

AAHRPP ADVANCE

One Standard Worldwide

SPRING 2020

From the President and CEO



AAHRPP President and CEO Elyse I. Summers, JD, highlights the strength, resilience, and collegiality of the research community during this unprecedented time. She cites the awe-inspiring efforts of those on the front lines and the connections and commitment that will help us weather the pandemic together. [LEARN MORE](#)

UNMC Activates Rapid Response IRB For COVID-19 Trials

The University of Nebraska Medical Center's Rapid Response IRB is once again at the forefront of the fight against a deadly pathogen—this time, the coronavirus that causes COVID-19. The IRB also is serving in an expanded role as the central IRB for the Special Pathogens Research Network and its 10 Regional Ebola and Special Pathogens Treatment Centers. [LEARN MORE](#)

First Accredited Organization in Australia

With the accreditation of Bellberry Limited of Australia, AAHRPP has extended our reach to another country and continent. A national nonprofit institution, Bellberry Limited is the largest independent reviewer of human subjects research in Australia. [LEARN MORE](#)

New Board & Council Members

Please join us in welcoming the newest members of our Board of Directors and Council on Accreditation. All were chosen for their depth of experience and unwavering commitment to protecting research participants. [LEARN MORE](#)

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COVID-19 GUIDANCE

AAHRPP has issued "[Guidance on HRPP Response to COVID-19](#)" to help accredited and not-yet-accredited organizations during the novel coronavirus pandemic. The document addresses issues including changes to research procedures, reporting changes to IRBs, consent and communication with research participants, and more.

LATEST ACCREDITATIONS

- **Bellberry Limited**, South Australia, Australia
- **Taichung Veterans General Hospital**, Taichung City, Taiwan
- **Walter Reed National Military Medical Center**, Department of Research Programs, Bethesda, Maryland

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From the President and CEO

Meeting the Challenges of Unprecedented Times

In any other year, right about now we'd be looking forward to seeing so many of you at our annual conference. We'd be anticipating the fascinating discussions, exchanges of information and best practices, and the countless interactions that reinforce our connections and sense of community.

This year, of course, things are different. We meet remotely instead of in offices and conference rooms. We no longer travel. In fact, many of us seldom leave our homes. Perhaps most concerning, we suspect that our lives and our world will be changed forever.

Yet, every day we are reminded that we are part of an extraordinary community.

It is humbling and inspiring to know that we are connected to individuals around the globe who are on the front lines of this pandemic. Many are completely immersed in protecting patients and research participants, treating those with COVID-19, or conducting research that could lead to effective therapies or vaccines.

All of us at AAHRPP are in awe of these efforts—and of you.

Lessons and reminders

At times like this, we learn from experience and each other. We see, firsthand, whether our “just-in-case” policies work as we expected. If we need to adjust, we do so. Promptly.

At AAHRPP, we acted quickly to anticipate questions and provide guidance on how to maintain research protections and standards during this unprecedented time. Most, if not all, of you provided similar information to IRBs, investigators, and other members of your HRPPs.

I trust your experience mirrored ours—that you were reminded how well AAHRPP's flexibility serves your organization. I hope that you witnessed, time and again, your team's passion for quality and commitment to research participants. I also trust that you benefited, and continue to benefit, from the support and collegiality that are hallmarks of our community.



ELYSE I. SUMMERS, JD

If you're looking for some good news, you'll find it in this issue of AAHRPP Advance. We highlight the impressive response of one of our accredited organizations, the University of Nebraska Medical Center (UNMC), whose Rapid Response IRB broke new ground recently as the first central IRB for the Special Pathogens Research Network. Within 48 hours, UNMC's Rapid Response IRB reviewed and approved the protocol for a clinical trial of the experimental drug remdesivir, which has been making a lot of news lately.

We also feature Bellberry Limited, the first organization in Australia to earn AAHRPP accreditation. And, we introduce you to the new members of our Board of Directors and Council on Accreditation.

All these stories are examples of bright spots during an often-frightening time. All are reminders of how our community plays a key role in shaping research and contributing to the progress it makes possible. All are reasons to be proud and grateful.

Stay well and keep up the excellent work.

Best,

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

UNMC Activates Rapid Response IRB For Pandemic Clinical Trials



Six years ago, the University of Nebraska Medical Center (UNMC) activated its Rapid Response IRB to review the protocol for an investigational drug to treat a patient critically ill with Ebola. Today, UNMC is once again on the front line of the fight against a deadly pathogen: the coronavirus that causes COVID-19.

This time, UNMC's Rapid Response IRB is serving in an expanded role as the central IRB for the Special Pathogens Research Network and its 10 Regional Ebola and Special Pathogens Treatment Centers (RESPTCs).

The RESPTCs enrolled nearly 300 of the 1,063 COVID-19 patients worldwide for a clinical trial of remdesivir, an experimental antiviral drug. That trial has completed; the next phase of the investigation compares remdesivir to remdesivir plus baricitinib. The National Institutes of Allergy and Infectious Diseases (NIAID) is the regulatory sponsor.

The remdesivir trial began in late February when UNMC enrolled the first patient. To facilitate the experimental treatment, in less than 48 hours the Rapid Response IRB reviewed and approved the protocol, including reliance agreements with other trial sites and procedures for obtaining informed consent.

It was the first test of the effectiveness of the central IRB process, "and it worked beautifully," says Bruce Gordon, MD, Assistant Vice Chancellor for Regulatory Affairs and Executive Chairman, Institutional Review Boards at UNMC.

A collaborative process

Dr. Gordon credits the quick turnaround, in part, to a process created during the Ebola outbreak and to recent tabletop training exercises involving the RESPTC IRB partners. To save time during the review of the investigational Ebola treatment, the Rapid Response IRB worked with the investigator to complete the IRB application.

"We changed the review paradigm and made it a collaborative process," Dr. Gordon says. "We had the investigator present at the IRB deliberations, so we could negotiate changes in the application and in the conduct of the research related to protecting subjects, and then make those changes on the spot." After Ebola, and until COVID-19, the process remained "tucked away," Dr. Gordon says, "used primarily during drills to keep us on our toes."

Those drills made a difference, especially since the most recent ones focused on adapting UNMC's rapid response process for central IRB review. The changes reflect updated Common Rule requirements for

single IRB (sIRB) review of federally funded multisite studies. As an NIAID study, the remdesivir trials are subject to this requirement.

"We were still testing the rapid response sIRB model," Dr. Gordon says, "when the pandemic struck," and 13 Americans arrived at UNMC after being exposed to the novel coronavirus. All were passengers on a cruise ship where nearly 700 guests and crew members tested positive for COVID-19. One passenger became the first participant in the remdesivir clinical trial.

A leading biocontainment and quarantine center

UNMC was the logical place to isolate, monitor, and treat the American passengers. The university is known worldwide for its infectious disease expertise. UNMC also is home to the nation's largest biocontainment unit and the only federal quarantine facility. In addition, UNMC was one of the first facilities authorized by the Centers for Disease Control and Prevention to conduct COVID-19 tests.

When the first coronavirus study request came in, for a biospecimen collection protocol, the Rapid Response IRB lived up to its name, seizing every opportunity to streamline the review while ensuring adequate protections for research participants.

Dr. Gordon and the investigators drafted the application and consent documents together. Reliance agreements, consent forms, and other necessary documents also were easy to pull together because they had been assembled as part of the multi-institutional tabletop exercises.

The goal of the exercises that had been conducted was to streamline a process that typically took weeks and cut review time down to 48 hours or less. That's exactly what happened.

"Before the pandemic, we conducted tabletop exercises to work out the processes and procedures, and we felt that we were 90% there," Dr. Gordon says. "All that was left was to conduct one more full-scale exercise, which we did—in real life."

UNMC's efforts are receiving national attention and drawing praise from the research community, including AAHRPP. Elyse I. Summers, JD, AAHRPP President and CEO, cites the "can-do spirit" and efficiency of UNMC's Rapid Response IRB.

"This is an inspiring example of the innovations that AAHRPP-accredited organizations are capable of, even in the midst of a global pandemic," she says. "It's also a powerful reminder of how AAHRPP-accredited organizations are equipped to respond to the challenges of an ever-more complex research environment."

Bellberry Is First in Australia to Achieve AAHRPP Accreditation

When Bellberry Limited earned AAHRPP accreditation, the distinction affirmed Bellberry's commitment to high-quality, ethical scientific review and the organization's place in the global research community.

The national nonprofit institution, which reviews human research projects across Australia, became that country's first AAHRPP-accredited entity in March. Bellberry's achievement was a milestone for the organization and for AAHRPP, which extended its reach to a new country and continent.

The accreditation also had significance for the more than 600 AAHRPP-accredited entities worldwide. In Bellberry, they now have an accredited partner that can take the lead on multisite reviews in Australia and serve as a gateway to additional opportunities in the Asia-Pacific region.

The “next improvement”

Bellberry was founded in 2004 in response to the need for a human research ethics committee (HREC) to review human subjects research for Australia's private sector. Initially, Bellberry's single HREC met monthly to review research conducted in South Australia. Today, Bellberry is the largest independent reviewer of human subjects research in Australia. The organization has 12 HRECs that provide research review services for about 1,000 entities across the country.

The company also has earned a reputation for innovation. Using a streamlined, secure electronic process, Bellberry typically completes protocol reviews within 20 days. Proceeds from review services benefit human research in Australia. To date, Bellberry has donated more than \$3.5 million to fund projects including research fellowships, education and training in ethical research practices, and advances in molecular imaging.

Last year, Bellberry marked its 15th anniversary and used the occasion, in part, to reflect on its growth and to chart a course for continued innovation.

“We looked at all we'd accomplished and began to ask ourselves, ‘Where does the next improvement come from?’” Bellberry CEO Kylie Sproston says.

After years of setting the benchmark for research review in Australia, Bellberry was seeking an objective, external perspective from an organization that had earned the respect of the international research community. “In our sector, AAHRPP is that organization,” she says.



KYLIE SPROSTON

The decision to pursue accreditation was reinforced by Bellberry's experience at AAHRPP's Annual Conference and the support Bellberry received from other AAHRPP-accredited entities.

“One of the most amazing aspects of the process—and one of the most positive—is the sense that we're really joining a community,” Ms. Sproston says. “AAHRPP's conference is incredibly welcoming and generous. There's very much a feeling of shared values, of working together to improve our practices. It really speaks to the credit AAHRPP deserves for building that type of community.”

Breaking new ground

All Bellberry HRECs are certified by Australia's National Health and Medical Research Council (NHMRC). As the first in Australia to undergo the AAHRPP accreditation process, it fell to Bellberry to map NHMRC requirements with the AAHRPP standards. The accreditation process also compelled Bellberry to conduct a comprehensive review of its quality manual.

Bellberry used both exercises to drive internal understanding of the rationale for each process and to identify areas for improvement.

“It was a phenomenally valuable process, especially for a growing organization. It challenged our thinking and prompted us to formalize our approach to continuous quality improvement,” Ms. Sproston says.

She describes the site visit, which included interviews with 73 investigators and staff from research sites throughout Australia, as an “amazingly validating experience.” Perhaps even more important, she says, the lessons learned “provided a framework for success for the next generation of our organization.”

AAHRPP Welcomes New Board, Council Members

AAHRPP recently named three new members to our Board of Directors: Quincy Byrdson, EdD, CIP, CCRP, of WellStar Health System; Harold “Hal” Hackerman, CPA, of Ellin & Tucker; and Heather Pierce, JD, MPH, of the Association of American Medical Colleges (AAMC).

We also added three Council on Accreditation members: Nichelle Cobb, PhD, of the University of Wisconsin-Madison; Bruce Gordon, MD, of University of Nebraska Medical Center (UNMC); and Megan Kasimatis Singleton, JD, MBE, CIP, of Johns Hopkins University School of Medicine. Like all council members, the three are experienced AAHRPP site visitors.

New Board Members



QUINCY BYRDSONG

Dr. Byrdson is the associate vice president for research administration at the WellStar Research Institute for WellStar Health System, the largest health system in Georgia. As such, he is the chief research administration officer and the institutional official on WellStar’s Federalwide Assurance. Dr. Byrdson has extensive experience in human research protections and has held research leadership positions at Virginia Commonwealth University, Morehouse School of Medicine, Meharry Medical College, and Vanderbilt University Medical Center. Dr. Byrdson is a member and the president-elect of the Board of Directors for the Society of Clinical Research Associates.



HAL HACKERMAN

Mr. Hackerman has served for more than three decades as a director in the Audit and Accounting Department of Ellin & Tucker, one of the mid-Atlantic region’s leading business consulting and certified public accounting firms. He has been a driving force behind the growth and development of the firm’s manufacturing and wholesale distribution services group. Mr. Hackerman also has extensive experience providing auditing and accounting services for clients in the brokerage, construction, not-for-profit, real estate, and professional services industry; assisting with mergers and acquisitions; and helping clients in financially troubled situations. He serves as treasurer of the Board of Directors of Northwest Hospital in Randallstown, Maryland.



HEATHER PIERCE

Ms. Pierce is the senior director for science policy and the regulatory counsel at AAMC. She serves as AAMC’s leader for scientific regulatory issues, including human subjects protections, clinical research, conflicts of interest, research data sharing, evidence-based regulation, and collaborations between industry, government, and academia in biomedical research. Ms. Pierce presents at national forums on issues related to protecting human subjects, regulatory burden, research ethics, biospecimens, scientific misconduct, legislation and policymaking related to research, and research compliance.

She has published articles and commentaries on these topics in *Nature*, *Science*, *The New England Journal of Medicine*, *JAMA*, and *The American Journal of Bioethics*. Ms. Pierce also has served on boards, committees, working groups, and task forces of organizations including the National Academies of Sciences, Engineering, and Medicine, The Pew Charitable Trusts, the National Dialogue on Healthcare Innovation, and Public Responsibility in Medicine and Research (PRIM&R).

AAHRPP Welcomes New Board, Council Members

New Council Members



NICHELLE COBB

Dr. Cobb has worked with IRBs for more than two decades, including 16 years as director of the Health Sciences Institutional Review Boards at the University of Wisconsin-Madison. Currently she is the human subjects protections officer for the Institute for Clinical and Translational Research at the University of Wisconsin-Madison and the director of operations for SMART IRB. Dr. Cobb was instrumental in the development of the initiative, sponsored by the National Center for Advancing Translational Science, to create a master IRB authorization agreement and support single IRB review. She also is a member of the SMART IRB Harmonization Steering Committee.



BRUCE GORDON

Dr. Gordon is the assistant vice chancellor for regulatory affairs and a professor of pediatrics at UNMC. He has been a member of the UNMC IRB since 1992, served as chair since 1996, and as executive chair since 2011. He also has served on numerous national committees, including the Secretary's Advisory Committee on Human Research Protections Subpart A Subcommittee, the American Society of Clinical Oncology Task Force on Oversight of Clinical Research, the AAMC Informed Consent Working Group, and the National Institute of Environmental Health Sciences Best Practices Working Group for IRB Review of Disaster Research. Dr. Gordon also was the first chair of the National Cancer Institute Pediatric Central IRB. He is a founding member of the Collaborative Institutional Training Initiative and a member of the PRIM&R Board of Directors. He is editor of the 3rd edition of "IRB: Management and Function" and the author of numerous original papers, chapters, review articles, and abstracts regarding human subjects protections and research ethics.



MEGAN KASIMATIS
SINGLETON

Ms. Singleton is the assistant dean for human research protections and director of the Human Research Protections Program at Johns Hopkins University School of Medicine. She oversees central IRB activities for the Johns Hopkins/Tufts Trial Innovation Center, leading the charge for innovations in operationalizing single IRB review. Ms. Singleton is a member of the SMART IRB Harmonization Steering Committee, co-chair of the PRIM&R Advancing Ethical Research Conference Workshop/Didactic Subcommittee, and a member of the PRIM&R Board of Directors. She also serves on the steering committee for AEREO, a consortium designed to advance effective research ethics oversight through empirical research.

Save the Date (and Cross Your Fingers)

2021 AAHRPP ANNUAL CONFERENCE

GRAND HYATT DENVER / COLORADO

MAY 18-20, 2021



Mark your calendars for one of the research community's must-attend annual events.

