Summiting 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	
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	**AM Break**	**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 Areas of Concern 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 I-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 University Medical Center	
		A5	**Participant Centered Research: Promoting the Disclosure of Individual Aggregate Research 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, JD, Quorum Review IRB Ivor Pritchard, PhD, OHRP Seth L. Schulman, MD, Pfizer, Inc.	
		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	**Pediatric Research: A Case Based Workshop on How to Apply the Regulations** 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	**PM 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–6:00pm	**Poster**	**Poster**	**2018 Poster Presentations**	
6:00pm – 7:30pm	**Social**	**Social**	**Social Hour**	

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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**	**Are the Criteria for Approval Sufficient to Protect Research Participants: Inquiring Minds Disagree** 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	
9:15am–10:30am	**Concurrent Sessions**	**D1**	**Continuing Review: Operationalizing the New Rule** Wesley G. Byerly, PharmD, University of Connecticut Khemraj Hirani, PhD, PharmD, University of Miami	
		D2	**Meaningful Consent Forms: The Reasonable Person Standard** Jonathan M. Green, MD, Washington University in St. Louis Jeanne Velders, JD, Washington University in St. Louis	
		D3	**Acquiring Accreditation Acumen & Lessons Learned from Research with Uniformed Military** Moderator: Robert Hood, PhD, AAHRPP Wayne M. Deutsch, DDS, CTR, 59th Medical Wing Earl Grant, Jr, PhD, 59th Medical Wing Debra Niemeyer, PhD, 59th Medical Wing	

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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, The University of Texas at Austin	
		D5	**Innovations and Strategies in Community Outreach** Kaveh Khoshnood, PhD, MPH, Yale University Richard R. Sharp, PhD, Mayo Clinic	
10:30am-10:45am	**AM Break**	**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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Time	Type	Session	Title	Location
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**	**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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Conference Day 2

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, University 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**	