AAHRPP ADVANCE
One Standard Worldwide
WINTER 2018

First Department of Defense Facility Earns AAHRPP Accreditation

The 59th Medical Wing (59th MDW) at Joint Base San Antonio-Lackland Air Force Base, Texas, is the first and only Department of Defense facility to earn AAHRPP Accreditation. The 59th MDW also received "an area of distinction" for its approach to protecting military recruits who volunteer for research. **LEARN MORE**

Introducing AAHRPP Board Chair Barbara Entwisle, PhD

Barbara Entwisle, PhD, a leading social behavioral scientist and champion for research, has been elected chair of the AAHRPP Board of Directors. Dr. Entwisle joined the Board in 2014. Inside, she shares her perspective on AAHRPP and her new role as chair. **LEARN MORE**

2018 AAHRPP Conference Plenary Tackles Age-Old Question

It's a question that's been raised for as long as research protection regulations have existed: Are the criteria for approval sufficient to protect research volunteers? AAHRPP will present opposing viewpoints during a plenary session at our 2018 conference April 20-22 in Denver. **Register** by February 8 for the early-bird rate. **LEARN MORE**

From the President and CEO

AAHRPP President and CEO Elyse I. Summers, JD, gives a shout-out to our Board of Directors and Council on Accreditation members. These volunteer leaders have been instrumental in AAHRPP's evolution from start-up to the world's foremost accrediting body for human research protection programs. **LEARN MORE**

Upcoming Webinars

February 13 & 15: New Common Rule? New (and We Hope) Improved AAHRPP Evaluation Instrument **LEARN MORE**

WINTER 2018

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LATEST ACCREDITATIONS

- **BC Diabetes,** Vancouver, British Columbia, Canada
- **Boston Medical Center and Boston University Medical Campus,** Boston, Massachusetts
- **Chang Gung Medical Foundation,** Taipei City, Taiwan
- **Korea University Medical Center,** Seoul, Korea

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UPDATES FROM AAHRPP

New Standard I-9 and related Tip Sheet 24

First DoD Facility Earns AAHRPP Accreditation

59th MDW recognized for approach to vulnerable participants

The 59th Medical Wing (59th MDW) at Joint Base San Antonio-Lackland Air Force Base, Texas, is accustomed to setting the pace for healthcare, medical education, research, and readiness in the U.S. Air Force. In September the 59th MDW led the way once more by becoming the first and only Department of Defense (DoD) facility to earn AAHRPP Accreditation.

The 59th MDW also received "an area of distinction" for recognizing the potential vulnerability of military recruits who participate in research—and for taking significant steps to protect them.

For the 59th MDW human research protection program (HRPP), being first is gratifying, but what matters more is the reputation for quality that comes with AAHRPP accreditation.

"Full AAHRPP accreditation distinguishes us as a high-reliability organization, one that's among the top tier for supporting human subjects," says Earl Grant Jr., PhD, Director, 59th MDW Clinical Research Division Quality Assurance and Education Branch.

As the gold standard for HRPPs, AAHRPP accreditation gives current and prospective sponsors another reason to turn to the 59th MDW for research. Accreditation also increases opportunities for the 59th MDW to collaborate on research.

"It makes us more competitive and more attractive to other institutions that have also obtained this internationally recognized standard of excellence," says Colonel Linda Steel-Goodwin, Director, 59th MDW Clinical Investigations and Research Support Division.

A distinctive approach

Joint Base San Antonio-Lackland is notable for the size and scope of its operations. The 59th MDW is the Air Force's largest clinical training facility and also maintains the largest medical readiness mobility teams. In addition, the 59th MDW supports the Air Force's largest training wing: the 37th TRW.

The 37th TRW provides basic military training for all enlisted recruits entering the Air Force, Air Force Reserve, and Air National Guard, graduating more than 80,000 students each year.

With so many active protocols, these recruits have ample opportunities to participate in research. Protecting these students is a priority.

"We are very sensitive to any perception of command influence by recruits when volunteering for research studies," says Wayne M. Deutsch, DDS, MPH, Conflict of Interest Manager at the 59th MDW. "Our IRB, with concurrence of the institutional official, determined that our students are a vulnerable population and need additional protections."

For every study, the Institutional Review Board (IRB) appoints an ombudsman to ensure that no student feels pressured to participate and that information on the research is clear, adequate, and accurate. The ombudsman cannot be associated with the study or research in any way and, prior to serving in this capacity, must complete CITI training for human subjects research.

During the recruitment and consent process:

- Everyone on the research team is in civilian clothing—no military uniforms.
- No members of the student's leadership (e.g., unit officers, senior non-commissioned officers, drill sergeants) are present.
- If any signs of coercion or undue influence are observed, the ombudsman must address the matter immediately with the principal investigator. The ombudsman must also provide a report to the IRB detailing the observed behavior of the research team and the resulting corrective action.
- The ombudsman can report to the IRB anytime they feel coercion or undue influence is observed during the consent process.
- The ombudsman has the authority to stop the recruitment/consent process if the investigators continue with their unapproved actions.

"The concept of volunteerism is different in the military, where individuals are highly motivated to step forward whenever they are asked," says Wesley Byerly, PharmD, Associate Vice President for Research Compliance at University of Connecticut Health Center, and a member of AAHRPP's Council on Accreditation. Dr. Byerly served as the Step 1 reviewer and site visit team leader for the 59th MDW.

In a military environment, "the difference between being told and being asked can blur," he adds. "The 59th MDW team understands this and has processes in place to mitigate the potential for undue influence to creep in. They make it possible for the researchers to secure participation and for the volunteers to understand that they can step out of the process without jeopardizing their careers or their standing among their peers."

As a result, AAHRPP commended the 59th MDW for meeting Standard II-4—*The IRB or Ethics Committee (EC) provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research*—with distinction.

Disclaimer: The views expressed are those of the authors and do not reflect the official views or policy of the Department of Defense or its Components.

Introducing AAHRPP Board Chair Barbara Entwisle, PhD

Barbara Entwisle, PhD, a leading social behavioral scientist and champion for research, has been elected chair of the AAHRPP Board of Directors. Dr. Entwisle is the Kenan Distinguished Professor of Sociology at the University of North Carolina (UNC) at Chapel Hill. She also is a fellow at the university's Carolina Population Center, where she serves as training director. Previously, Dr. Entwisle was vice chancellor for research at UNC at Chapel Hill, overseeing a program that routinely attracted over $800 million a year in contract and grant funding.

Dr. Entwisle joined the AAHRPP Board in 2014. Below, she responds to three questions about AAHRPP and her new role as chair.

Q. Why did you join the AAHRPP Board?

A. I'm a researcher, a social behavioral scientist, and a believer in the AAHRPP mission. I really value human subjects research and am enormously grateful to the millions of participants worldwide who make this research possible. We owe them our utmost respect and assurances that we will do everything possible to maximize the benefits of research and protect them from harm.

The AAHRPP Board is wonderfully diverse in terms of the perspectives that are represented and the talents that Board members bring. I was honored to be asked to join. Equally important, given my research background and experience as vice chancellor of research, I felt I had a lot to contribute.

I was the institutional official at the University of North Carolina at Chapel Hill when we attained AAHRPP accreditation. I know a lot about how universities operate and how they make decisions. They're not the only clients AAHRPP has, but they are an important constituency, and that background is helpful. In addition, I have conducted research in the U.S., China, Egypt, and Thailand, so I have a real interest in and understanding of how views vary from place to place. I also serve on advisory and review committees for the NIH (National Institutes of Health), NSF (National Science Foundation), and National Academy of Sciences. I welcomed the opportunity to draw on my experience and perspective to support AAHRPP and benefit research participants.

Q. What will be your primary focus as chair?

A. The Board recently engaged in a strategic planning effort and, as vice chair at the time, I helped get that effort off the ground. One of my goals is to move this plan to completion, identify and formalize our priorities, and launch the execution of those priorities. As a scientist, I'd like to see AAHRPP use the data it collects in a more efficacious way to streamline operations and assist accredited organizations with their decision-making.

I also intend to build on some of the efforts already underway. AAHRPP will continue to strengthen relationships with accredited organizations and partners throughout the research enterprise, and reach out strategically to international organizations with the ultimate goal of achieving research protection worldwide. AAHRPP also will seek ways to further streamline processes. The goal is to reduce some of the burden on organizations while maintaining the highest standards and quality. In its role as a "go-to" resource, AAHRPP will provide leadership on how accredited organizations can fulfill the requirements of the revised Common Rule.

Through these and other efforts, AAHRPP will communicate the value of accreditation and of AAHRPP as an organization. That's something I'm very passionate about. AAHRPP's work touches so many different types of entities and has enormous value to research participants, investigators, IRBs, research institutions, and sponsors.

Q: What are AAHRPP's biggest challenges right now?

A. We're in a challenging, dynamic environment. The nature of research—and the way it's conducted—is changing. It's become a global enterprise, involving complex, interdisciplinary teams. As an accrediting body, AAHRPP will continue to keep a close eye on these relationships and how these teams work together.

The research community also is facing the first revision of the Common Rule, and there are questions about how the changes will be operationalized and enforced, and when. At the same time, we're seeing a change in how people view science and research, and we're hearing concerns about the way research is funded and the role of public and private institutions.

It's important that AAHRPP respond proactively to these issues, and that's exactly what AAHRPP is doing. On the Common Rule, for example, AAHRPP has issued a new standard on single IRB review, a new element on limited IRB review, and a new evaluation instrument that incorporates the revised regulatory requirements. More than half the sessions at AAHRPP's upcoming conference are designed specifically to help organizations prepare for the changes to the Common Rule—and be ready to implement them on day one.

Conference Plenary Tackles Age-Old Question

Do the approval criteria provide adequate protections?

It's a question that's been raised for as long as research protection regulations have existed: Are the criteria for approval sufficient to protect research volunteers?

AAHRPP will tackle the question—and present opposing viewpoints—during a plenary session at our 2018 conference on April 20-22 in Denver.

Daniel Nelson, MS, U.S. Environmental Protection Agency, will moderate the discussion, which features two highly respected members of the research community: Jeffrey Cooper, MD, MMM, of WIRB Copernicus Group, and David H. Strauss, MD, of the New York State Psychiatric Institute (NYSPI), Columbia University, and HSNA Consulting.

The session is one of more than 30 at the **conference**, "Summiting New Heights in the Mile-High City: Early Experiences, Strategies, and Solutions." Many are designed to help research organizations prepare for changes to the Common Rule. Additional pre-conference sessions help organizations prepare for the AAHRPP accreditation process.

DAVID H. STRAUSS, MD

Dr. Strauss, Director of Research Operations and Compliance at NYSPI, believes that latitude and flexibility are intentionally built into the regulations to better protect participants.

"The regulations allow significant discretion on the part of IRBs," he says. "They're intended to empower a well-constituted, representative expert panel to exercise judgment within the structure of the regulations."

Dr. Cooper, Vice President for Process and Strategic Improvement for WIRB Copernicus Group, is one of two "practical ethicist" columnists for the *Journal of Empirical Research on Human Research Ethics*. He takes a different view, calling for a quality review process that codifies approval criteria in writing and permits little, if any, variation.

In a recent column, Dr. Cooper wrote, "Written policy should indicate that research meeting the approval criteria gets approved, and research not meeting approval criteria does not get approved unless changes are made that allow the research to meet approval criteria."

JEFFREY COOPER, MD, MMM

To ensure that IRB and research ethics committee (REC) members remain focused on the criteria, Dr. Cooper suggests that members express any concerns about proposed research by indicating which approval criterion is not being met and why.

"Approval criteria ought to be the floor and the ceiling," he wrote. "RECs/IRBs should take steps to eliminate ad hoc criteria to eliminate special cause variation and to recognize that the elimination of special cause variation better protects research participants."

Dr. Strauss counters that the issue at the core of any research review is whether the risks are reasonable in light of the anticipated benefits to participants and others.

"Saying the regulations are the floor and the ceiling doesn't mean much. There's no objective standard or benchmark to determine what is reasonable," he says. "If our general approach to human research protections is to say we do the minimum necessary under the regulations, then to me that might suggest we are not doing enough.

"The regulations are neither the ceiling nor the floor because they permit enormous discretion and judgment—and that's as it should be," he adds.

Other conference sessions offer insights on how to prepare for single IRB review, new consent requirements, limited IRB review, and continuing review. Still others cover topics such as vulnerable populations, participant comprehension, exempt research, and research biobanking.

For a complete list, view the conference **agenda**.

From the President and CEO

Acknowledging significant contributions

ELYSE I. SUMMERS, JD

From the beginning, AAHRPP has benefited from the talent, expertise, and dedication of the individuals who have graciously agreed to serve on our Board of Directors and Council on Accreditation. Without them, AAHRPP would not be where it is today.

Over the years, these volunteers have helped AAHRPP evolve from a startup to the world's leading accrediting body for research protections. Even more important, these individuals have played a role in strengthening research protections, improving the quality of research, and affirming the research community's fundamental commitment to those who make discovery possible.

We are grateful, always, for the contributions of our volunteers. I call your attention to them now because the first quarter often is a time of transition among this leadership. This year, although there's been no change in membership on our Board, we did bid farewell to three longstanding members of our Council on Accreditation: **John Baumann, PhD,** Associate Vice President, Research Compliance, Indiana University; **Wesley Byerly, PharmD**, Associate Vice President for Research Compliance, University of Connecticut Health Center; and **Robert Frenck, MD**, Professor of Pediatrics, IRB Chair, Cincinnati Children's Hospital Medical Center. **Candice A. Yekel, MS**, Associate Vice President for Research and Director, Office for Research Protections, The Pennsylvania State University, completed her term as chair and will remain a Council member. On behalf of AAHRPP and the broader research protections community, I extend our heartfelt appreciation to these Council members for their exceptional service.

I also am delighted to welcome the following who joined—and, in one case, re-joined—the Council this year: **John Andrew Bertolatus, MD**, Associate Professor, Internal Medicine, The University of Iowa; **Monika Markowitz, PhD, MA, MSN, RN**, Director, Office of Research Integrity and Ethics, Office of the Vice President for Research and Innovation, Virginia Commonwealth University; and **Julie Ozier, MHL, CIP,** Director, Human Research Protection Program, Vanderbilt University.

K. Sue Haddock, PhD, RN, FAAN, Associate Chief of Staff, Research, William Jennings Bryan Dorn Veterans Affairs Medical Center, is now Council chair.

On our Board of Directors, **Barbara Entwisle, PhD**, Kenan Distinguished Professor of Sociology, University of North Carolina at Chapel Hill, Training Director and Fellow, Carolina Population Center, has been elected chair. **Jeffrey Wendel, MBA**, President, Chesapeake Research Review, Inc., is immediate past chair. We are extremely grateful for Jeff's leadership, support, and vision during his tenure as chair.

Finally, it is my pleasure to announce our newest AAHRPP staff members, **Kate Vulakovich**, Assistant Director of Accreditation, and **Lori Kravchick**, Office Manager, who are welcome additions to our exceptional team. I will provide a more formal introduction of them during the 2018 AAHRPP Conference, April 20-22, in Denver.

If you haven't yet registered for the conference, time is running out to take advantage of our early-bird discount. **Register** by February 8 to receive the reduced rate. This year's conference, "Summiting New Heights in the Mile-High City: Early Experiences, Strategies, and Solutions," is a must for anyone with questions on the new Common Rule.

You'll hear from representatives of the Office for Human Research Protections and the Secretary's Advisory Committee on Human Research Protections, as well as other experts from across the research enterprise. In session after session, we'll offer information to help you interpret—and comply—with the updated regulations.

You'll also have lots of opportunities to network, reconnect with colleagues, and enjoy. I look forward to seeing you there.

Elyse I. Summers, JD
AAHRPP President and CEO

Register Now for the 2018 AAHRPP Conference

"Summiting New Heights in the Mile-High City: Early Experiences, Strategies, and Solutions"

AAHRPP
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Early-bird rate available through February 8

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**

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