

***Summitting New Heights in the Mile-High City:
Early Experiences, Strategies, and Solutions***
AAHRPP 2018 Annual Conference Agenda

Friday, April 20, 2018

Pre-Conference Workshop

Time	Type	Session	Title	Location
7:00am–7:00pm	Registration		Attendee Registration	
7:00am–8:00am	Breakfast		Continental Breakfast	
7:00am–4:00pm	Exhibit		Exhibitor Hours	
8:00am–8:15am	Welcome	PC1	Welcome: Opening Elyse I. Summers, JD, AAHRPP	
8:15am–8:30am	Pre-Conference	PC2	Overview of AAHRPP Elyse I. Summers, JD, AAHRPP	
8:30am–9:15am	Pre-Conference	PC3	Accreditation Process: What to Expect When You’re Expecting Accreditation Kathleen Lawry, MSSA, AAHRPP Consultant Julie Ozier, MHL, CHRC, Vanderbilt University, Vanderbilt University Medical Center Robert Withrow, AAHRPP	
9:15am–10:15am	Pre-Conference	PC4	How to Conduct the Self-Assessment John Baumann, PhD, Indiana University Robert Hood, PhD, AAHRPP	
10:15am–10:30am	Break	Break	AM Break Visit Exhibitors	
10:30am–11:45am	Pre-Conference	PC5	What to Expect During and After the Site Visit Monika Markowitz, PhD, MSN, Virginia Commonwealth University Michele Kennett, MSN, LLM, University of Missouri, Columbia	
12:00pm–1:00pm	Lunch	Lunch	Lunch	

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1:00pm–3:15pm	Pre-Conference	PC6	Review of Accreditation Standards Wesley G. Byerly, PharmD, University of Connecticut Kristin J. Craun, MPH, University of Southern California Russell Price, MArch, Utah State University	
3:15pm–3:30pm	Break	Break	PM Break Visit Exhibitors	
3:30pm–4:00pm	Pre-Conference	PC7	Questions and Answers All Faculty	
4:00pm	Adjourn		Adjourn	

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Conference Day 1

Time	Type	Session	Title	Location
7:00am–4:45pm	Registration		Attendee Registration	
7:00am–8:00am	Breakfast		Continental Breakfast	
7:00am–5:00pm	Exhibit		Exhibitor Hours	
8:00am–8:30am	Welcome Opening	W1	Welcome: Opening Ceremony Barbara Entwisle, PhD, University of North Carolina, Chapel Hill; Chair, Board of Directors, AAHRPP Elyse I. Summers, JD, AAHRPP	
8:30am–10:00am	Plenary	P1	Informed Consent under the Revised Common Rule Jeremy Sugarman, MD, MPH, MA, Johns Hopkins Berman Institute of Bioethics	
10:00am–10:30am	Break		AM Break Visit Exhibitors	
10:30am–11:45am	Concurrent Sessions	A1	New Exemption Categories: Recalibrating the Approach to Low Risk Research Michele Russell-Einhorn, JD, Shulman IRB David Borasky, MPH, WIRB-Copernicus Group	
		A2	Top Ten Findings in AAHRPP Applications and Site Visits Robert Hood, PhD, AAHRPP Candice A. Yekel, MS, The Pennsylvania State University	

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Time	Type	Session	Title	Location
10:30am–11:45am	Concurrent Sessions	A3	Quality Improvement and Quality Assurance: Successes and Innovations (Making the Most of Standard 1-5) K. Sue Haddock, PhD, RN, FAAN, William Jennings Bryan Dorn Veterans Affairs Medical Center Delia Wolf, MD, JD, Harvard School of Public Health	
		A4	Overlapping Roles of DSMBs and IRBs in the Protection of Human Research Participants Michael Linke, PhD, University of Cincinnati College of Medicine Megan Kasimatis Singleton, JD, MBE, Johns Hopkins School of Medicine Robert Silbergleit, MD, University of Michigan Todd Rice, MD, MSc, Vanderbilt Univeristy Medical Center	
		A5	Participant Centered Research: From Study Design to Return of Results Barbara E. Bierer, MD, Harvard Medical School, and Brigham and Women’s Hospital Carol Weil, JD, National Cancer Institute	
11:45am–1:00pm	Lunch	Lunch	Presentations of Certificates of Accreditation and Awards	
1:00pm–2:15pm	Concurrent Sessions	B1	Big Data and Confidentiality Elizabeth Buchanan, PhD, University of Wisconsin-Stout	
		B2	Single IRB Review: Are You Ready? Nichelle Cobb, PhD, University of Wisconsin-Madison, SMART IRB Megan Kasimatis Singleton, JD, MBE, Johns Hopkins School of Medicine	

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1:00pm–2:15pm	Concurrent Sessions	B3	Exempt Research: Experiences and Solutions for Social Behavioral Research Russell Price, MArch, Utah State University Jodi Roberts, PhD, Utah State University	
		B4	Trying to Reach the Pinnacle of Participant Comprehension Cami Gearhart, BS, JD, Quorum Review IRB	
		B5	Learning from International Experiences with AAHRPP Site Visits John R. Baumann, PhD, Indiana University Ian Chen, MD, LLM, National Taiwan University Hospital, Taiwan	
2:30pm–3:45pm	Concurrent Sessions	C1	Single IRB Review: Operational Solutions Martha F. Jones, MA, Washington University in St. Louis Megan Kasimatis Singleton, JD, MBE, Johns Hopkins School of Medicine	
		C2	Vulnerable Populations: Overview and Updates Bruce Gordon, MD, University of Nebraska Medical Center Susan Kornetsky, MPH, Boston Children’s Hospital	
		C3	Defining Human Subject Research under the New Common Rule: Approaches to Initial HRPP Review Cynthia Gates, JD, RN, University of California, Davis Ivor Pritchard, PhD, OHRP	

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Time	Type	Session	Title	Location
2:30pm–3:45pm	Concurrent Sessions	C4	Implementing Central IRBs: Two Perspectives Moderator: Dushyantha Jayaweera, MD, University of Miami Khemraj Hirani, PhD, PharmD, University of Miami Ann Johnson, PhD, MPH, University of Utah Julie Ozier, MHL, CHRC, Vanderbilt University, Vanderbilt University Medical Center Emily Serdoz, MPA, Vanderbilt University, Vanderbilt University Medical Center	
		C5	SACHRP Guidance and the New Rule Jonathan M. Green, MD, Washington University in St. Louis, SACHRP Stephen Rosenfeld, MD, MBA, Quorum Review, Chair, SACHRP	
3:45pm–4:00pm	Break	Break	PM Break Visit Exhibitors and Poster Presentations	
4:00pm–5:00pm	Plenary	P2	Examining the Potential and Challenges of Broad Consent Mark Barnes, JD, Ropes and Gray LLP, Multi-Regional Clinical Trials Center of Harvard and Brigham and Women’s Hospital	
5:00pm–6:30pm	Social	Social	Social Hour/Visit Poster Presentation and Exhibits	

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Sunday, April 22, 2018

Conference Day 2

Time	Type	Session	Title	Location
7:00am–12:00pm	Registration		Attendee Registration	
7:00am–8:00am	Breakfast		Continental Breakfast	
7:00am–1:00pm	Exhibit		Exhibitor Hours	
8:00am–9:00am	Plenary	P3	<p>Are the Criteria for Approval Sufficient to Protect Research Participants: Inquiring Minds Disagree</p> <p>Moderator: Daniel Nelson, MS, US Environmental Protection Agency Jeffery Cooper, MD, MMM, WIRB-Copernicus Group David Strauss, MD, New York State Psychiatric Institute, Columbia University</p>	
9:15am–10:30am	Concurrent Sessions	<p>D1</p> <p>Continuing Review: Operationalizing the New Rule Wesley G. Byerly, PharmD, University of Connecticut Khemraj Hirani, PhD, PharmD, University of Miami</p> <p>D2</p> <p>Meaningful Consent Forms: The Reasonable Person Standard Jonathan M. Green, MD, Washington University in St. Louis Martha F. Jones, MA, Washington University in St. Louis</p> <p>D3</p> <p>“Generalizable” Lessons Learned from Research with Uniformed Military Participants Earl Grant, Jr, PhD, Wilford Hall Ambulatory Surgical Center, 59th Medical Wing</p>		

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Time	Type	Session	Title	Location
9:15am–10:30am	Concurrent Sessions	D4	Research Methods and Models for Measuring and Implementing HRPP Compliance John Baumann, PhD, Indiana University Scott J Lipkin, DPM, FTI Consulting Elicia Preslan, MS, Virginia Commonwealth University Michelle C. Stickler, DEd, Virginia Commonwealth University	
		D5	Innovations and Strategies in Community Outreach Kaveh Khoshnood, PhD, MPH, Yale University Richard R. Sharp, PhD, Mayo Clinic	
10:30am-10:45am	Break		AM Break Visit Exhibitors and Poster Presentations	
10:45am-12:00pm	Concurrent Sessions	E1	Reliance Agreements: Operational Strategies for Staffing, Verifying IRB Quality, and Comprehensive Templates Lauri Carlile, MS, Chesapeake IRB Nancy A. Olson, JD, University of Mississippi Medical Center	
		E2	Applying the Approval Criteria Consistently: Do It and Document It Robert Hood, PhD, AAHRPP Warren Capell, MD, University of Colorado, Denver	
		E3	Biobanking Beyond Broad Consent: Has Research Biobanking Taken a Hit in the Final Rule? Carol Weil, JD, National Cancer Institute	

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10:45am–12:00pm	Concurrent Sessions	E4	Tools and Strategies for Measuring and Improving HRPP Efficiency and Effectiveness Courtney Jarboe, MA, MS, University of Minnesota Felicia Mroczkowski, University of Minnesota Julie Quinn, MURP, University of Minnesota	
		E5	New Consent Requirements Under the Common Rule Ivor Pritchard, PhD, OHRP Stephen Rosenfeld, MD, MBA, Quorum Review, Chair, SACHRP	
12:00pm-1:00pm	Lunch		Networking Lunch FLEX Coalition & SMART IRB Lunch (pre-registration required)	
1:00pm–2:00pm	Plenary	P4	Do New Tools Need New Ethics? The Challenge of Advancing Biotechnology for Ethics and Policy Jeffrey Kahn, PhD, MPH, Johns Hopkins Berman Institute of Bioethics	

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Time	Type	Session	Title	Location
2:15pm- 3:30pm	Concurrent Sessions	F1	The Expedited Review List: What Should be Included in the Revised Categories? (Participatory/Workshop Session) David Borasky, MPH, WIRB-Copernicus Group Ivor Pritchard, PhD, OHRP Michele Russell-Einhorn, JD, Shulman IRB	
		F2	Implementing the NIH Policy on Certificates of Confidentiality John Heldens, BA, Univeristy of Colorado, Denver.	
		F3	Understanding and Implementing Limited IRB Review Daniel Nelson, MS, US Environmental Protection Agency	
		F4	Research with Individuals Lacking Consent Capacity Rachel Barber, DNP, RN, St. Jude Children's Research Hospital Wendy Hayes, MSN, RN, St. Jude Children's Research Hospital Jessica Huening, JD, Yale University Amy Waltz, JD, Indiana University	
		F5	AAHRPP Standard I-9 in Action: Panel Discussion with Tips for Implementation Nichelle Cobb, PhD, University of Wisconsin-Madison, SMART IRB Michelle Feige, MSW, LCSW-C, AAHRPP Robert Hood, PhD, AAHRPP Ann Johnson, PhD, MPH, University of Utah	
3:30pm	Adjourn		Adjourn	