

2018 AAHRPP Annual Conference: April 20-22, 2018

AAHRPP 2018 Annual Conference Agenda

Friday, April 20, 2018 Pre-Conference Workshop

7:00 am – 7:00 pm		ATTENDEE REGISTRATION	REGISTRATION DESK
7:00 am – 8:00 am		CONTINENTAL BREAKFAST	COLORADO FOYER/BALL
7:00 am – 4:00 pm		EXHIBITOR HOURS	COLORADO FOYER
8:00 am – 8:15 am	Welcome PC1	WELCOME: OPENING Elyse I. Summers, JD, AAHRPP	COLORADO BALLROOM
8:15 am – 8:30 am	PC2	OVERVIEW OF AAHRPP Elyse I. Summers, JD, AAHRPP	COLORADO BALLROOM
8:30 am – 9:15 am	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, BA, AAHRPP	COLORADO BALLROOM
9:15 am – 10:15 am	PC4	HOW TO CONDUCT THE SELF-ASSESSMENT John Baumann, PhD, Indiana University Robert Hood, PhD, AAHRPP	COLORADO BALLROOM
10:15 am – 10:30 am	BREAK	AM BREAK Visit Exhibitors	COLORADO FOYER
10:30 am – 11:45 am	PC5	WHAT TO EXPECT DURING AND AFTER THE SITE VISIT Monika Markowitz, PhD, MA, MSN, RN, Virginia Commonwealth University Michele Kennett, JD, MSN, LLM, University of Missouri	COLORADO BALLROOM
11:45 am – 1:00 pm	LUNCH	LUNCH	ASPEN BALLROOM
1:00 pm – 3:15 pm	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	COLORADO BALLROOM
3:15 pm – 3:30 pm	BREAK	PM BREAK Visit Exhibitors	COLORADO FOYER
3:30 pm – 4:00 pm	PC7	QUESTIONS & ANSWERS All Faculty	COLORADO BALLROOM
4:00 pm		ADJOURN	

AAHRPP 2018 Annual Conference Agenda

Saturday, April 21, 2018 Conference Day 1

7:00 am – 4:45 pm		ATTENDEE REGISTRATION	REGISTRATION DESK
7:00 am – 8:00 am		CONTINENTAL BREAKFAST	COLORADO FOYER/BALL
7:00 am – 5:00 pm		EXHIBITOR HOURS	COLORADO FOYER
8:00 am – 8:30 am	Welcome W1	WELCOME: OPENING CEREMONY Barbara Entwisle, PhD, University of North Carolina, Chapel Hill; Chair, Board of Directors, AAHRPP Elyse I. Summers, JD, AAHRPP	COLORADO BALLROOM
8:30 am – 10:00 am	P1	INFORMED CONSENT UNDER THE REVISED COMMON RULE Jeremy Sugarman, MD, MPH, MA, Johns Hopkins Berman Institute of Bioethics	COLORADO BALLROOM
10:00 am – 10:30 am	BREAK	AM BREAK Visit Exhibitors	COLORADO FOYER
10:30 am – 11:45 am	A1	NEW EXEMPTION CATEGORIES: RECALIBRATING THE APPROACH TO LOW RISK RESEARCH Michele Russell-Einhorn, JD, Advarra David Borasky, Jr., MPH, WIRB-Copernicus Group	ASPEN BALLROOM
	A2	TOP TEN AREAS OF CONCERN IN AAHRPP APPLICATIONS AND SITE VISITS Robert Hood, PhD, AAHRPP Candice A. Yekel, MS, The Pennsylvania State University	MT. SOPRIS A
	A3	QUALITY IMPROVEMENT AND QUALITY ASSURANCE: SUCCESSSES 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, MSCI, Harvard C.H. Chan School of Public Health	MT. SOPRIS B
	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 University School of Medicine Robert Silbergleit, MD, University of Michigan Todd W. Rice, MD, MSc, Vanderbilt University Medical Center	MT. OXFORD
	A5	PARTICIPANT CENTERED RESEARCH: PROMOTING THE DISCLO- SURE OF INDIVIDUAL AND AGGREGATE RESEARCH RESULTS Barbara E. Bierer, MD, Harvard Medical School, and Brigham and Women's Hospital Carol J. Weil, JD, National Cancer Institute	MAROON PEAK

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Saturday, April 21, 2018 Conference Day 1

11:45 am – 1:00 pm	LUNCH Presentations of Certificates of Accreditation and Awards	COLORADO BALLROOM
1:00 pm – 2:15 pm	B1 BIG DATA AND CONFIDENTIALITY David Peloquin, JD, Ropes & Gray, LLP	MT. SOPRIS A
	B2 SINGLE IRB REVIEW: ARE YOU READY? Nichelle Cobb, PhD, University of Wisconsin-Madison, SMART IRB Megan Kasimatis Singleton, JD, MBE, Johns Hopkins University School of Medicine	ASPEN BALLROOM
	B3 EXEMPT RESEARCH: EXPERIENCES AND SOLUTIONS FOR SOCIAL BEHAVIORAL RESEARCH Russell Price, MArch, Utah State University Jodi Roberts, PhD, CIM, CRC, Utah State University	MT. SOPRIS B
	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.	MT. COLUMBIA
	B5 LEARNING FROM INTERNATIONAL EXPERIENCES WITH AAHRPP SITE VISITS John R. Baumann, PhD, Indiana University Ian Chen, MD, LLM, JSD, National Taiwan University Hospital, Taiwan	MT. OXFORD
2:30 pm – 3:45 pm	C1 SINGLE IRB REVIEW: OPERATIONAL SOLUTIONS Martha F. Jones, MA, Washington University in St. Louis Megan Kasimatis Singleton, JD, MBE, Johns Hopkins University School of Medicine	MT. COLUMBIA
	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	MT. SOPRIS A
	C3 DEFINING HUMAN SUBJECT RESEARCH UNDER THE NEW COMMON RULE: APPROACHES TO INITIAL HRPP REVIEW Cynthia Gates, JD, ADN, CCRP, University of California, Davis Ivor Pritchard, PhD, OHRP	ASPEN BALLROOM

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Saturday, April 21, 2018 Conference Day 1

2:30 pm – 3:45 pm	C4	IMPLEMENTING CENTRAL IRBS: TWO PERSPECTIVES Moderator: Dushyantha Jayaweera, MD, MRCOG (UK), FACP, University of Miami Khemraj Hirani, MPharm, PhD, RPh, CCRP, RAC, MBA, 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	MAROON PEAK
	C5	SACHRP GUIDANCE AND THE NEW RULE Jonathan M. Green, MD, MBA, Washington University in St. Louis, SACHRP Stephen Rosenfeld, MD, MBA, Quorum Review, Chair, SACHRP	MT. SOPRIS B
3:45 pm – 4:00 pm	BREAK	PM BREAK Visit Exhibitors and Poster Presentations	COLORADO FOYER
4:00 pm – 5:00 pm	P2	EXAMINING THE POTENTIAL AND CHALLENGES OF BROAD CONSENT Mark Barnes, JD, Ropes & Gray LLP, Multi-Regional Clinical Trials Center of Harvard and Brigham and Women's Hospital	COLORADO BALLROOM
5:00 pm – 6:00 pm	POSTER	2018 POSTER PRESENTATIONS	ASPEN BALLROOM
6:00 pm – 7:30 pm	SOCIAL	SOCIAL HOUR	CAPITOL PEAK

AAHRPP 2018 Annual Conference Agenda

Sunday, April 22, 2018 Conference Day 2

7:00 am – 12:00 pm		ATTENDEE REGISTRATION	REGISTRATION DESK
7:00 am – 8:00 am		CONTINENTAL BREAKFAST	COLORADO FOYER/BALL
7:00 am – 1:00 pm		EXHIBITOR HOURS	COLORADO FOYER
8:00 am – 9:00 am	Plenary P3	ARE THE CRITERIA FOR APPROVAL SUFFICIENT TO PROTECT RESEARCH PARTICIPANTS: INQUIRING MINDS DISAGREE Moderator: Daniel Nelson, MSc, US Environmental Protection Agency Jeffery Cooper, MD, MMM, WIRB-Copernicus Group David Strauss, MD, New York State Psychiatric Institute, Columbia University	COLORADO BALLROOM
9:15 am – 10:30 am	D1	CONTINUING REVIEW: OPERATIONALIZING THE NEW RULE Wesley G. Byerly, PharmD, University of Connecticut Khemraj Hirani, MPharm, PhD, RPh, CCRP, RAC, MBA, University of Miami	ASPEN BALLROOM
	D2	MEANINGFUL CONSENT FORMS: THE REASONABLE PERSON STANDARD Jonathan M. Green, MD, MBA, Washington University in St. Louis Jeanne Velders, JD, Washington University in St. Louis	COLORADO BALLROOM
	D3	ACQUIRING ACCREDITATION ACUMEN & LESSONS LEARNED FROM RESEARCH WITH UNIFORMED MILITARY Moderator: Robert Hood, PhD, AAHRPP Wayne M. Deutsch, DDS, MPH, 59th Medical Wing Earl Grant, Jr, PhD, 59th Medical Wing Debra Niemeyer, MS, MA, PhD, 59th Medical Wing	MAROON PEAK
	D4	RESEARCH METHODS AND MODELS FOR MEASURING AND IMPLEMENTING HRPP COMPLIANCE John Baumann, PhD, Indiana University Scott J. Lipkin, DPM, Ankura Consulting Elicia Preslan, MS, Virginia Commonwealth University Michelle C. Stickler, DEd, The University of Texas at Austin	MT. COLUMBIA
	D5	INNOVATIONS AND STRATEGIES IN COMMUNITY OUTREACH Richard R. Sharp, PhD, Mayo Clinic Delia Wolf, MD, JD, MSCI, Harvard C.H. Chan School of Public Health	MT. OXFORD
10:30 am – 10:45 am	BREAK	AM BREAK Visit Exhibitors and Poster Presentations	COLORADO FOYER
10:45 am – 12:00 pm	E1	RELIANCE AGREEMENTS: OPERATIONAL STRATEGIES FOR STAFFING, VERIFYING IRB QUALITY, AND COMPREHENSIVE TEMPLATES Lauri Carlile, MS, Advarra Nancy A. Olson, JD, University of Mississippi Medical Center	MAROON PEAK

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Sunday, April 22, 2018 Conference Day 2

10:45 am – 12:00 pm	E2	APPLYING THE APPROVAL CRITERIA CONSISTENTLY: DO IT AND DOCUMENT IT Robert Hood, PhD, AAHRPP Warren Capell, MD, University of Colorado, Denver	MT. SOPRIS A
	E3	BIOBANKING BEYOND BROAD CONSENT: HAS RESEARCH BIOBANKING TAKEN A HIT IN THE FINAL RULE? (PARTICIPATORY SESSION) Carol J. Weil, JD, National Cancer Institute	MT. COLUMBIA
	E4	TOOLS AND STRATEGIES FOR MEASURING AND IMPROVING HRPP EFFICIENCY AND EFFECTIVENESS Courtney Jarboe, MS, MA, University of Minnesota Felicia Mroczkowski, BS, University of Minnesota Julie Quinn, MURP, University of Minnesota	MT. SOPRIS B
	E5	NEW CONSENT REQUIREMENTS UNDER THE COMMON RULE Ivor Pritchard, PhD, OHRP Stephen Rosenfeld, MD, MBA, Quorum Review, Chair, SACHRP	ASPEN BALLROOM
12:00 pm – 1:00 pm	LUNCH	NETWORKING LUNCH FLEX COALITION & SMART IRB LUNCH (pre-registration required)	COLORADO BALLROOM ASPEN BALLROOM
1:00 pm – 2:00 pm	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	COLORADO BALLROOM
2:15 pm – 3:30 pm	F1	THE EXPEDITED REVIEW LIST: WHAT SHOULD BE INCLUDED IN THE REVISED CATEGORIES? (PARTICIPATORY/WORKSHOP SESSION) David Borasky, Jr., MPH, WIRB-Copernicus Group Ivor Pritchard, PhD, OHRP Michele Russell-Einhorn, JD, Advarra	ASPEN BALLROOM
	F2	IMPLEMENTING THE NIH POLICY ON CERTIFICATES OF CONFIDENTIALITY John Heldens, BA, University of Colorado, Denver	MT. SOPRIS A
	F3	UNDERSTANDING AND IMPLEMENTING LIMITED IRB REVIEW Daniel Nelson, MSc, US Environmental Protection Agency	MT. SOPRIS B
	F4	RESEARCH WITH INDIVIDUALS LACKING CONSENT CAPACITY Rachel Barber, DNP, RN, St. Jude Children's Research Hospital Wendy Hayes, MSN, RN, CPHON, St. Jude Children's Research Hospital Jessica Huening, JD, Yale University Amy Waltz, JD, Indiana University	MT. COLUMBIA

AAHRPP 2018 Annual Conference Agenda

Sunday, April 22, 2018 Conference Day 2

2:15 pm – 3:30 pm

F5

AAHRPP STANDARD I-9 IN ACTION: PANEL DISCUSSION WITH TIPS FOR IMPLEMENTATION

MAROON PEAK

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

3:30 pm

ADJOURN