# *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**<br>Elyse I. Summers, JD, AAHRPP | |
| **8:15am–8:30am** | **Pre-Conference** | **PC2** | **Overview of AAHRPP**<br>Elyse I. Summers, JD, AAHRPP | |
| **8:30am–9:15am** | **Pre-Conference** | **PC3** | **Accreditation Process: What to Expect When You're Expecting Accreditation**<br>Kathleen Lawry, MSSA, AAHRPP Consultant<br>Julie Ozier, MHL, CHRC, Vanderbilt University, Vanderbilt University Medical Center<br>Robert Withrow, AAHRPP | |
| **9:15am–10:15am** | **Pre-Conference** | **PC4** | **How to Conduct the Self-Assessment**<br>John Baumann, PhD, Indiana University<br>Robert Hood, PhD, AAHRPP | |
| **10:15am–10:30am** | **Break** | **Break** | **AM Break**<br>Visit Exhibitors | |
| **10:30am–11:45am** | **Pre-Conference** | **PC5** | **What to Expect During and After the Site Visit**<br>Monika Markowitz, PhD, MSN, Virginia Commonwealth University<br>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**<br>Wesley G. Byerly, PharmD, University of Connecticut<br>Kristin J. Craun, MPH, University of Southern California<br>Russell Price, MArch, Utah State University | |
| **3:15pm–3:30pm** | **Break** | **Break** | **PM Break**<br>Visit Exhibitors | |
| **3:30pm–4:00pm** | **Pre-Conference** | **PC7** | **Questions and Answers**<br>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**<br>Barbara Entwisle, PhD, University of North Carolina, Chapel Hill; Chair, Board of Directors, AAHRPP<br>Elyse I. Summers, JD, AAHRPP | |
| **8:30am–10:00am** | **Plenary** | **P1** | **Informed Consent under the Revised Common Rule**<br>Jeremy Sugarman, MD, MPH, MA, Johns Hopkins Berman Institute of Bioethics | |
| **10:00am–10:30am** | **Break** | | **AM Break**<br>Visit Exhibitors | |
| **10:30am–11:45am** | **Concurrent Sessions** | **A1** | **New Exemption Categories: Recalibrating the Approach to Low Risk Research**<br>Michele Russell-Einhorn, JD, Shulman IRB<br>David Borasky, MPH, WIRB-Copernicus Group | |
| | | **A2** | **Top Ten Areas of Concern in AAHRPP Applications and Site Visits**<br>Robert Hood, PhD, AAHRPP<br>Candice A. Yekel, MS, The Pennsylvania State University | |

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| **10:30am–11:45am** | **Concurrent Sessions** | **A3** | **Quality Improvement and Quality Assurance: Successes and Innovations (Making the Most of Standard I-5)**<br>K. Sue Haddock, PhD, RN, FAAN, William Jennings Bryan Dorn Veterans Affairs Medical Center<br>Delia Wolf, MD, JD, Harvard School of Public Health | |
| | | **A4** | **Overlapping Roles of DSMBs and IRBs in the Protection of Human Research Participants**<br>Michael Linke, PhD, University of Cincinnati College of Medicine<br>Megan Kasimatis Singleton, JD, MBE, Johns Hopkins School of Medicine<br>Robert Silbergleit, MD, University of Michigan<br>Todd Rice, MD, MSc, Vanderbilt University Medical Center | |
| | | **A5** | **Participant Centered Research: From Study Design to Return of Results**<br>Barbara E. Bierer, MD, Harvard Medical School, and Brigham and Women's Hospital<br>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**<br>Elizabeth Buchanan, PhD, University of Wisconsin-Stout | |
| | | **B2** | **Single IRB Review: Are You Ready?**<br>Nichelle Cobb, PhD, University of Wisconsin-Madison, SMART IRB<br>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**<br>Russell Price, MArch, Utah State University<br>Jodi Roberts, PhD, Utah State University | |
| | | **B4** | **Trying to Reach the Pinnacle of Participant Comprehension**<br>Cami Gearhart, JD, Quorum Review IRB<br>Ivor Pritchard, PhD, OHRP | |
| | | **B5** | **Learning from International Experiences with AAHRPP Site Visits**<br>John R. Baumann, PhD, Indiana University<br>Ian Chen, MD, LLM, National Taiwan University Hospital, Taiwan | |
| **2:30pm–3:45pm** | **Concurrent Sessions** | **C1** | **Single IRB Review: Operational Solutions**<br>Martha F. Jones, MA, Washington University in St. Louis<br>Megan Kasimatis Singleton, JD, MBE, Johns Hopkins School of Medicine | |
| | | **C2** | **Vulnerable Populations: Overview and Updates**<br>Bruce Gordon, MD, University of Nebraska Medical Center<br>Susan Kornetsky, MPH, Boston Children's Hospital | |
| | | **C3** | **Defining Human Subject Research under the New Common Rule: Approaches to Initial HRPP Review**<br>Cynthia Gates, JD, RN, University of California, Davis<br>Ivor Pritchard, PhD, OHRP | |

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| **2:30pm–3:45pm** | **Concurrent Sessions** | **C4** | **Implementing Central IRBs: Two Perspectives**<br>Moderator: Dushyantha Jayaweera, MD, University of Miami<br>Khemraj Hirani, PhD, PharmD, University of Miami<br>Ann Johnson, PhD, MPH, University of Utah<br>Julie Ozier, MHL, CHRC, Vanderbilt University, Vanderbilt University Medical Center<br>Emily Serdoz, MPA, Vanderbilt University, Vanderbilt University Medical Center | |
| | | **C5** | **SACHRP Guidance and the New Rule**<br>Jonathan M. Green, MD, Washington University in St. Louis, SACHRP<br>Stephen Rosenfeld, MD, MBA, Quorum Review, Chair, SACHRP | |
| **3:45pm–4:00pm** | **Break** | **Break** | **PM Break**<br>Visit Exhibitors and Poster Presentations | |
| **4:00pm–5:00pm** | **Plenary** | **P2** | **Examining the Potential and Challenges of Broad Consent**<br>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**<br>Moderator: Daniel Nelson, MS, US Environmental Protection Agency<br>Jeffery Cooper, MD, MMM, WIRB-Copernicus Group<br>David Strauss, MD, New York State Psychiatric Institute, Columbia University | |
| **9:15am–10:30am** | **Concurrent Sessions** | **D1** | **Continuing Review: Operationalizing the New Rule**<br>Wesley G. Byerly, PharmD, University of Connecticut<br>Khemraj Hirani, PhD, PharmD, University of Miami | |
| | | **D2** | **Meaningful Consent Forms: The Reasonable Person Standard**<br>Jonathan M. Green, MD, Washington University in St. Louis<br>Jeanne Velders, Washington University in St. Louis | |
| | | **D3** | **Acquiring Accreditation Acumen & Lessons Learned from Research with Uniformed Military**<br>Moderator: Robert Hood, PhD, AAHRPP<br>Earl Grant, Jr, PhD, 59th Medical Wing<br>Debra Niemeyer, PhD, 59th Medical Wing | |

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|---|---|---|---|---|
| **9:15am–10:30am** | **Concurrent Sessions** | **D4** | **Research Methods and Models for Measuring and Implementing HRPP Compliance**<br>John Baumann, PhD, Indiana University<br>Scott J. Lipkin, DPM, FTI Consulting<br>Elicia Preslan, MS, Virginia Commonwealth University<br>Michelle C. Stickler, DEd, The University of Texas at Austin | |
| | | **D5** | **Innovations and Strategies in Community Outreach**<br>Kaveh Khoshnood, PhD, MPH, Yale University<br>Richard R. Sharp, PhD, Mayo Clinic | |
| **10:30am-10:45am** | **Break** | | **AM Break**<br>Visit Exhibitors and Poster Presentations | |
| **10:45am-12:00pm** | **Concurrent Sessions** | **E1** | **Reliance Agreements: Operational Strategies for Staffing, Verifying IRB Quality, and Comprehensive Templates**<br>Lauri Carlile, MS, Chesapeake IRB<br>Nancy A. Olson, JD, University of Mississippi Medical Center | |
| | | **E2** | **Applying the Approval Criteria Consistently: Do It and Document It**<br>Robert Hood, PhD, AAHRPP<br>Warren Capell, MD, University of Colorado, Denver | |
| | | **E3** | **Biobanking Beyond Broad Consent: Has Research Biobanking Taken a Hit in the Final Rule?**<br>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**<br>Courtney Jarboe, MA, MS, University of Minnesota<br>Felicia Mroczkowski, University of Minnesota<br>Julie Quinn, MURP, University of Minnesota | |
| | | **E5** | **New Consent Requirements Under the Common Rule**<br>Ivor Pritchard, PhD, OHRP<br>Stephen Rosenfeld, MD, MBA, Quorum Review, Chair, SACHRP | |
| **12:00pm-1:00pm** | **Lunch** | | **Networking Lunch**<br><br>**FLEX Coalition & SMART IRB Lunch**<br>**(pre-registration required)** | |
| **1:00pm–2:00pm** | **Plenary** | **P4** | **Do New Tools Need New Ethics? The Challenge of Advancing Biotechnology for Ethics and Policy**<br>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)**<br>David Borasky, MPH, WIRB-Copernicus Group<br>Ivor Pritchard, PhD, OHRP<br>Michele Russell-Einhorn, JD, Shulman IRB | |
| | | **F2** | **Implementing the NIH Policy on Certificates of Confidentiality**<br>John Heldens, BA, University of Colorado, Denver. | |
| | | **F3** | **Understanding and Implementing Limited IRB Review**<br>Daniel Nelson, MS, US Environmental Protection Agency | |
| | | **F4** | **Research with Individuals Lacking Consent Capacity**<br>Rachel Barber, DNP, RN, St. Jude Children's Research Hospital<br>Wendy Hayes, MSN, RN, St. Jude Children's Research Hospital<br>Jessica Huening, JD, Yale University<br>Amy Waltz, JD, Indiana University | |
| | | **F5** | **AAHRPP Standard I-9 in Action: Panel Discussion with Tips for Implementation**<br>Nichelle Cobb, PhD, University of Wisconsin-Madison, SMART IRB<br>Michelle Feige, MSW, LCSW-C, AAHRPP<br>Robert Hood, PhD, AAHRPP<br>Ann Johnson, PhD, MPH, University of Utah | |
| **3:30pm** | **Adjourn** | | **Adjourn** | |