Evolving, Adapting, and Thriving in the New Research Environment

AAHRPP 2017 Annual Conference Agenda

Tuesday, May 9, 2017

Pre- Conference Workshop

Time	Type	Session	Title	Location
7:00am–7:00pm	**Registration**		**Attendee Registration**	**Woodward Foyer**
7:00am–8:00am	**Breakfast**		**Continental Breakfast**	**Woodward Foyer**
8:00am–8:15am	**Welcome**	**PC1**	**Welcome: Opening** Elyse I. Summers, JD, AAHRPP	**Woodward Ballroom**
8:15am–8:30am	**Pre-Conference**	**PC2**	**Overview of AAHRPP** Elyse I. Summers, JD, AAHRPP	**Woodward Ballroom**
8:30am–9:15am	**Pre-Conference**	**PC3**	**Accreditation Process: What to Expect When You're Expecting Accreditation** Sarah H. Kiskaddon, JD, AAHRPP Kathleen Lawry, MSSA, CIP, AAHRPP, Consultant Robert Withrow, AAHRPP	**Woodward Ballroom**
9:15am–10:15am	**Pre-Conference**	**PC4**	**How to Conduct the Self-Assessment** Robert Hood, PhD, AAHRPP Sujatha Sridhar, MBBS, MCE, The University of Texas Health Science Center at Houston Fanny K. Ennever, PhD, CIP, Boston University Medical Center James Feldman, MD, MPH, FACEP, Boston University Medical Center	**Woodward Ballroom**
10:15am–10:30am	**Break**	**Break**	**AM Break**	**Woodward Foyer**
10:30am–11:30am	**Pre-Conference**	**PC5**	**What to Expect During and After the Site Visit** Robert Frenck Jr., MD, Cincinnati Children's Hospital Medical Center Delia Y. Wolf, MD, JD, Harvard School of Public Health	**Woodward Ballroom**
12:00pm–1:00pm	**Lunch**	**Lunch**	**Lunch**	**Woodward Ballroom**

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Time	Type	Session	Title	Location
1:00pm–3:15pm	**Pre-Conference**	**PC6**	**Review of Accreditation Standards** John R. Baumann, PhD, Indiana University Wesley G. Byerly, PharmD, University of Connecticut	**Woodward Ballroom**
3:15pm–3:30pm	**Break**	**Break**	**PM Break**	**Woodward Foyer**
3:30pm–4:00pm	**Pre-Conference**	**PC7**	**Questions and Answers** All Faculty	**Woodward Ballroom**
4:00pm		**Adjourn**	**Adjourn**	
4:30pm–6:30pm	**SVT**	**SVT**	**Site Visitor Training**	**Woodward Ballroom**

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Wednesday, May 10, 2017

Conference Day 1

Time	Type	Session	Title	Location
7:00am–4:45pm	**Registration**		**Attendee Registration**	**Woodward Foyer**
7:00am–8:00am	**Breakfast**		**Continental Breakfast**	**Woodward Foyer**
7:00am–5:00pm	**Exhibit**		**Exhibitor Hours**	**Woodward Foyer**
8:00am–9:00am	**Welcome Opening**	**W1**	**Welcome: Opening Ceremony** Elyse I. Summers, JD, AAHRPP Jeffrey Wendel, BS, MBA, Chair, Board of Directors, AAHRPP	**Woodward Ballroom**
9:00am–10:15am	**Plenary**	**P1**	**Human Genome Editing (CRISPR): Scientific and Ethical Considerations** Moderator: Bernard Lo, MD, UCSF and Greenwall Foundation Co-Presenters: Matthew Porteus, MD, Stanford University Natasha Bonhomme, Genetic Alliance	**Woodward Ballroom**
10:15am–10:30am	**Break**		**AM Break**	**Woodward Foyer**
10:30am–11:45am	**Concurrent Sessions**	**A1**	**Digital and Emerging Technologies in Clinical Trials: Ethical and Regulatory (FDA) Guidance** Elizabeth Buchanan, PhD, University of Wisconsin-Stout David G. Forster, JD, MA, CIP, Western IRB	**Crystal Ballroom**
		A2	**International Panel: Integrating Local Law and Context into AAHRPP Standards (Examples from the Republic of Korea, China, and India)** Sujatha Sridhar, MBBS, MCE (moderator and presenter) B. I. Choe, LLM, PhD, The Catholic University of Korea Xiuqin Wang, MD, PhD, Jiangsu Province Hospital, Nanjing Medical University	**Boulevard**

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Conference Day 1

Time	Type	Session	Title	Location
10:30am–11:45am	**Concurrent Sessions**	**A3**	**Single IRB Review: Getting Prepared Beyond the National Reliance Model Agreement** Nichelle Cobb, PhD, University of Wisconsin-Madison Kathleen Lawry, MSSA, CIP, Consultant, AAHRPP	**Venetian Ballroom**
		A4	**Data Privacy: Biorepositories, Social Behavioral Research, and Biomedical Research** Suzanne M. Rivera, PhD, MSW, Case Western Reserve University Stephen J. Rosenfeld, MD, MBA, Quorum Review	**Founders AB**
		A5	**Return of Research Results: Should the US Follow EU Rules?** Rebecca Li, PhD, MRCT, Harvard University James Riddle, MCSE, CIP, CPIA, Kinetiq	**Esquire**
11:45am–1:00pm	**Lunch**	**Lunch**	**Presentations of Certificates of Accreditation and Awards**	**Woodward Ballroom**
1:00pm–2:15pm	**Concurrent Sessions**	**B1**	**Innovations and Distinctions in Researcher Training Programs** Kristen Burt, JD, Michigan State University Rebecca Gore, MS, CIP, Michigan State University Judy McMillan, BS, CIP, Michigan State University Chandana Pal, Apollo Research and Innovation Group, India	**Boulevard**
		B2	**Preparing for Reliance: What AAHRPP Accredited Organizations Need to Know** Michelle Feige, MSW, AAHRPP Ada Sue Selwitz, MA, University of Kentucky Megan Kasimatis Singleton, JD, MBE, CIP, Johns Hopkins University School of Medicine	**Crystal Ballroom**

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Time	Type	Session	Title	Location
1:00pm–2:15pm	**Concurrent Sessions**	**B3**	**Pediatric Research: When Can Minors Consent for Themselves?** Francis J. DiMario, MD, Connecticut Children's Medical Center Heather H. Pierce, JD, AAMC	**Esquire**
		B4	**Innovations in Outreach Activities: Communicating with the Research and Local Communities** Jennifer Kucera, MS, CIP, University of Nebraska Medical Center Linda Petree, BA, CIP, University of New Mexico	**Founders AB**
		B5	**Promoting High Quality Research by Integrating the Research Compliance Program in the HRPP** John R. Baumann, PhD, Indiana University Scott Lipkin, DPM, FTI Consulting	**Venetian Ballroom**
2:30pm–3:45pm	**Concurrent Sessions**	**C1**	**Implementing Single IRB Review: Practical Considerations and Cost Models** Martha F. Jones, MA, Washington University in St. Louis Pearl O'Rourke, MD, Partners HealthCare Systems, Harvard University	**Crystal Ballroom**
		C2	**Pediatric Research: Analyzing and Documenting Risk/Benefit and Permission/Assent Determinations** Robert Frenck Jr., MD, Cincinnati Children's Hospital Medical Center Susan Kornetsky, MPH, Boston Children's Hospital	**Boulevard**
		C3	**Global Trends in Clinical Trials: Patient Centric Research** Rebecca Li, PhD, MRCT, Harvard University Ann Meeker-O'Connell, MS, Johnson & Johnson Family of Consumer Companies Delia Y. Wolf, MD, JD, Harvard School of Public Health	**Venetian Ballroom**

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Conference Day 1

Time	Type	Session	Title	Location
2:30pm–3:45pm	**Concurrent Sessions**	**C4**	**Working with Independent IRBs: View from Both Sides** Lauri Carlile, MS, CIP, Chesapeake Research Review George Gasparis, CIP, The PEER Consulting Group	**Esquire**
		C5	**Planning, Developing, and Implementing a Quality Assurance and Quality Improvement Program: Putting Standard I-5 into Action** Elicia Preslan, MS, CIP, Virginia Commonwealth University Karen Blaszczyk Skinner, MSN, RN, CCRP, Drexel University Michelle Stickler, DEd, CIP, Virginia Commonwealth University	**Venetian Ballroom**
3:45pm–4:00pm	**Break**	**Break**	**PM Break** Visit Exhibitors and Poster Presentations	**Woodward Foyer**
4:00pm–5:00pm	**Plenary**	**P2**	**Patient-Driven Research: A Perspective from the National Health Council** Moderator: Tracy Blumenfeld, MBA, Rapid Trials Marc M. Boutin, JD, CEO, National Health Council	**Woodward Ballroom**
5:00pm–6:30pm	**Social**	**Social**	**Social Hour/Visit Poster Presentation and Exhibits**	**4th Floor Pre-Function Lounge**
6:30pm–8:00pm	**Dinner**	**Dinner**	**Motown Meal: "Dinner in the D"**	**Woodward Ballroom**

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AAHRPP 2017 Annual Conference Agenda

Thursday, May 11, 2017

Conference Day 2

Time	Type	Session	Title	Location
7:00am–4:45pm	**Registration**		**Attendee Registration**	**Woodward Foyer**
7:00am–8:00am	**Breakfast**		**Continental Breakfast**	**Woodward Foyer**
7:00am–1:00pm	**Exhibit**		**Exhibitor Hours**	**Woodward Foyer**
8:00am–9:00am	**Plenary**	**P3**	**Engaging the Community: The Michigan Experience** Lois Brako, PhD, University of Michigan Sonia Hassan, MD, Wayne State University School of Medicine Shawn McElmurry, PhD, Wayne State University	**Woodward Ballroom**
9:15am–10:30am	**Concurrent Sessions**	**D1**	**Following ICH-GCP (E6): Strategies and New Guidance** Wesley G. Byerly, PharmD, University of Connecticut Robert Hood, PhD, AAHRPP	**Crystal Ballroom**
		D2	**Getting IRB Minutes Right: Learning from Observations on Site Visits** Sara Harnish, JD, Schulman IRB Sarah H. Kiskaddon JD, AAHRPP Nancy A. Olson, JD, University of Mississippi Medical Center	**Boulevard**
		D3	**Strategies for Achieving Compliance in DOD Supported Research** Kimberly Odam, MS, CIP, US Army Medical Research and Materiel Command Martha F. Jones, MA, Washington University in St. Louis	**Esquire**

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Conference Day 2

Time	Type	Session	Title	Location
9:15am–10:30am	**Concurrent Sessions**	**D4**	**Rolling Out the New Rule: Questions and Answers** Ivor Pritchard, PhD, Office for Human Research Protection	**Venetian Ballroom**
		D5	**Getting Ready for E-Consent** Moderator: Cami Gearhart, JD, Quorum Review IRB Linda M. Coleman, JD, Yale University Jessica Huening, JD, Kinetiq, a Division of Quorum Review Tracy Stewart, MBA, Quintiles IMS	**Founders AB**
10:30am-10:45am	**Break**		**AM Break** Visit Exhibitors and Poster Presentations	**Woodward Foyer**
10:45am-12:00pm	**Concurrent Sessions**	**E1**	**Maintaining a Robust HRPP between Accreditation Cycles** Jeffrey A. Cooper, MD, WIRB-Copernicus Group	**Venetian Ballroom**
		E2	**Top Ten Findings: International and Domestic Applications** K. Sue Haddock, PhD, RN, William Jennings Bryan Dorn Veterans Affairs Medical Center Robert Hood, PhD, AAHRPP Sarah H. Kiskaddon JD, AAHRPP	**Esquire**
		E3	**Compliance Under the New Rule: What Will be the New Features on the 2018 Model?** Ivor Pritchard, PhD, Office for Human Research Protection	**Crystal Ballroom**

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Time	Type	Session	Title	Location
10:45am–12:00pm	**Concurrent Sessions**	**E4**	**Post-Approval Monitoring: Social Behavioral and Biomedical Research** Jeffrey Cohen, PhD, HRP Consulting Sana Khoury-Shakour, PhD, University of Michigan	**Founders AB**
		E5	**Research Involving Participants with Mental Disorders: Assessing and Enhancing Capacity for Consent** Tamyra Armbrust, CIP, Mayo Clinic Maria I. Lapid, MD, Mayo Clinic R. Scott Wright, MD, Mayo Clinic	**Boulevard**
12:00pm-1:00pm	**Lunch**		**Networking Lunch**	**Woodward Ballroom**
			FLEX Coalition Lunch (pre-registration required)	**Founders AB**
			SMART IRB Lunch (pre-registration required)	**Boulevard**
1:00pm–2:15pm	**Concurrent Sessions**	**F1**	**Developing a Novel App to Educate Children on the Human Subject Assent Process** Rebecca Dahl, PhD, Children's Hospital Los Angeles	**Esquire**
		F2	**Can We Measure IRB Quality?: Identifying the Right Metrics to Increase Consistency and Improve Results** David A. Borasky Jr., MPH, CIP, Copernicus Group IRB Jonathan M. Green, MD, Washington University at St. Louis	**Venetian Ballroom**

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Time	Type	Session	Title	Location
1:00pm–2:15pm	**Concurrent Sessions**	**F3**	**Getting a Handle on Conflict of Interest: Disclosure and Management** Ross McKinney, MD, AAMC Heather H. Pierce, JD, AAMC	**Crystal Ballroom**
		F4	**International Collaboration in Research and IRB/Ethics Review: Lessons Learned** Yali Cong, PhD, Peking University, China Michael E. Geisser, PhD, University of Michigan Ray Hutchinson, MD, University of Michigan Haihong Zhang, PhD, Peking University, China	**Boulevard**
		F5	**Should I Serve as the IRB of Record for a Multicentered Trial?** Rebecca Abel, MA, CIP, Vanderbilt University Michael Linke, PhD, University of Cincinnati Todd W. Rice, MD, MSC, Vanderbilt University Emily Sheffer, MPA, Vanderbilt University	**Founders AB**
2:30pm- 3:30pm	**Plenary**	**P4**	**The Final Rule: Natural Selection, or Intelligent Design?** Moderator: Elisa Hurley, PhD, PRIM&R P. Pearl O'Rourke, MD, Partners Healthcare Systems Ivor Pritchard, PhD, Office for Human Research Protections	**Woodward Ballroom**
3:30pm	**Adjourn**		**ADJOURN**	