

# Innovations in Research: Collaborations & Transformations

Cleveland, Ohio  
September 16, 2015  
Cleveland Convention Center

Time	Session	Session Title/Location	Presenter
7:30-8:00 a.m.		<b>Breakfast and Registration/Packet Pick-up  Global Center for Health Innovation</b>	
8:00-8:15 a.m.		<b>Welcome  Junior Ballroom AB</b>	<p>Philip A. Cola, PhD Vice-President, Research and Technology University Hospitals Case Medical Center</p> <p>Sue Rivera, PhD, MSW Vice President for Research, Assistant Professor of Bioethics Case Western Reserve University</p> <p>Carrie O'Neill, BS, CCRC Research Compliance and Education Specialist University Hospitals Case Medical Center</p>
8:15-9:15 a.m.	Plenary	<b>Informed Consent and the Teach Back Method  Junior Ballroom AB</b>	Elizabeth Bankert, MA Assistant Provost Dartmouth College
9:15-10:00 a.m.	Panel	<b>Innovative Approaches to IRB Review: National and Regional Reliance Models  Junior Ballroom AB</b>	<p>Philip A. Cola, PhD (Moderator) Vice-President, Research and Technology University Hospitals Case Medical Center</p> <p>Nichelle Cobb, PhD Director, Health Sciences Institutional Review Boards Office University of Wisconsin School of Medicine and Public Health</p> <p>Kathy Lawry, MSSA, CIP Director Reliant Review MetroHealth Medical Center</p> <p>Carson Reider, PhD Clinical Research Consultant/RSA The Ohio State University</p> <p>Sabune Winkler, JD Director, Regulatory Affairs Operations Harvard Catalyst   The Harvard Clinical and Translational Science Center</p>
10:00-10:15 a.m.		<b>BREAK/TRAVEL</b>	
10:15 -11:10 am		<b>A: The Nuts and Bolts of HHS Human Subject Protections at 45 CFR Part 46  Room 03</b>	Kristina Borrer, PhD Director, Division of Compliance Office for Human Research Protections

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<b>10:15-11:10 a.m.</b>	<b>Breakout 1</b>	<b>B: Finding Flexibility in the Regulations</b>	Lisa Buchanan, MAOM, CIP Public Health Analyst Office for Human Research Protections	
		<b>Room 04</b>	Madeleine A. Williams, MA, CIP Senior Director Huron Consulting Group	
		<b>C: Conflict of Interest Panel</b>	<b>Junior Ballroom AB</b>	Philip A. Cola, PhD (Moderator) Vice- President, Research and Technology University Hospitals Case Medical Center
				Jessica Berg, JD, MPH Dean of Case Western Reserve University Law School Case Western Reserve University
				Lydia Furman, MD Associate Professor of Pediatrics Case Western Reserve University School of Medicine University Hospitals Case Medical Center
				Raymond Onders, MD Professor of Surgery, Remen Chair in Surgical Innovation University Hospitals Case Medical Center, Case Western Reserve University
		Cory Schmidt, JD Director COI Compliance Cleveland Clinic		
<b>11:10-11:15 p.m.</b>		<b>BREAK/TRAVEL</b>		
<b>11:15-12:15 p.m.</b>	<b>NPRM</b>	<b>The Notice of Proposed Rulemaking (NPRM) on Federal Policy for the Protection of Human Research Subjects – An Overview</b>	Julie Kaneshiro, MA Deputy Director Office for Human Research Protections	
		<b>Junior Ballroom AB</b>	Ivor Pritchard, PhD Senior Advisor to the Director Office for Human Research	
			Sue Rivera, PhD, MSW (Moderator) Vice President for Research, Assistant Professor of Bioethics Case Western Reserve University	
<b>12:15-1:15 p.m.</b>		<b>LUNCH</b> <b>Junior Grand Ballroom</b>		
<b>1:15-2:15 p.m.</b>	<b>Breakout 2</b>	<b>A: Auditing the Consent Process &amp; Making Improvements</b>	Carol Fedor, RN, ND, CCRC Director, Human Research Protection Program University Hospitals Case Medical Center	
		<b>Junior Ballroom AB</b>	Linda Lewicki, PhD IRB Senior Research Nurse Cleveland Clinic	
			Laura Morello, MA, LSW Research Subject Advocate Center for Biomedical Ethics at MetroHealth System	

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1:15-2:15 p.m.		<b>B: Innovations in Vulnerable populations (FIND Lab)</b>  <b>Room 03</b>	Ann Williams, PhD, RN, CDE Research Associate Professor Frances Payne Bolton School of Nursing, CWRU
1:15-2:15 p.m.		<b>C: Protecting Health Information in Research</b>  <b>Room 04</b>	Peggy Beat, Esq Senior Director, Research Compliance Cleveland Clinic  Joseph A. Dickinson, Esq., CHPC Office of the General Counsel MetroHealth System
2:15-2:30 p.m.		<b>BREAK/TRAVEL</b>	
2:30 - 3:30 p.m.	<b>Breakout 3</b>	<b>A: Internet Research</b>  <b>Room 03</b>	Ivor Pritchard, PhD Senior Advisor to the Director Office for Human Research Protections
		<b>B: Innovative Practices from the field: Stem Cell Research</b>  <b>Junior Ballroom AB</b>	Hillard Lazarus, MD Disease Team Leader, CTIS, Director, Novel Cell Therapy, Professor, Medicine University Hospitals Case Medical Center, Case Western Reserve University  Insoo Hyun, PhD Associate Professor of Bioethics and Philosophy Case Western Reserve University
		<b>C: Best Strategies for Meeting IND/IDE Requirements</b>  <b>Room 04</b>	Paul Tesar, PhD Associate Professor Department of Genetics and Genome Sciences, Case Western School of Medicine, Case Western Reserve University  Susan Stein, RN IND/IDE Manager Cleveland Clinic  Jenna Stump, MS, CCRP Research Regulatory Specialist University Hospitals Case Medical Center
3:30-3:45 p.m.		<b>Afternoon Snack</b> <b>Global Center for Health Innovation</b>	

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<b>3:45-4:45 p.m.</b>	<b>Panel</b>	<b>Ask the Feds</b>	Julie Kaneshiro, MA Deputy Director Office for Human Research Protections
		<b>Junior Ballroom AB</b>	Ivor Pritchard, PhD Senior Advisor to the Director Office for Human Research Protections
			Kristina Borrer, PhD Director, Division of Compliance Office for Human Research Protections
			Lisa Buchanan, MAOM, CIP Public Health Analyst Division of Compliance Oversight Office for Human Research Protections
<b>4:45-5:00 p.m.</b>		<b>Closing Remarks</b>	Carol Fedor, RN, ND, CCRC Director, Human Research Protection Program University Hospitals Case Medical Center
		<b>Junior Ballroom AB</b>	Tracy J. Wilson-Holden, MA Director, Research Integrity and Education Office of Research Administration Adjunct Instructor, Department of Bioethics Case Western Reserve University
<b>5:00-6:00 p.m.</b>		<b>RECEPTION</b>	
		<b>Global Center for Health Innovation</b>	