

# AAHRPP ADVANCE

One Standard Worldwide

SUMMER 2017

## Accreditation Adds Value at Memorial Sloan Kettering

For Memorial Sloan Kettering (MSK), AAHRPP accreditation affirms the institution's commitment to quality and supports its leadership in multisite research. Four of the nation's top five cancer research centers, including MSK, are AAHRPP accredited.

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## Broad Earns AAHRPP Accreditation with Distinction

The Broad Institute of MIT and Harvard was awarded full accreditation, with an area of distinction for the organization's requirement that all staff members—from security guards to scientists to the CEO—complete training in human research protections. [LEARN MORE](#)

## Highlights from Our 2017 Conference

More than 400 members of accredited and non-accredited organizations turned out for the 2017 AAHRPP conference, which featured some of the nation's most respected experts on the Common Rule, CRISPR, and other complex research protection issues.

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## From the President and CEO



AAHRPP President and CEO Elyse I. Summers, JD, provides information and assurances on AAHRPP's approach to implementing changes to the Common Rule. Count on AAHRPP to be flexible and work with accredited and not-yet-accredited organizations.

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## Upcoming Webinars

**October 17 and 19:** AAHRPP Proposed Single IRB Review Standard

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SUMMER 2017

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## News and Notes

### LATEST ACCREDITATIONS

- **Broad Institute of MIT and Harvard**, Cambridge, Massachusetts
- **Central Michigan University**, Mount Pleasant, Michigan
- **University of Hawaii System**, Honolulu, Hawaii

[LEARN MORE](#)

### LATEST NEWS

**Board Member Honored**

**NIH Seeks AAHRPP-Accredited IRB**

## Memorial Sloan Kettering: Bolstering a Stellar Reputation

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For Memorial Sloan Kettering (MSK), AAHRPP accreditation affirms the institution's commitment to quality and leadership in multisite research.

As one of the top U.S. cancer centers, MSK has a global reputation for exceptional patient care and cutting-edge research. In 2015, the organization seized the opportunity to strengthen its reputation and processes by pursuing AAHRPP accreditation.

A year later, MSK achieved its goal, earning full accreditation in December 2016. Four of the nation's top five cancer research hospitals are AAHRPP accredited.

“Within the research realm, having the highest quality clinical research program is our primary goal, and AAHRPP standards support that,” says Ann Rodavitch, MA, Director of Protocol Activation & Human Research Protection Programs in MSK Clinical Research Administration. “We also know, from speaking with external sponsors and other partners, that the AAHRPP seal makes a difference. It means something.”

MSK is the sponsor of more than 120 protocols involving over 250 sites around the globe. “Many of the sites are AAHRPP accredited and preferred that we be AAHRPP accredited as well,” Ms. Rodavitch says. “Looking ahead to future studies, we expect our accreditation to increase the likelihood that we will be the IRB of record.”

Accreditation also supports the Memorial Sloan Kettering Cancer Alliance. The alliance seeks to improve the quality of cancer care and the lives of cancer patients by bringing evidence-based, world-class standards to community healthcare providers. Since more than 80 percent of U.S. cancer patients receive care in community settings, MSK establishes clinical trials sites at specific alliance member hospitals where their patients can benefit from the latest cancer breakthroughs.

To date, the alliance has three members: Hartford Healthcare Cancer Institute in Connecticut, Lehigh Valley Health Network in Pennsylvania, and Miami Cancer Institute at Baptist Health South Florida. Two of the three members are AAHRPP accredited, and MSK is the IRB of record for all alliance trials—two more reasons for MSK to pursue accreditation.



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**ANN RODAVITCH, MA**

Director, Protocol Activation & HRPPs  
Memorial Sloan Kettering

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### Making the most of the accreditation process

Like most organizations, MSK made some changes to policies and practices while preparing for accreditation. In fact, the intent of the required, thorough review is for organizations to identify and address areas in need of improvement.

“We used the accreditation process as an opportunity to tweak some procedures and processes to make them more efficient and effective,” Ms. Rodavitch says. “With a portfolio of our size, small changes can really help us perform better. Everyone, from investigators to IRB members, is happy with the changes we’ve made.”

MSK also used the accreditation process to make sure everyone involved in clinical research at the cancer center knows its policies and procedures and is comfortable discussing them. During the site visit, 99 MSK staff members were interviewed and fared well.

“It was a really good team-building experience, and everyone was ready,” Ms. Rodavitch says. “We had fun.”

# Broad Institute Accredited with Distinction

At the Broad Institute of MIT and Harvard, all staff members—from security guards to scientists to the CEO—must complete training on human research protections.

The institute requirement is designed to ensure that “from top to bottom, everyone has a baseline understanding of protecting the people who participate in research,” says Andrea Saltzman, RN, CIP, Associate Director of Broad’s Office of Research Subject Protection.

The requirement also helped Broad earn AAHRPP accreditation with distinction in meeting Element I.1.E, which focuses on education practices.

Broad was awarded full accreditation in June. In announcing its decision, AAHRPP’s Council on Accreditation praised the Broad policy for creating “an awareness at every level in the institute of the mission and its importance and positive impact on people’s lives.”

Based in Cambridge, Massachusetts, Broad is a genetic research institute that’s committed to advancing science and healthcare. The Broad community includes more than 3,000 scientists from Boston’s leading institutions: Beth Israel Deaconess Medical Center, Boston Children’s Hospital, Brigham and Women’s Hospital, Dana-Farber Cancer Institute, Harvard University, Massachusetts General Hospital, and Massachusetts Institute of Technology. All but one of the seven partners are AAHRPP accredited.

Since its founding in 2004, Broad has emerged as a flagship center for biomedical and genomic research, with a repository of more than 1.7 million biological samples.

“Because we don’t have patients, research protections can be an abstract concept here,” Ms. Saltzman says. “The education requirement reminds people that there’s a person behind each one of those specimens, and that there’s a lot of trust placed in our organization to handle specimens and data in a very careful way.”

## Meeting SMART IRB requirements with accreditation

The institute does not have its own IRB. Instead, Broad typically cedes IRB review to a partner organization, usually the home institution of the principal investigator.



**ANDREA SALTZMAN, RN, CIP**  
Associate Director  
Office of Research Subject Protection  
Broad Institute

Broad and its partners are members of Harvard Catalyst, the Harvard Clinical and Translational Science Center. All Harvard Catalyst members recently signed the SMART IRB Agreement, which requires participating organizations to demonstrate that their HRPP has been assessed for quality within the past five years.

For Broad, it made sense to fulfill this requirement by pursuing AAHRPP accreditation. “We were already pulling together the documents for Harvard Catalyst and SMART IRB, so it was the right time to consider accreditation,” Ms. Saltzman says.

She credits the accreditation process with prompting Broad to review its practices, identify strengths and areas in need of improvement, and educate individuals on standard operating procedures.

The Broad team was not surprised that the accreditation preparation strengthened their organization. “That’s expected any time you update processes and make them more systematic,” Ms. Saltzman says. “What we didn’t expect was the community building.”

“The accreditation process really brought the community together and provided opportunities for us to work with groups we typically don’t interact with on a day-to-day basis,” she adds. “In the end, people were very proud of the work that gets done here—and it was nice to have the opportunity to showcase that.”

# AAHRPP 2017 Conference Highlights / Detroit, Michigan

Attendees at one of our many breakout sessions



Bernard Lo, UCSF, Greenwall Foundation, AAHRPP Board member

"Ethics of CRISPR" panel, from left: Matthew Porteus, Stanford University; Natasha Bonhomme, Genetic Alliance; Bernard Lo, Greenwall Foundation



Christopher States, California Department of Transportation, AAHRPP Board member

New AAHRPP staff, from left: Harry Frazier, Controller; Marianna Suleymonova, Operations Coordinator; Oscar Platero, Associate Director of Operations



Ivor Pritchard, OHRP, and Stephen Rosenfeld, SACHRP, Quorum Review

# AAHRPP 2017 Conference Highlights / Detroit, Michigan

Marc Boutin, CEO, National Health Council



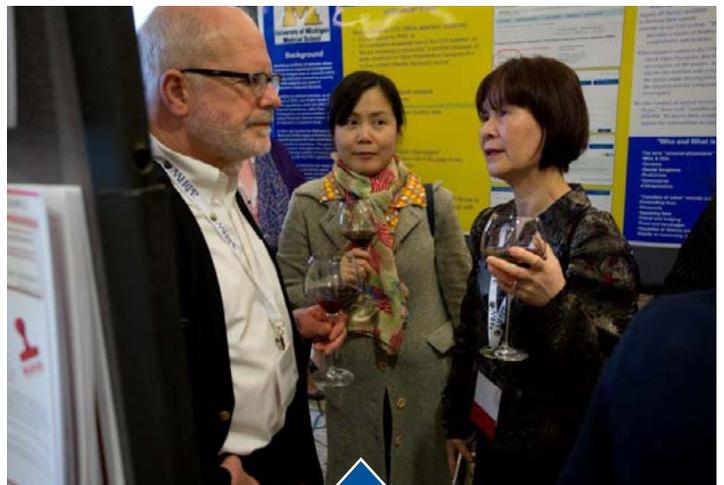
Linda Petree, University of New Mexico

Toasting AAHRPP



Tracy Blumenfeld, Rapid Trials, AAHRPP Board member

Elyse Summers, AAHRPP President & CEO, with Chung-His Hsing from Chi Mei Medical Center, Taiwan



Making the most of networking opportunities

## From the President and CEO

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### *Preparing for the new final rule*

As you know, if the schedule holds, the first provisions of the updated Common Rule are slated to take effect in January. AAHRPP is among those who have requested a delay, but there has been no word on whether that request will be granted.

We realize that many of you have questions about how the changes to the Common Rule affect the AAHRPP standards. In fact, a record number of you participated in our recent webinars on this topic. The information below should provide some clarification and assurance. Above all, please know that we understand the difficulties that the current situation is creating—and that we will work with you and be flexible.

Because AAHRPP standards are broad, **the vast majority of standards and elements are not affected by the revised regulations.** However, we still anticipate that AAHRPP-accredited organizations will have to revise some policies and forms, update electronic systems, and conduct training on the changes. We are developing AAHRPP guidance, including a revised Evaluation Instrument, and plan to get those to you by late fall. We also will devote much of our 2018 **conference** to the new Common Rule.

The organizations most affected by the present uncertainty are those applying for accreditation or reaccreditation between now and January 19. If you have any questions whatsoever, please don't hesitate to reach out to Dr. Robert Hood, AAHRPP Director of Accreditation, at 202-783-1112 or [rhood@aahrpp.org](mailto:rhood@aahrpp.org).

Meanwhile, here's a brief explanation of what you can expect.

- **If you are in the midst of the accreditation process** (you have already submitted your Step 1 application and expect your site visit to occur by year-end): You will finish the process under the existing Evaluation Instrument (dated October 2016).



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ELYSE I. SUMMERS, JD

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- **If your Step 1 application is submitted before January 19, but your site visit will occur after that date:** Your Step 1 application will be reviewed using the current Evaluation Instrument (dated October 2016). Your site visit will include discussions regarding your plans to meet the new regulatory requirements but will be flexible as to implementation timelines. You will have the option of submitting policies, forms, and other updated materials for AAHRPP to provide comments.
- **If your entire accreditation/reaccreditation process occurs after January 19:** Your Step 1 application will be reviewed using the new Evaluation Instrument, which will reflect the new final rule. Because the new rule will be in effect, site visitors will discuss compliance with the new Common Rule and evaluate plans regarding implementation.
- **All accredited organizations: When filing your 2017 Annual Report,** as appropriate, please discuss your plans for implementing the new regulations.

## From the President and CEO (cont.)

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### Single IRB review

We have a bit more time to address the new requirement for single IRB review of multisite studies. That change does not take effect until 2020. I encourage you to join us for our October [webinar](#), when we address AAHRPP's proposed single IRB review standard.

Thank you for your patience as we make the necessary adjustments to respond to the new rule. Our goal, as always, is to ensure that our standards and elements provide the protections that research participants deserve without placing undue burden on you.

### NCI seeking AAHRPP-accredited IRB

Finally, on a separate note, and a significant example of "AAHRPP on the march," I am pleased to pass along that the National Cancer Institute is seeking an AAHRPP-accredited IRB to provide expedited reviews. More information is available on the NCI [posting](#).



Elyse I. Summers, JD  
AAHRPP President and CEO

## AAHRPP Board Member Honored With National ABA Award

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EDWARD TUCKER

AAHRPP Board member Edward Tucker has been named the 2017 recipient of the American Bar Association's (ABA's) Robert J. Kutak Award. The ABA Section of Legal Education and Admissions to the Bar presents the award annually to honor an individual for significant contributions to the legal academy, the bench, and the bar.

A certified public accountant for 45 years, Mr. Tucker spent 40 years as a senior director, officer, and stockholder at Ellin & Tucker, Chartered, before becoming a consultant to the Maryland-based accounting and consulting firm in 2009. He has served on the Section's Council since 2008 and currently is secretary of the Council and chair of the Council's Finance Committee.

The ABA award was established in memory of Mr. Kutak, a respected Omaha lawyer, who was committed to legal reform and was a strong advocate for legal education.

# Save the Date: April 20-22, 2018

## Grand Hyatt, Denver



## 2018 Annual AAHRPP Conference

### LEARN ABOUT

- The New Common Rule: Early Experience, Strategies, and Successes
- Innovative Practices
- Implementing Single IRB Review

### Registration Begins November 6, 2017

Come network with colleagues from around the world.  
Share your innovative solutions in poster presentations and breakout sessions.