AAHRPP ADVANCE
One Standard Worldwide
WINTER 2017

A Patient-Centered Approach to Research

The research enterprise increasingly is taking a patient-centered approach to clinical trials to help improve patient recruitment and retention rates. That, in turn, could decrease drug development costs and advance discovery. **LEARN MORE**

An IRB's Rapid Response to Ebola

During the Ebola outbreak of 2014, University of Nebraska Medical Center (UNMC) set the standard not only for isolation and treatment of Ebola patients but also for prompt IRB review of an emergency investigational drug protocol. **LEARN MORE**

UNMC: Choosing the Gold Standard

In a Q & A with AAHRPP, Ernest D. Prentice, PhD, UNMC Associate Vice Chancellor for Academic Affairs and Institutional Official, discusses the organization's decision to pursue AAHRPP accreditation, the accreditation process, and the UNMC organization. **LEARN MORE**

Our New Year's Resolutions

AAHRPP President and CEO Elyse I. Summers, JD, starts the new year by sharing AAHRPP's resolutions for 2017. Expect increased support for accredited and not-yet-accredited organizations, meaningful guidance on emerging research issues, and continued progress on achieving one standard worldwide for research protections. **LEARN MORE**

AAHRPP Conference: Save by Registering Now

The 2017 conference, "Evolving, Adapting, and Thriving in the New Research Environment," will be held May 9-11 in Detroit. Take advantage of the early-bird rate by registering by March 9. **REGISTER NOW**

WINTER 2017

INSIDE

Latest Accreditations

- **Memorial Sloan-Kettering Cancer Center,** New York, New York
- **Northwestern University,** Evanston and Chicago, Illinois
- **Trustees of Boston University,** Charles River Campus, Boston, Massachusetts
- **University of Mississippi Medical Center,** Jackson, Mississippi

LEARN MORE

AAHRPP
Association for the Accreditation of Human Research Protection Programs, Inc.®

Enhancing Research with a Patient-Centered Approach

TRACY H. BLUMENFELD, MBA

The research enterprise is increasingly recognizing the value of a patient-centered approach to clinical trials—one that moves beyond a focus restricted to issues of safety and welfare to truly understanding and responding more broadly to patients' and research participants' needs.

"There is a lot of discussion about being more aware of the burdens a study places on the patient and caregiver," says Tracy H. Blumenfeld, MBA, a member of the AAHRPP Board of Directors and the Co-Founder, President, and CEO of RapidTrials. A pharmaceutical services provider, RapidTrials helps improve the efficiency, quality, and compliance of research sites.

"Many in the industry are rethinking study design and focusing, step by step, on what we're asking patients to do," Ms. Blumenfeld says.

"Is it reasonable, for example, to expect a terminally ill patient—especially one who's not feeling well—to travel to a research site once a week for the duration of a trial?" she asks. "Does it make sense to require an already sick person to come to a research site and spend an entire day trying to navigate their way around the facility, moving from department to department for imaging procedures and blood draws?"

Such burdensome requirements can dissuade patients from signing up for a study in the first place or prompt them to drop out partway through, compromising the study results. Insufficient enrollment and poor retention rates increase drug development costs and delay discoveries that can benefit the public.

Experts increasingly cite greater patient involvement as an effective way to address recruitment, retention, and other study-related issues. For those interested in taking a more patient-centered approach, following are some essential steps to consider.

Get to know today's patients. These days, patients tend to be more sophisticated and better informed than in the past. "In most cases, it takes more than their physician offering a clinical trial to persuade patients to enroll," Ms. Blumenfeld says. Be prepared to discuss the trial at length, listen to patients' concerns, and provide information to support their ability to make an informed decision about participating in the study.

Bring the research to familiar settings. From both economical and emotional perspectives, it can be smarter to offer clinical research studies in places where patients are already accustomed to receiving care. Not only is doing so more convenient and cost-effective, it also pairs the patient with an already trusted provider and can strengthen the existing patient-provider relationship.

Involve patients, caregivers, and patient surrogates in the study design. Investing extra time with patients, caregivers, and surrogates upfront can pay dividends in higher retention rates later. A truly patient-centric approach to clinical trials requires the involvement of patients, caregivers, and site personnel from the very beginning, during the protocol design phase, when the study design and schedule of events can still be altered and plans can be put in place to minimize the burdens of volunteering to participate. As an example, Ms. Blumenfeld cites the added stress that a trial can place on caregivers of Alzheimer's study participants. "We can lose sight of how difficult and taxing it can be to get a loved one up, dressed, fed, and ready for a study visit for a clinical trial," she says. "For someone who's already stretched, another visit can put them over the edge."

Looking ahead, Ms. Blumenfeld anticipates even greater focus on trial participants and more willingness from sponsors to be creative about how and where research is conducted. For instance, for those who cannot come to a trial site, nurses and investigators could conduct some study-related activities in the participant's home.

Ms. Blumenfeld also foresees increased sponsor involvement—through staffing support and centralized participant services, such as travel assistance and expense reimbursements—to support research sites and free them to focus on patient interaction. The key is for sponsors to work with sites upfront in the study planning stage, tailoring solutions that meet patient needs on a study-by-study basis.

"Supporting patient and caregiver needs can be logistically complex and time-consuming," Ms. Blumenfeld admits. Yet she is optimistic, adding, "I think sponsors are more willing to get involved and collaborate with research sites to make participation easier for patients and keep them engaged in the research."

An IRB's Rapid Response to Ebola

When an American physician contracted Ebola in West Africa in 2014, the U.S. State Department arranged for the patient to be treated at the University of Nebraska Medical Center (UNMC), which was at the time home to one of only four biocontainment patient care units in the United States.

UNMC infectious disease specialists had been preparing for such a scenario for more than a decade, and their protocol has since become the standard for isolation and treatment of Ebola patients. The same is true for the actions taken by UNMC's Rapid Response IRB.

In a matter of hours, IRB members reviewed the protocol for use of an investigational drug, met with the researcher involved, and finalized the informed consent form.

"Because it was an emergency situation, we could have administered the investigational drug without IRB review and patient consent," says UNMC Associate Vice Chancellor for Academic Affairs and Institutional Official Ernest D. Prentice, PhD. "But we preferred to conduct a review of the protocol first. Since then, we have had a lot of interest in how our Rapid Response IRB works."

As its name indicates, the Rapid Response IRB is designed—and expected—to act quickly. Unlike the other three UNMC IRBs, the Rapid Response IRB is specifically constituted to have fewer members, who have committed to being available on short notice to attend an IRB meeting that could be scheduled at any time, night or day.

The UNMC IRB took less than 26 hours to review and approve the protocol for use of the investigational drug. At 9:07 a.m. on September 4, 2014, the IRB administrator was alerted that an Ebola patient was en route. The administrator was asked to convene an IRB meeting to review the protocol. Calls to IRB members began immediately. By 2:00 p.m., a quorum had been identified and the IRB meeting was scheduled for the next day.

The patient arrived under police escort at UNMC on September 5 at 6:48 a.m. By then, the IRB had reviewed multiple drafts of the IRB application, consent form, and protocol. To expedite matters, much of the prereview work had been done online and via email overnight.

The IRB convened at 7:00 a.m., conducted its final review and discussion, and requested additional modifications. At 10:11 a.m.—just 25 hours and 4 minutes after the first call about the Ebola patient—the study was approved and released. The IRB-approved consent form was delivered to the biocontainment unit, a consent process was initiated, and the study was implemented.

Although the data concerning how effective the investigational drug itself proved to be are still unclear, three weeks later, UNMC's first Ebola patient walked out through the center's doors, weak but healthy.

UNMC: Choosing the "Gold Standard"

Last fall, University of Nebraska Medical Center (UNMC) joined the more than 225 organizations worldwide that have attained AAHRPP accreditation. Below, UNMC Associate Vice Chancellor for Academic Affairs and Institutional Official Ernest D. Prentice, PhD, answers questions about the decision to pursue AAHRPP accreditation, the accreditation process, and the UNMC organization.

ERNEST D. PRENTICE, PhD

Q. Congratulations on your recent AAHRPP accreditation. Can you tell us why UNMC made the decision to go with AAHRPP?

A. We have long recognized the value of accreditation. Originally, we sought accreditation from Alion Science and Technology, primarily because of their work for the U.S. Department of Defense (DOD). UNMC is one of only 13 DOD University Affiliated Research Centers, so the connection made sense for us. We figured we would follow that with AAHRPP accreditation and become dually accredited.

CONTINUED NEXT PAGE

The annual bill for Alion was coming due, and we began to rethink dual accreditation, particularly because, like organizations in so many states, we have financial concerns. Clearly AAHRPP represents the gold standard, so we decided to pursue AAHRPP accreditation instead. It's the right thing to do for any organization that has an HRPP.

It's essential that HRPPs meet certain standards, and AAHRPP helps ensure that. They have created an accepted set of standards on what an HRPP ought to be and how it should function. They conduct a rigorous site visit after a comprehensive Step 1 and Step 2 application. They look at what you're doing and recommend areas where you can improve. Without that peer review process, you're not going to identify some of those areas—and your program is not going to be as strong.

AAHRPP accreditation gives your program credibility. It's one thing to say you have a "fantastic HRPP," but it's another thing to prove it. You do that by getting AAHRPP accreditation. As the research enterprise evolves, more and more consortiums require evidence of AAHRPP accreditation. It's considered the mark of quality.

Q. Did you make changes as a result of the AAHRPP accreditation process?

A. As part of the accreditation process, we went through every policy for content, clarity, and scope, and we made adjustments as needed. Those adjustments made our policies better.

After we submitted our Step 1 application, AAHRPP came back to us with some questions that prompted us to take another look—and to make some changes. In one instance, quality improvement, AAHRPP felt that we could evaluate our HRPP in a more comprehensive way. We were doing a great job with some components, but others needed more attention and we fixed that. In another area, community outreach, we went back and took a second look based on AAHRPP's questions. We discovered that we were doing a lot more outreach than we realized through our medical center. We ended up with a much better understanding and documentation of our community outreach efforts.

That's the value of AAHRPP accreditation. Even when you have a good program, an expert external reviewer can see things you don't, and you can make your program stronger. That wouldn't happen without AAHRPP.

Q. How was the site visit experience?

A. Our site visitors were Kathleen Lawry, MSSA, CIP, CIM, and Candice Yekel, MS, and I have to compliment them. They were proactive, accommodating, helpful, and thorough. There's always a lot of apprehension among the individuals who are going to be interviewed by the accreditation site visitors. After the visit, every single investigator, coordinator, IRB staff member, and HRPP administrator said how much they appreciated the way the site visit was conducted. They went into the interviews feeling apprehensive and came out feeling positive. That's exactly what you want after a site visit.

Q. Can you describe the structure of your HRPP?

A. Our HRPP oversees all research involving human participants at the University of Nebraska at Omaha, UNMC, Children's Hospital and Medical Center, and our teaching hospital, Nebraska Medicine. Our AAHRPP accreditation covers all these facilities.

We have four IRBs: two that review research involving adults, one that reviews pediatric research, and a Rapid Response IRB that we can mobilize immediately if an emergency meeting is required. [See "An IRB's Rapid Response to Ebola" on page 3.]

Q. Does UNMC use central IRBs (CIRBs)? If so, for what type of research?

A. More than 95 percent of our research is reviewed by our own IRBs. As of late last year, we have allowed the use of other select independent IRBs for industry-sponsored research. We expect those CIRBs to be AAHRPP accredited.

Our researchers routinely rely on CIRBs for Greater Plains Collaborative studies sponsored by the Patient-Centered Outcomes Research Institute. For National Cancer Institute (NCI) oncology trials conducted under the NCI Cooperative Group Program, our researchers typically rely on the NCI CIRB. [AAHRPP note: The NCI CIRB is AAHRPP accredited.]

UNMC is not alone in this. Across the research enterprise, we're seeing increased use of CIRBs because we recognize the efficiencies and other benefits that can result from CIRB review of multisite trials.

From the President and CEO

Our New Year's Resolutions

ELYSE I. SUMMERS, JD

For many of us, January is a time to take stock. We look back on what we have accomplished during the previous 12 months and where we might have fallen short. Perhaps even more important, we look forward to the year ahead and vow to do better. In the spirit of January, AAHRPP shares the following New Year's resolutions.

We will continue to lead the way in strengthening human research protection programs (HRPPs) by supporting accredited and not-yet-accredited organizations and helping you to implement best practices. As many of you know, we have already begun identifying ways to maintain AAHRPP's high standards while streamlining documentation requirements and other processes to make them more client friendly. We will build upon these efforts in 2017, especially for organizations seeking reaccreditation.

AAHRPP standards have always required accredited organizations to commit to continuous quality improvement. We believe in holding ourselves to that same standard, so we make that same commitment to you. We will routinely review our processes with an eye toward better meeting the needs of those seeking to attain and maintain AAHRPP accreditation. We also renew our pledge to help as many organizations as possible reap the benefits of AAHRPP accreditation, both for those who conduct and oversee research and for study participants.

We will offer meaningful guidance to help you keep pace with the changes expected in the coming year. The research enterprise is facing a host of new issues related to technological advances, globalization, and calls for more efficient, cost-effective drug discovery and development. Look to AAHRPP for the latest information on the increasing reliance on single or central IRBs for multisite studies, changes in ICH-GCP guidelines, precision medicine, patient-centered research, and other trends affecting HRPPs. We will continue to tackle these and other emerging issues through webinars, in our quarterly *Advance* newsletter, and at our annual conference. (Note that our 2017 conference, Evolving, Adapting, and Thriving in the New Research Environment, will be held May 9–11 in Detroit. **Registration** is underway, and we look forward to seeing you there.) I remind you that you don't have to wait for an event to reach out to us. We are just a phone call or email away.

We will continue to develop and advance global standards for human research protections. AAHRPP has made great progress in forging and strengthening relationships with our international colleagues and working toward the common goal of promoting best-quality research and research protections. Of the 227 AAHRPP-accredited organizations, 36 (nearly 16 percent) are located outside the United States. Other international organizations have begun the accreditation process, and we look forward to welcoming them into the family of AAHRPP-accredited organizations. We anticipate increased collaboration with the research protection community in both developed and developing nations as we strive, together, to achieve our goal of "one standard worldwide."

Finally, we look forward to another exciting and successful year with all of you.

Best wishes for 2017.

Elyse I. Summers, JD
AAHRPP President and CEO

Register by March 9 to save with the early-bird rate

2017 AAHRPP CONFERENCE

Evolving, Adapting, and Thriving in the New Research Environment

AAHRPP
Association for the Accreditation of Human Research Protection Programs, Inc.®

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