

AAHRPP ADVANCE

One Standard Worldwide

SUMMER 2019

Accreditation Is Latest Milestone For King Hussein Cancer Center

King Hussein Cancer Center (KHCC) recently became the first organization in Jordan—and the first comprehensive cancer center in the Middle East—to earn AAHRPP accreditation. This distinction is the latest example of KHCC's leadership in the pursuit of excellence. [LEARN MORE](#)

Two New Board Members

Please join us in welcoming SACHRP Chair Stephen Rosenfeld, MD, MBA, and regulatory policy and communications expert Julie Anne Zawisza, MA, to the AAHRPP board of directors. [LEARN MORE](#)

Highlights from 'Big Ideas and Big Ethics In the Big Easy'

Nearly 500 individuals from 200 organizations and nine countries attended the 2019 AAHRPP Conference in New Orleans. Don't see yourself in the photos here? Check out the [You Tube](#) or [PDF](#) versions of our conference slide show. [LEARN MORE](#)

From the President and CEO



AAHRPP President and CEO Elyse I. Summers, JD, calls attention to today's increasingly complex research landscape and AAHRPP's growing role as a thought-leader and go-to-resource for information and support. [LEARN MORE](#)

SUMMER 2019

INSIDE

2 First Accreditation in Jordan

3 Two New Board Members

4 Conference Photos

6 From the President & CEO

LATEST ACCREDITATIONS

- **Intermountain Healthcare**, Murray, Utah
- **King Hussein Cancer Center**, Amman, Jordan
- **The University of Texas Southwestern Medical Center**, Dallas, Texas

[LEARN MORE](#)

SAVE THE DATE

We're heading to "Charm City." Join us May 19-21, 2020, for the AAHRPP Annual Conference in Baltimore, Maryland.

Reminder: We Have a New Address

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King Hussein Cancer Center Earns AAHRPP Accreditation

Another 'first' for major Middle East facility

In June, King Hussein Cancer Center (KHCC) became the first organization in Jordan—and the first comprehensive cancer center in the Middle East—to earn AAHRPP accreditation. This distinction is the latest example of KHCC's commitment to leadership in the pursuit of excellence.

Just months before, KHCC became the first cancer center outside the U.S. to earn Magnet® designation for nursing excellence from the American Nurses Credentialing Center. KHCC was also the first hospital in Jordan to attain Joint Commission International (JCI) accreditation and the first cancer center outside the U.S. to earn JCI Clinical Care Program Certification for its oncology program.

These and other quality designations provide external, objective affirmations of KHCC's adherence to the highest global standards. That, in turn, helps facilitate partnerships that can benefit KHCC patients.

"In today's global, collaborative research environment, AAHRPP accreditation can identify us as a trusted research partner," says Amal Al Omari, MS, PhD, Chief Scientific Officer at KHCC. "This will provide our patients with opportunities to try new drugs and interventions in the context of well-designed, ethically conducted clinical trials that contribute to advancing knowledge and to the fight against cancer."

KHCC treats over 60% of all cancer cases in Jordan and has survival rates comparable to those in international databases, including the Surveillance, Epidemiology, and End Results (SEER) Program of the U.S. National Cancer Institute. The center's research program contin-

ues to grow, with investigators submitting 164 research applications in 2018. In addition, 20 clinical trials are active and enrolling patients.

Currently, 3.5% of KHCC patients are enrolled in interventional clinical trials, in line with participation rates for cancer patients worldwide. Through KHCC's membership in the European Organization of Research and Treatment of Cancer and the Worldwide Innovative Networking in Personalized Cancer Medicine (WIN) Consortium, patients also have access to clinical trials conducted in other leading cancer centers around the globe. The goal is to do even more for Jordan's cancer patients, and KHCC believes AAHRPP accreditation supports that objective.

"We view it as an investment in our research program," Dr. Al Omari says. "We believe AAHRPP accreditation will help us grow our program, establish partnerships with organizations worldwide, and increase the trust that Jordanian patients have in research and our center."

A valuable, rigorous process

Dr. Al Omari became aware of AAHRPP years ago as a doctoral student at The University of Iowa, the first U.S. academic institution to earn AAHRPP accreditation. She began considering accreditation in earnest after assuming a research leadership role at KHCC and attending the 2015 AAHRPP conference. In January 2016, KHCC began its accreditation journey by starting the required self-assessment.

"We formed a team and started working meticulously towards accreditation," Dr. Al Omari recalls. Throughout the process, "we took a strong program and made it even stronger. Even when you're doing a great job, there's always room to do better."



King Hussein Cancer Center celebrates AAHRPP accreditation.

King Hussein Cancer Center Earns AAHRPP Accreditation (cont from pg. 2)

“Some of the changes we made weren’t required,” she adds, “but we believe in the continuous quality improvement that’s at the heart of AAHRPP accreditation.”

The biggest change involved integrating KHCC’s research efforts into a comprehensive Human Research Protection Program (HRPP), including investigators and research teams, the KHCC Research Council, Conflict of Interest Committee, IRB Committee, HRPP Steering Committee, HRPP Office, Pharmacy/Investigational Drug Services, the Office of Scientific Affairs and Research, and the Director General/Institutional Official.

KHCC also developed numerous written policies and procedures; implemented an efficient, centralized research application process and standardized forms; and created an internal auditing and monitoring system. Public outreach was increased, as were educational programs

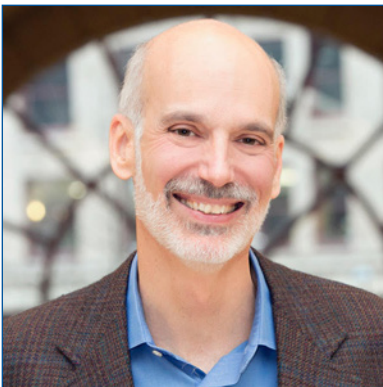
for investigators, research staff, and students who help conduct research involving human participants. All of these efforts drove home the fundamental belief that everyone involved in research shares the responsibility for protecting research participants.

The accreditation preparation had other benefits, as well. It increased the visibility of the HRPP throughout the KHCC organization and raised public awareness about the value of research for cancer patients in Jordan. The accreditation process also shined a spotlight on the strengths of KHCC’s research program, including its extensive infrastructure, the resources devoted to high-quality ethical research, and the dedication of countless individuals.

“We have a culture of excellence,” Dr. Al Omari says, “and AAHRPP accreditation will help us maintain and strengthen that.”

AAHRPP Welcomes Two New Board Members

SACHRP Chair Stephen Rosenfeld, MD, MBA, and regulatory policy and communications expert Julie Anne Zawisza, MA, have been named to the AAHRPP board of directors.



STEPHEN ROSENFELD, MD, MBA

Dr. Rosenfeld is trained in hematology and has significant experience in clinical research, IRB oversight, and health informatics. In addition to the Secretary’s Advisory Committee on Human Research Protections (SACHRP), he serves on the board of Public Responsibility in Medicine and Research (PRIM&R) and is a member of the Consortium to Advance Effective Research Ethics Oversight (AEREO).

Dr. Rosenfeld spent 19 years at the National Institutes of Health (NIH) in positions of increasing responsibility, including chief information officer (CIO) of the Clinical Center. He also has served as CIO of MaineHealth and, most recently, as executive IRB chair at Quorum Review IRB (now Advarra). A graduate of Weill Cornell Medical College, he completed a residency at Dartmouth-Hitchcock Medical Center and a fellowship at the National Heart, Lung, and Blood Institute of the NIH. He holds an MBA from Georgetown University McDonough School of Business.



JULIE ANNE ZAWISZA, MA

Ms. Zawisza is the director of global regulatory policy at Merck. She has extensive experience in strategic communications related to science and research, public policy, and public health. Ms. Zawisza’s career includes more than a decade at the Food and Drug Administration (FDA) in public affairs, communications, external relations, and global regulatory policy. She serves on the board of directors of the Alliance for a Stronger FDA.

A graduate of the University of Michigan, Ms. Zawisza has a master’s degree in science, technology, and public policy from The George Washington University and a certificate in public health from Georgetown University.

“Stephen and Julie bring considerable, complementary expertise to the AAHRPP board,” AAHRPP President and CEO Elyse I. Summers says. “They join an exceptional group of thought leaders and subject-matter experts who share AAHRPP’s commitment to research participants and high-quality ethical research.”

At the 2019 AAHRPP Conference

Barbara Entwisle, PhD, Chair, AAHRPP Board of Directors



Monika Markowitz, PhD, MSN, RN, Virginia Commonwealth University, (left), recipient of the Distinguished Team Leader award, with AAHRPP President and CEO Elyse I. Summers, JD

Jonathan Miller, MPPA, CIP, University of Alabama at Birmingham, recipient of the Distinguished Site Visitor award, with Ms. Summers



Delia Wolf, JD, Harvard School of Public Health, one of three panelists for a presentation on "International Research in the Era of the New Rule"

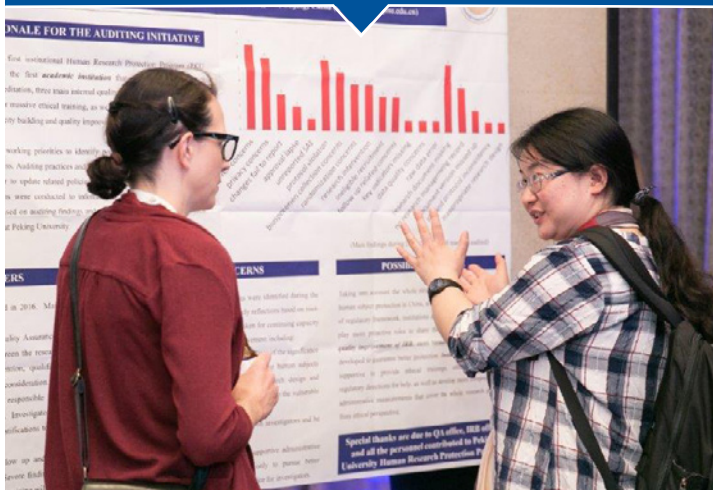
Susie Hoffman, RN, BSN, CIP, (left) and Bronwyn Blackwood, MPH, CIP, both of the University of Virginia



Madeleine Williams, MA, CIP, Huron Consulting Group, discusses AAHRPP's Standard I-9.

At the 2019 AAHRPP Conference

Poster presentation by Dr. Haihong Zhang, Peking University



Carol Weil, JD, National Cancer Institute, NIH (center) and Cecilia Brooke Cholka, MA, CIP, University of New Mexico



Elyse I. Summers, JD, AAHRPP President and CEO



Kory Trott, JD, MPH, Centers for Disease Control and Prevention



AAHRPP Team, from bottom left: Kate Vulakovich, CCRP; Robert Hood, PhD; Elyse I. Summers, JD; Harry Frazier; Mary Fields, CIP; Danielle Randolph; Dominique Hunter; Lori Kravchick; Jemelle Williams; and Michelle Feige, MSW, LCSW-C

From the President and CEO

A go-to resource for accredited and not-yet-accredited organizations

Earlier this month, the world got some of the first positive news about Ebola since the virus was discovered 43 years ago. There'd been a breakthrough: Two of four drugs being tested in a clinical trial were dramatically improving survival rates for patients who were treated early.

The results were so striking that the independent data and safety monitoring board (DSMB) recommended stopping the trial early to end testing of the less effective experimental medicines. The trial will now enter an extension phase that includes only the two promising treatments.

My first reaction to the news was probably similar to yours: excitement, hope, and relief that perhaps we're finally making some progress in treating this highly contagious, often deadly disease. As I read more about the trial and the role of the DSMB, I put on my "AAHRPP hat," and my thoughts turned to one of our recent, more popular conference sessions, "Overlapping Roles of DSMBs and IRBs in the Protection of Human Research Participants." (The session was so well-received last year that we arranged an encore presentation this past May. You can read more in the [summer 2018](#) issue of *AAHRPP Advance*.)

The conference presentation focused on an unusual situation, when a central IRB made the decision—independent of the DSMB—to suspend enrollment of a specific group of patients in a multisite StrokeNet study. That certainly wasn't the case in the Ebola trial where, as is more typical, the suspension followed the DSMB recommendation.

Despite these differences, there are similarities between the StrokeNet and Ebola decisions. Both underscore how reliable, compelling data can change the course of a study. Both showcase the systems in place to put the safety and well-being of participants above all else.

A powerful reminder

For those of us at AAHRPP, both trial decisions also remind us of the complex issues research organizations can face and the need for a go-to resource to provide information and support. Increasingly, that resource is AAHRPP.

More and more accredited and not-yet-accredited organizations are relying on AAHRPP to help fill gaps in information and guidance, identify innovative approaches to new challenges, and connect accredited colleagues. And we embrace that role.



ELYSE I. SUMMERS, JD

The most visible example is our annual conference, which recently drew nearly 500 individuals from 200 organizations and nine countries. The event, "Big Ideas and Big Ethics in the Big Easy," featured more than 30 sessions on topics including harmonization, big data, informed consent, and genetic research. Not surprisingly, the new rule—and best practices for meeting its requirements—figured prominently.

For the first time, we also offered two simultaneous preconference programs. The AAHRPP overview was for those considering accreditation for the first time or coming up on their reaccreditation cycle. The Collaborative AAHRPP Network (CAN) provided an opportunity for accredited organizations to exchange ideas and tackle challenges together.

The response to both was extremely gratifying. The first demonstrated continued, significant interest in AAHRPP accreditation. The second showcased the long-term value of being part of the peer-driven, collaborative AAHRPP-accredited community.

To give you a taste of the event, we've included some conference photos in this issue of *AAHRPP Advance*. You can see even more in the [You Tube](#) or [PDF](#) versions of our conference slide show. We hope they give you a feeling for the energy and camaraderie that attendees enjoy. Even more, we hope they persuade you to join us next year. We'll be heading to Baltimore, Maryland ("Charm City"), May 19-21. Mark your calendars!

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

Save the Date

Hyatt Regency Baltimore, Maryland



2020 AAHRPP Annual Conference



SAVE THE DATE
May 19-21, 2020

More details to follow.

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