

AAHRPP ADVANCE

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SPRING 2018

Conference Plenary Focuses on Changes to Informed Consent



AAHRPP will kick off its 2018 **conference** with “Informed Consent and the Revised Common Rule,” a plenary session that tackles some of the most significant revisions to the Federal Policy for the Protection of Human Subjects. [LEARN MORE](#)

Single IRB Review: From Proposal to Practice

To help organizations meet new requirements for single IRB review, AAHRPP is hosting presentations at its annual conference and via webinar on approaches for the IRB of record and the relying institution. [LEARN MORE](#)

Updated Evaluation Instrument Reflects New Common Rule

The AAHRPP **Evaluation Instrument for Accreditation** has been revised to reflect changes to the Common Rule. The most significant revision, the new Standard 1-9, helps organizations safeguard participants while sharing research oversight.

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Council of Experts

At the heart of AAHRPP’s peer-driven accreditation process is the Council on Accreditation. Read about their role and get to know our newly appointed members.

[LEARN MORE](#)

From the President and CEO



AAHRPP President and CEO Elyse I. Summers, JD, extends a final invitation to the 2018 conference. Join us in “Summitting New Heights in the Mile-High City” and see AAHRPP in action as the voice of the research community worldwide. [LEARN MORE](#)

SPRING 2018

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News and Notes

LATEST ACCREDITATIONS

- Singapore Management University, Singapore
- University of Florida, Gainesville, Florida

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UPCOMING WEBINARS

May 15 & 17, 2018:

Overcoming Barriers in Single IRB Review

July 17 & 19, 2018:

Successful Strategies for Adjusting to the New Rule

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Conference Plenary Focuses on Changes to Informed Consent

15 sessions highlight revisions, responses to the Common Rule

AAHRPP will kick off its 2018 **conference** with “Informed Consent and the Revised Common Rule,” a plenary session that tackles some of the most significant revisions to the Federal Policy for the Protection of Human Subjects.

Featured speaker Jeremy Sugarman, MD, MPH, MA, will discuss the newly required consent elements and the increased emphasis on requirements for comprehension and transparency.

The Harvey M. Meyerhoff Professor of Bioethics and Medicine and deputy director for medicine of the Johns Hopkins Berman Institute of Bioethics, Dr. Sugarman is an internationally recognized leader in biomedical ethics, including the ethics of informed consent. He has written extensively on these topics, recently preparing a target article in *The American Journal of Bioethics* entitled, “**Examining Provisions Related to Consent in the Revised Common Rule.**”



JEREMY SUGARMAN, MD, MPH, MA

“Some of the new requirements are welcome, and some have potential shortfalls,” Dr. Sugarman says, cautioning against “conflating the consent process with the consent form.” With a new prescribed order for presenting information, “there is potential for consent to turn into a scripted process,” Dr. Sugarman says, “when, in fact, obtaining meaningful informed consent is not.”

His session is one of more than 30 at the conference, “Summitting New Heights in the Mile-High City: Early Experiences, Strategies, and Solutions,” which will be held April 21-22 in Denver. A full-day preconference, focusing on the nuts and bolts of the accreditation process, will be held on April 20. About half of the **sessions** are designed specifically to help research organizations interpret and comply with the new Common Rule provisions, many of which are scheduled to take effect July 19. Other Common Rule-related topics include new exemption categories, single IRB review, and continuing, expedited, and limited review.

“The research community is preparing to implement the first changes to the Common Rule in more than a quarter-century,” AAHRPP President and CEO Elyse I. Summers says. “In keeping with our role as a resource, AAHRPP has convened experts from throughout the research community to provide ethical, regulatory, and operational perspectives. The information will be invaluable to anyone involved in protecting research participants or conducting or reviewing human research.”

The conference is open to individuals from both AAHRPP-accredited and non-accredited organizations.

Single IRB Review: From Proposal to Practice

To help organizations meet new federal requirements for single IRB review, AAHRPP is hosting presentations—at its annual [conference](#) and via [webinar](#)—on various approaches for both the IRB of record and the relying institution.

“Our goal is to provide practical advice, based on our own institutional experience with how we’ve addressed the single IRB requirement,” says Martha F. Jones, MA, Executive Director, Human Research Protection Office, Washington University in St. Louis.

She and Megan Kasimatis Singleton, JD, MBE, CIP, Assistant Dean for Human Research Protection and Director of the Human Research Protection Program, Johns Hopkins School of Medicine, will present “Single IRB Review: Operational Solutions” on April 21 at the AAHRPP 2018 annual conference. On May 15 and 17, they will present webinars on “Overcoming Barriers in Single IRB Review.”



MARTHA F. JONES, MA

Jones and Singleton are ideal presenters, in part because both hold leadership positions at institutions that have extensive experience as the IRB of record on National Institutes of Health (NIH) research studies. Their organizations have systems in place that make it easy for researchers to submit requests for their institution to serve as the IRB of record or to cede that responsibility to another institution.

For example, Johns Hopkins School of Medicine, has an online reliance request [tool](#). Washington University in St. Louis offers two guidance documents for investigators: [Relying on an External IRB](#) and [Using WU IRB as a Single IRB](#). A [Single IRB Intake Form](#) makes it easy for investigators to request that Washington University acts as a single IRB.

Jones and Singleton also served on the advisory group that helped create AAHRPP’s Standard 1.9, which covers AAHRPP’s requirements for shared oversight of research.

The presenters recognize that their conference and webinar audiences will have a broad range of experience with single IRBs. Some attendees will represent organizations that already are



MEGAN KASIMATIS
SINGLETON, JD, MBE, CIP

comfortable serving as the lead IRB or ceding that responsibility. Others will be adjusting to the new landscape. Still others will fall somewhere in between.

“We want to get people thinking about the principles behind how you deal with change—how you identify your stakeholders and develop strategies to anticipate and address the challenges you might face,” Singleton says.

She and Jones will use examples from case studies and their own organizations, and will invite others in the audience to highlight their experiences.

“AAHRPP sessions are very collegial,” Jones says. “As we talk about some of the operational approaches, there will be opportunities for those who are further along to share what they’ve done so we can learn from each other.”

Thank You, Advisory Group Members

AAHRPP extends its appreciation to the following individuals who helped develop our new Standard 1.9 regarding shared oversight of research:

Co-chair Michelle Feige, MSW, LCSW-C, AAHRPP

Co-chair Megan Kasimatis Singleton, JD, MBE, CIP,

Johns Hopkins University School of Medicine

Rebecca Ballard, JD, MA, CIP, MedStar Health Research Institute

Lauri Carlile, MS, CIP, Advarra

Nichelle Cobb, PhD, SMART IRB and University of Wisconsin-Madison

Robert Hood, PhD, AAHRPP

Martha Jones, MA, CIP, CTSA Clinical Trials Task Force and Washington University in St. Louis

Nancy Klunder, BS, CHC, CPC, NREMT-I, Regional Health

Kathy Lawry, MSSA, CIP, SMART IRB and AAHRPP

Michael Linke, PhD, CIP, NIH StrokeNet CIRB and Department of Veterans Affairs Medical Center-Cincinnati

Michele Russell-Einhorn, JD, Advarra

Ada Sue Selwitz, MA, University of Kentucky

Updated Evaluation Instrument

The AAHRPP [Evaluation Instrument for Accreditation](#) has been revised to reflect changes to the Common Rule, many of which are expected to take effect July 19. **The most significant revision is the new Standard 1-9, created to help organizations safeguard participants while sharing research oversight.**

“The vast majority of AAHRPP standards are not affected by the new Common Rule,” AAHRPP President and CEO Elyse I. Summers, JD, says. “In cases where we have made revisions, AAHRPP standards are flexible and continue to encourage organizations to decide how best to meet the AAHRPP requirements.”

Along with the evaluation instrument, AAHRPP has developed [guidance](#) for organizations that comply with the Common Rule and are in the midst of the accreditation process. The guidance includes accommodations for organizations that applied for accreditation under the currently operative Common Rule but will undergo their site visit on or after the new rule is in effect.

“We recognize that these are unusual circumstances and will work with organizations closely to help them realize their goal of achieving accreditation,” Director of Accreditation Robert Hood, PhD, says.

An interim review process

To accommodate organizations in different stages of the accreditation process, AAHRPP has adopted the following:

- **For organizations that will complete the accreditation process before July 19, 2018:** AAHRPP will conduct the entire review in accordance with the [October 2016](#) evaluation instrument and will *not* evaluate compliance with the new Common Rule.
- **For organizations that will submit applications before July 19, 2018 and will undergo site visits on or after July 19:** The organization will use the [February 2018](#) evaluation instrument. AAHRPP will *not* evaluate compliance with the revised Common Rule in Step 1 unless the organization requests it. The 2018 site visit will include a discussion of the organization’s plans to comply with the new rule.
- **For organizations whose entire accreditation process occurs after July 19:** Organizations will use the [February 2018](#) evaluation instrument and *will* be evaluated for their compliance with the new Common Rule.

To make it easy for all organizations to identify and address the revisions to the evaluation instrument, AAHRPP has published a [Summary of Revisions](#) to the Evaluation Instrument that includes:

- Revisions organized by Standards and Elements
- Revisions organized by sections of the revised Common Rule
- The text of the revised Standards and Elements, with changes underlined and highlighted in a different color.

“AAHRPP is committed to transparency and to helping organizations understand the revisions to both the Common Rule and to AAHRPP standards,” Dr. Hood says. “This summary shows organizations exactly what has changed, line by line.”

Council of Experts

At the heart of AAHRPP's peer-driven accreditation process is the nine-member Council on Accreditation, whose members are selected for their knowledge of AAHRPP standards, experience as site visitors and team leaders and, above all, commitment to high-quality, ethical research.

Council members review applications and site visitor reports and make decisions about an organization's qualification for accreditation and reaccreditation. Council decisions are objective and independent of the AAHRPP staff or Board of Directors. Perhaps most important, decisions are rooted in extensive, firsthand experience in leadership roles with AAHRPP-accredited human research protection programs (HRPPs).

"Our Council members have an invaluable perspective," AAHRPP President and CEO Elyse I. Summers, JD, says. "They have lived and breathed the AAHRPP standards as members of accredited HRPPs, and they have seen the standards in action—both within their own organizations and at the multitude of other organizations they've reviewed during site visits."

The path to the Council begins with an invitation to serve as a site visitor. After several years of exceptional performance and positive feedback, site visitors may advance to the role of team leader and, ultimately, to a seat on the Council on Accreditation.

Council terms are two years, and members may serve a maximum of six consecutive years. Below, we introduce you to the most recent Council additions.



JOHN ANDREW BERTOLATUS, MD

John Andrew Bertolatus, MD, is associate professor emeritus, internal medicine, and primary IRB chair for the Biomedical IRB at The University of Iowa. He has returned to the Council after serving several terms during AAHRPP's early years. In April 2003, The University of Iowa became one of the first organizations to achieve AAHRPP accreditation, and AAHRPP quickly tapped Dr. Bertolatus' expertise.

He has nearly 15 years of experience as an AAHRPP site visitor to over 50 organizations in the U.S., China, India, Saudi Arabia, South Korea, and Taiwan. During those visits, Dr. Bertolatus has gained invaluable insight into research oversight outside the U.S. He also has seen the impact that AAHRPP accreditation has had on research protections and HRPPs.

"Organizations are better prepared," he says. "There's definitely been a shift toward greater compliance and upholding of the AAHRPP standards."

Dr. Bertolatus attributes that, in part, to organizations' long-term commitment to accreditation. "More and more of our site visits are for reaccreditation," he says. "These organizations have already made the changes necessary to attain accreditation—and are determined to keep improving. On almost every site visit, we see at least one example of a new, better way to do something that AAHRPP requires."

Council of Experts *(continued from pg 5)*



**MONIKA MARKOWITZ, PHD, MA,
MSN, RN**

Monika Markowitz, PhD, MA, MSN, RN, is director of the Office of Research Integrity & Ethics in the Office of the Vice President for Research and Innovation at Virginia Commonwealth University. She became a site visitor because of Virginia Commonwealth University's positive accreditation experience. "The process has great value," she says. "In our case, it provided an incentive to add some policies, strengthen others, and increase understanding of the role and importance of our HRPP."

During her seven years as a site visitor, Dr. Markowitz has visited about a dozen U.S. and international organizations. Time and again, she has been struck by the flexibility that is built into the AAHRPP standards, the different ways organizations approach their HRPPs, "and that it works."

She accepted the invitation to join the Council on Accreditation to support AAHRPP as an organization and to further its mission. "Accreditation is an indication to the public that, at our institution, research integrity and ethics matter," Dr. Markowitz says. "AAHRPP accreditation says that we have sought this distinction and that we think about ethics all the time. Everything we do is about improving the ethical environment for research."



JULIE OZIER, MHL, CHRC, CIP

Julie Ozier, MHL, CHRC, CIP, is director of the Human Research Protection Program at Vanderbilt University and Medical Center. One of her first roles with Vanderbilt University and Medical Center was to help secure AAHRPP accreditation. That goal was achieved in 2004, and not long afterward, Ozier joined AAHRPP's team of site visitors. Since then, she has conducted about 20 site visits, primarily at U.S. hospitals and academic medical centers. In every case, "We get as much from the organization we're visiting as they do from us. There's no one right way, so it's educational to talk with people in other programs and see how they do things."

Ozier sees enormous benefit in AAHRPP accreditation—for individual HRPPs and the research community as a whole. She cites the assurance that an accredited program has robust policies and procedures and organization-wide support. With the shift to single IRB review of multisite research, "if you're accredited, it lets other IRBs know that you meet the AAHRPP standards, so they can rely on you," Ozier says.

She, too, joined the Council as a way to give back to AAHRPP and acknowledge its critical role in strengthening research protections. "AAHRPP accreditation promotes trust in the process of human subject protections," Ozier says. "The results may be difficult to measure, but you know that it's working—and that it completely improves your program."

From the President and CEO

Summitting new heights together

The 2018 AAHRPP **conference**—“Summitting New Heights in the Mile-High City: Early Experiences, Strategies, and Solutions,” April 20-22 in Denver—is just weeks away, and we’re thrilled that so many of you will be attending. The conference is especially timely because research organizations across the U.S. are preparing for the new Common Rule. Roughly half of our conference sessions are designed to help you with that transition.

As an international organization, we also have sessions on topics of great interest to the global research community. Our vision is to “be the voice” of the research community worldwide—both accredited and not-yet-accredited organizations. All of our efforts, including our annual conference, reflect that goal.

One of the most significant challenges of implementing the new Common Rule is the uncertainty surrounding both its timing and interpretation. Although we have an effective date for many of the provisions, we also know that the federal departments and agencies involved are developing a notice of proposed rulemaking (NPRM) seeking public comment on whether to further delay implementation. The AAHRPP conference provides a wonderful opportunity for those of us in the trenches to share ideas on how best to navigate the current landscape.

As you can see from the conference **agenda**, we have an impressive cadre of speakers from across the research enterprise. We are extremely grateful to all of them for sharing their expertise and for their continuing collaboration with AAHRPP. These relationships with our peers and colleagues have always been central to our success. In fact, in many ways, they help define who we are.

In addition to being the world’s accrediting body for human research protection programs, AAHRPP is a convener and partner, a resource and thought leader. On issues of research quality and human research protections, count on us to bring the research community together, to express and amplify your concerns, and to help find solutions.

I invite you to experience that in person later this month at our conference in Denver. Although online registration is closed, you can still sign up in person. I look forward to seeing you there and to “summitting new heights” together.



ELYSE I. SUMMERS, JD

Finally, on a completely different note—but one that is related to the new Common Rule—I call your attention to our updated **Evaluation Instrument**, which is also discussed in this **newsletter**. Here again, we recognize the challenges created by the uncertainty surrounding the implementation of the new rule. Please be assured that we will be flexible and will work with you to help you achieve the gold standard of AAHRPP accreditation.

A handwritten signature in blue ink that reads "Elyse I. Summers". The signature is fluid and cursive, with a long horizontal stroke at the end.

Elyse I. Summers, JD
AAHRPP President and CEO

Join us at the 2018 AAHRPP Annual Conference

April 20-22, Denver, Colorado



“Summitting New Heights in the Mile-High City: Early Experiences, Strategies, and Solutions”



Online registration is closed, but you can still register at the conference at the Grand Hyatt Denver.

Featuring leaders in the research protections community, including experts from OHRP and SACHRP

LEARN ABOUT

- Successful strategies for implementing the new Common Rule
- Ways to share experiences and innovative practices
- Implementing broad consent
- Interpreting the reasonable person standard
- And much more

Check out the conference [agenda](#)