

# AAHRPP ADVANCE

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SPRING 2017

## Coming Soon: More CRISPR Clinical Trials

Rapid advances in CRISPR-Cas9 technology increase the likelihood that IRBs will soon be reviewing clinical trials that use genetically modified somatic cells. AAHRPP will help IRBs prepare with a conference plenary session on “Human Genome Editing (CRISPR): Scientific and Ethical Considerations,” moderated by bioethics leader Bernard Lo, MD. [LEARN MORE](#)

## 2017 SACHRP Agenda: The Common Rule

SACHRP will spend much of 2017 interpreting and addressing the recently released updates to the Common Rule. The next SACHRP meeting is May 26. AAHRPP will provide insights on the Common Rule at the annual conference May 9-11 and in webinars in July. [LEARN MORE](#)

## New Roles for Three Research Leaders

Three distinguished research professionals—Ross McKinney Jr., MD; Stephen Rosenfeld, MD, MBA; and Michele Russell-Einhorn, JD—have taken on new roles that provide significant opportunities to shape the research enterprise. [LEARN MORE](#)

## Coming Together at the Right Time and Place



AAHRPP President and CEO Elyse I. Summers, JD, provides highlights of the upcoming conference, which is a must for anyone involved in research protections. Join us in Detroit for “Evolving, Adapting, and Thriving in the New Research Environment.” [LEARN MORE](#)

## Upcoming Webinars

**July 18 and 20:** The Final Common Rule: Guidance for AAHRPP-Accredited and Soon-to-be-Accredited Organizations

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

[LEARN MORE](#)

SPRING 2017

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## Latest Accreditations

- **Beijing Tiantan Hospital, Capital Medical University**, Beijing, China
- **Chi Mei Medical Center**, Tainan, Taiwan
- **Houston Methodist**, Houston, Texas
- **St. Joseph Health**, Irvine, California
- **State University of New York College of Optometry**, New York, New York
- **Taipei Veterans General Hospital**, Taipei, Taiwan
- **Universitair Ziekenhuis Brussel**, Brussels, Belgium
- **The University of New Mexico**, Albuquerque, New Mexico
- **Xiyuan Hospital of China Academy of Chinese Medical Sciences**, Beijing, China

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# Coming Soon: More CRISPR Clinical Trials

## Plenary session to help IRBs get ready for protocol review

Rapid advances in CRISPR-Cas9 technology are accelerating research involving human gene editing, increasing the likelihood that IRBs will soon be reviewing clinical trials that use genetically modified somatic cells.

CRISPR-Cas9 technology offers significant promise for treating serious genetic conditions, such as sickle cell anemia, thalassemia, Huntington's disease, and cystic fibrosis. But for many organizations, the ethical considerations weigh heavily.

Bernard Lo, MD, a world-renowned leader in bioethics, urges human research protection programs (HRPPs) to begin tackling those issues head on in preparation for the research review that's likely to come within the next year or two.

"Human gene editing is advancing at a dizzying pace. HRPPs should begin to prepare now so that they can carry out careful and timely review when such clinical trial protocols are submitted," Dr. Lo says.

To assist in this effort, Dr. Lo will moderate an AAHRPP **conference** plenary session on "Human Genome Editing (CRISPR): Scientific and Ethical Considerations." Co-presenters are Matthew Porteus, MD, of Stanford University, and Natasha Bonhomme of Genetic Alliance.

An AAHRPP board member, Dr. Lo is president of the Greenwall Foundation in New York, which promotes bioethics research to improve patient care, inform biomedical research, and enhance public policy. He also is professor of medicine emeritus and director of the Program in Medical Ethics emeritus at the University of California, San Francisco.

The plenary session is designed to give IRBs an overview of what to consider as they review studies that involve gene editing. Topics will include:

- Scientific aspects of CRISPR-Cas9 gene editing;
- Recommendations of the 2017 National Academies of Science report, *Human Genome Editing: Science, Ethics, and Governance*;
- Issues that IRBs will soon face during reviews of clinical trials using genetically modified somatic cells;
- Perspectives of the public and patient advocacy groups regarding human gene editing.

Dr. Lo stresses that IRBs will be reviewing studies that edit somatic cells—not germ-line cells. Germ-line cell editing is not permitted in the U.S.

"Genetic modifications in somatic cells, like red blood cells, are not transmitted to future generations, unlike genetic modifications of human germ-line cells," he says. "With somatic cell editing, we would just be treating the disease in the patient of the moment."

Among the concerns for IRBs is whether they have the scientific expertise to conduct the review. Some might have to add committee members or bring in consultants with gene editing-related expertise. Another issue is ensuring that patients truly understand the potential benefits and risks of the study.

"IRBs need to anticipate, so they're not caught off guard," Dr. Lo says.

## National Academies Recommendations on Somatic Genome Editing

- Use existing regulatory processes for human gene therapy to oversee somatic human genome editing research and uses.
- Limit clinical trials or therapies to treatment and prevention of disease or disability at this time.
- Evaluate safety and efficacy in the context of risks and benefits of intended use.
- Require broad public input prior to extending uses.

Source: **Report Highlights**, *Human Genome Editing: Science, Ethics, and Governance*. National Academy of Sciences and National Academy of Medicine.

# 2017 SACHRP Agenda: The Common Rule

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Like many in the research community, SACHRP will spend much of 2017 interpreting and addressing the recently released updates to the Federal Policy for the Protection of Human Subjects, also known as the Common Rule. Most provisions in the new rule take effect January 19, 2018. The requirement for cooperative research is effective January 20, 2020.

The updates represent the first significant effort since 1991 to realign the regulations with a more global, technologically advanced research enterprise.

“One of the goals was to recalibrate IRB oversight, focusing review on where it’s really needed and reducing burden when the research is of minimal risk,” says SACHRP Chair Stephen Rosenfeld, MD, MBA. “I think this moves us in the right direction.”

The Secretary’s Advisory Committee for Human Research Protections (SACHRP) provides expert advice and recommendations to the secretary of the U.S. Department of Health and Human Services (HHS) on issues related to protecting research participants. The research community often looks to SACHRP to interpret regulations and help organizations turn policy into practice.

Because of the complexity of the Common Rule, Dr. Rosenfeld expects it to dominate SACHRP discussions for at least the next two years. The next SACHRP meeting is scheduled for May 26 and will be available via webinar at <http://videocast.nih.gov>.

## Changes and a notable omission

The final rule will require research organizations to adjust policies and practices for activities that are fundamental to research oversight. Examples include:

- **Continuing review** – Continuing review will no longer be required for ongoing research that poses little risk or for studies where interventions are complete and activities are limited to data analysis and observational follow-up.
- **Additional exemptions** – New exemption categories will help reduce burden by acknowledging the minimal risk of certain types of research. Under some of the new categories, limited IRB review will be required to ensure that study design includes adequate privacy safeguards for identifiable private information and biospecimens.
- **Cooperative research** – Starting in 2020, U.S. institutions that engage in federally funded cooperative research will be required to use a single IRB for the portion of the research conducted within the United States, with certain exceptions.
- **Research involving biospecimens** – In response to public input, the final rule does not include a provision that would have required research involving non-identified biospecimens to be subject to the Common Rule. Instead, in most instances, researchers can continue current practices for using biospecimens.

The issuance of the final rule marked the culmination of a process that began in July 2011 with the publication of an advanced notice of proposed rulemaking. In September 2015, HHS and the 15 other Common Rule agencies issued a 131-page notice of proposed rulemaking (NPRM).

The NPRM generated more than 2,100 comments. The resulting final rule reflects those comments as well as the consensus of 17 federal departments.

- **Informed consent** – Requirements for clearer, more focused language are intended to ensure that prospective participants understand the scope of the research, including its potential risks and benefits. Organizations must also provide participants with information, such as commercial use and return of research results, that wasn’t required in the past.

- **Broad consent** – This will be an additional option for researchers who are requesting participants’ permission for storage, maintenance, and secondary use of identifiable private information and biospecimens.

## New roles for three research leaders

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Three distinguished research professionals—Ross McKinney Jr., MD; Stephen Rosenfeld, MD, MBA; and Michele Russell-Einhorn, JD—have taken on new roles that provide significant opportunities to shape the research enterprise and its response to emerging issues.

All three research leaders bring decades of experience to influential positions at a time when technological advances present unprecedented challenges and potential benefits.



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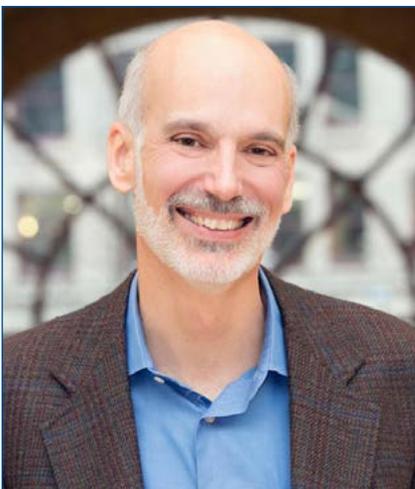
**ROSS MCKINNEY JR., MD**  
AAMC Chief Scientific Officer

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Dr. McKinney joined the Association of American Medical Colleges (AAMC) last September. As chief scientific officer, he leads an array of AAMC programs that support all aspects of medical research and training. He also represents the AAMC on issues related to research and science policy, administration, and workforce development, education, and training.

“These are challenging times in the world of academic medical research, and the AAMC is uniquely positioned to make a difference,” Dr. McKinney says.

Previously, he was director of the Trent Center for Bioethics, Humanities & History of Medicine at Duke University Medical Center, where he also served as professor of pediatric infectious diseases. A member of the Duke faculty since 1985, Dr. McKinney went on to become director of the division of pediatric infectious diseases and, later, vice dean for research.



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**STEPHEN ROSENFELD, MD, MBA**  
SACHRP Chair

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Dr. Rosenfeld has been named chair of the U.S. Department of Health and Human Services (HHS) Secretary’s Advisory Committee for Human Research Protections (SACHRP) through July 2020. He was appointed to the committee in July 2013 and became chair last December.

One month later, HHS and 15 other federal departments and agencies issued final revisions to the Federal Policy for the Protection of Human Subjects, also known as the Common Rule. (See related story, page 3.) Dr. Rosenfeld expects much of his term to be devoted to helping organizations interpret and transition to the updated rule.

A board-certified hematologist, Dr. Rosenfeld is executive IRB chair for Quorum Review IRB. He is active in the Multi-Regional Clinical Trials (MRCT) initiative, Clinical Trials Transformation Initiative (CTTI), Alliance for Clinical Research Excellence and Safety (ACRES), and Northwest Association for Biomedical Research (NWABR). For much of his career, Dr. Rosenfeld worked in medical informatics at the National Institutes of Health (NIH), where his experience culminated in the role of chief information officer (CIO) of the Clinical Center. He also served as CIO of Maine Health.

## New roles for three research leaders

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**MICHELE RUSSELL-EINHORN, JD**

Schulman IRB, Vice President for  
Human Research Protection Services  
and Institutional Official

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Ms. Russell-Einhorn joined Schulman IRB in September to build and lead the company's central oncology review (COR) division. With the successful launch of COR, her role was expanded. As vice president for human research protection services and institutional official, she now is charged with overseeing the entire Schulman human research protection program and establishing additional therapy-specific IRBs.

An expert in oncology research administration and human research protections, Ms. Russell-Einhorn served most recently as senior director of the Dana-Farber Cancer Institute Office for Human Research Studies. Her decision to move from an academic to institutional setting reflects the growing importance of independent IRBs as the research enterprise shifts to central IRB review of multisite studies.

Ms. Russell-Einhorn has held leadership positions at the NIH, the Office for the Protection from Research Risks (OPRR) and its successor office, the Office for Human Research Protections (OHRP). She also is an AAHRPP site visitor and co-chair of the SACHRP Subcommittee on Part A.

## Dr. Kimberly Andrews Espy Joins AAHRPP Board

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Please join us in welcoming Kimberly Andrews Espy, PhD, to the AAHRPP Board of Directors. As senior vice president for research at the University of Arizona, Dr. Espy is the university's chief research officer, responsible for research enterprise, including more than 100 interdisciplinary centers and institutes, research administration and compliance, core facilities, corporate engagement, and the innovation portfolio.

Dr. Espy also is a clinical neuroscientist whose research focuses on identifying the antecedents of learning, attention, and behavioral disorders in medically at-risk populations. In addition, Dr. Espy studies the development of cognitive skills in infants and young children.

As a researcher and organizational official, Dr. Espy considers it a privilege to be able to conduct research. She views serving on the AAHRPP board as another way to fulfill her commitment to research participants and the research community.

"AAHRPP accreditation indicates that an organization is meeting its responsibility to protect participants and conduct high-quality research," Dr. Espy says. "I am a firm believer in the AAHRPP process, its standards, and its recognition that different organizations can find different ways to meet those standards.

"That's why AAHRPP has been so successful," she adds. "It emphasizes high standards but takes a non-prescriptive approach, so institutions have flexibility to meet these standards in a manner that is true to their culture and history."



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**KIMBERLY ANDREWS ESPY, PhD**

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## From the President and CEO

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### *Coming together at the right time and place*

Soon we will gather for our annual AAHRPP conference, and the timing could not be better. Just months after the publication of the final rule, we will offer three sessions—featuring some of the most respected experts on the Common Rule—to help you understand and prepare for the coming changes in how research is reviewed and conducted.

We also will tackle some of today's most complex issues, including **CRISPR** human genome editing, data privacy, pediatric research, and patient-driven studies. In session after session, we will work together, as always, to strengthen protections for research participants and support the progress that science and research make possible.

As usual, we will start with a full day of pre-conference workshops for those who are interested in pursuing AAHRPP accreditation or are approaching reaccreditation. AAHRPP's position on this is straightforward and, we hope, welcoming: If your organization aspires to or is committed to achieving accreditation or reaccreditation, we will work with you to make it happen. Our pre-conference is a great place to start.

The theme of this year's conference is "Evolving, Adapting, and Thriving in the New Research Environment." Accordingly, we are featuring a robust **program**, notable for both its content and the expertise and diversity of talent. Our team of presenters includes some of the most highly regarded members of the research community, from the AAHRPP board, OHRP, AAMC, NHC, PRIM&R and other AAHRPP founding organizations, and top research institutions in the U.S. and overseas. We owe a debt of gratitude to all of you.

The location of the conference is no accident. Those of you who know me also know that Michigan is my ancestral homeland. But there's an even more significant reason we've chosen Detroit as the



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ELYSE I. SUMMERS, JD

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site of this year's conference. To put it simply, this part of America is AAHRPP country. We have accredited organizations in all of the heartland states—Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Ohio, Pennsylvania, Nebraska, North Dakota, South Dakota, and Wisconsin—and we are thrilled to be hosting our conference in a region where we are so well-represented.

I look forward to seeing and meeting with as many of you as possible at the conference, May 9-11. I am confident that you will be interested, engaged, and often challenged from start to finish. Since we'll be in Motown, also count on having some fun, and forgive me in advance if I happen to break into song.

A handwritten signature in blue ink that reads "Elyse I. Summers". The signature is fluid and cursive.

Elyse I. Summers, JD  
AAHRPP President and CEO

May 9-11, Detroit, Michigan



## 2017 AAHRPP CONFERENCE

Evolving, Adapting, and Thriving in the New Research Environment



**REGISTER NOW**

Learn about:

- Thriving in a Changing Research Environment
- Adapting to Single IRB Review
- Evolving Patient-Centric Approaches to Research
- The Ethics of CRISPR (genome editing) Research
- And much more!

Other highlights:

- Social hour and poster presentations on innovative practices
- Network with friends and colleagues

**Who should attend?** Individuals from non-accredited and accredited organizations, international organizations, researchers, organizational officials, IRB professionals and chairs, compliance professionals, sponsors, patient group leaders, government, industry, voluntary health agencies, and community groups.

**Where?** The Westin Book Cadillac, 1114 Washington Blvd, Detroit, MI 48226