should members prepare?</li> </ul>		

• 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	<ul> <li>Preparing and documenting IRB Review</li> <li>Meeting agendas &amp; minutes</li> <li>What needs to be retained in a protocol file?</li> <li>Reporting &amp; metrics</li> </ul>
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	<ul> <li>Informed Consent</li> <li>Waiver of consent</li> <li>Waiver of documentation</li> <li>Assent forms &amp; process</li> <li>Non-English consent documents</li> </ul>
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.