AAHRPP ADVANCE
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JULY 2016

Revamped IRB Model Improves Efficiency, Consistency

Three years ago, Washington University in St. Louis revamped its IRB structure—with impressive results. Review times have improved, committee members are more engaged, and researcher satisfaction has increased. **LEARN MORE**

Metrics Highlight Advances in Quality, Review Times

The latest metrics on HRPP performance indicate that IRBs at accredited organizations are conducting reviews more efficiently and that quality improvement efforts are paying off. The 2015 metrics are available **online** and will be discussed at **webinars** in July.
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A Resource, Convener, and Partner

AAHRPP President and CEO Elyse I. Summers, JD, shares highlights from the 2016 AAHRPP Conference and emphasizes the partnerships that will continue to be instrumental in strengthening research protections. See **conference photos**. **LEARN MORE**

Latest Accreditations

Of note: first organizations in Africa, South America

- **Adventist Health System-Sunbelt, Inc. DBA Florida Hospital,** Orlando, Florida
- **Affiliated Hospital of Nanjing University of Traditional Chinese Medicine,** Nanjing, Jiangsu, China
- **Case Western Reserve University,** Cleveland, Ohio
- **The First Affiliated Hospital of the Fourth Military Medical University**, Xi'an, Shaanxi, China
- **Geisinger Health System**, Danville, Pennsylvania
- **King Abdullah Medical City in Holy Capital**, Makkah Al-Mokarramah, Saudi Arabia
- **Palmetto Health**, Columbia, South Carolina
- **Sharp HealthCare,** San Diego, California
- **Sociedade Beneficente Israelita Brasileira Albert Einstein**, São Paulo, Brazil
- **TREAD Research**, Cape Town, South Africa
- **University of Illinois at Chicago College of Medicine at Peoria**, Peoria, Illinois
- **Valley Health System,** Ridgewood, New Jersey

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Upcoming Webinars

- **July 26 and 28:** HRPP Metrics: Discussion of AAHRPP Data and Trends from 2015
- **October 25 and 27:** Measuring the Quality and Process of Informed Consent

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Save the Date

AAHRPP Conference
May 9-11, 2017 in Detroit

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

IRB Review: A Model for Improving Efficiency, Consistency

At Washington University in St. Louis (AAHRPP accredited since 2004), the full IRB reviews roughly 600 new studies each year, provides continuing review for 1,000, and modifies another 800. In addition, about 1,100 new studies undergo expedited review. With such high volumes, quality, efficiency, and consistency are paramount.

Three years ago, the university revamped its IRB structure, transitioning from 10 separate IRB committees that met monthly to one IRB that holds meetings six times a week. Eight IRB chairs take turns leading one-hour sessions: two each on Tuesdays, Wednesdays, and Thursdays, As a result, review times have improved, committee members are more engaged, and researcher satisfaction has increased.

The number of IRB members has held steady at about 180. But under the new model, studies are reviewed by committees of four to seven members, instead of the previous 15 to 18. Agendas have been streamlined and typically include only seven or eight studies compared with 15 to 20 under the old system. And meeting times have been cut in half, to about an hour.

Equally important, every submission is held to the same standard: Does the study meet the regulatory approval criteria?

"Understanding and applying the regulatory criteria is an effective way of making sure the IRB is accomplishing what it's supposed to," says Jonathan Green, MD, Associate Dean for Human Studies, IRB Executive Chair, and professor of medicine, pathology, and immunology. Dr. Green also is a member of the Secretary's Advisory Committee on Human Research Protections within the U.S. Department of Health and Human Services.

For each study, the IRB members involved receive a review sheet that lists the "111" criteria. Next to each criterion, the reviewers mark yes or no to indicate whether the criterion is met.

"If contingencies are raised during the meeting, the reviewer expresses his or her concerns and cites the applicable criterion," Dr. Green says. "It's a way to help us stay focused and to prevent mission creep, which can be a problem both within and across institutions."

This approach ensures that every study review is complete and that every approval is based on quality and compliance. Improvements in consistency and efficiency have helped strengthen relationships with investigators.

Although the new system was designed to meet the needs of a large university, many of the features could help streamline IRB review at organizations of any size. Following are some examples:

- **Highly qualified, dedicated IRB chairs.** Washington University has a group of experienced IRB chairs, who review submissions to identify potential issues and address them with researchers before the study is presented to a committee. As a result, protocols tend to be more complete and are less likely to be tabled. Committee chairs communicate with each other frequently, one of many practices that help ensure consistency.

- **Self-scheduling.** IRB members use an online calendar to indicate which meetings they will attend. Chairs can use this information to better match protocols with the qualifications of the reviewers.

- **Shorter agendas and smaller committees.** Committees review seven or eight submissions per session, giving IRB members more time to devote to individual studies—both in preparation for and during their meetings. Because each meeting is now attended by only four to seven committee members rather than the previous 15 to 18, all participants tend to contribute more fully and effectively to the committee's deliberations; this is especially true of community members, who tend to feel less intimidated in the more intimate setting.

- **Extensive education.** New members receive comprehensive training on research involving human participants, the regulatory criteria, and Washington University's electronic systems. New members also participate in a mock IRB meeting and are assigned an "IRB buddy" who serves as a resource for the first few reviews. Each IRB meeting also includes 10 minutes of education for all members to help keep them up to date.

"The previous structure had become too cumbersome," Dr. Green says. "Now, we've improved efficiency, reduced inconsistencies, and are catching potential issues upfront, before they become a problem. We've increased capacity while decreasing the burden on committee members. They're happier, and so are our investigators."

2015 Metrics for HRPP Performance Now Available

Results highlight advances in quality, improved review times

The latest metrics on human research protection program (HRPP) performance indicate that IRBs at accredited organizations are conducting reviews more efficiently and that quality improvement efforts are paying off.

AAHRPP has posted the 2015 metrics **online** and will discuss them during upcoming webinars. **Registration** is required.

The metrics are designed to help organizations compare their performance with that of their AAHRPP-accredited peers—to identify and acknowledge areas of strength and target those in need of improvement.

AAHRPP has been collecting data from accredited organizations since 2009 and publishing annual metrics reports starting with data for 2010. Since then, AAHRPP-accredited organizations have trimmed an average of seven days off the convened IRB approval process and have seen decreases in for-cause audits of researchers and IRBs, from an average of 7.1 for-cause audits of researchers and 4.4 for-cause audits of IRBs in 2009 to three and two for-cause audits, respectively, in 2015.

Following are some highlights from the 2015 metrics report.

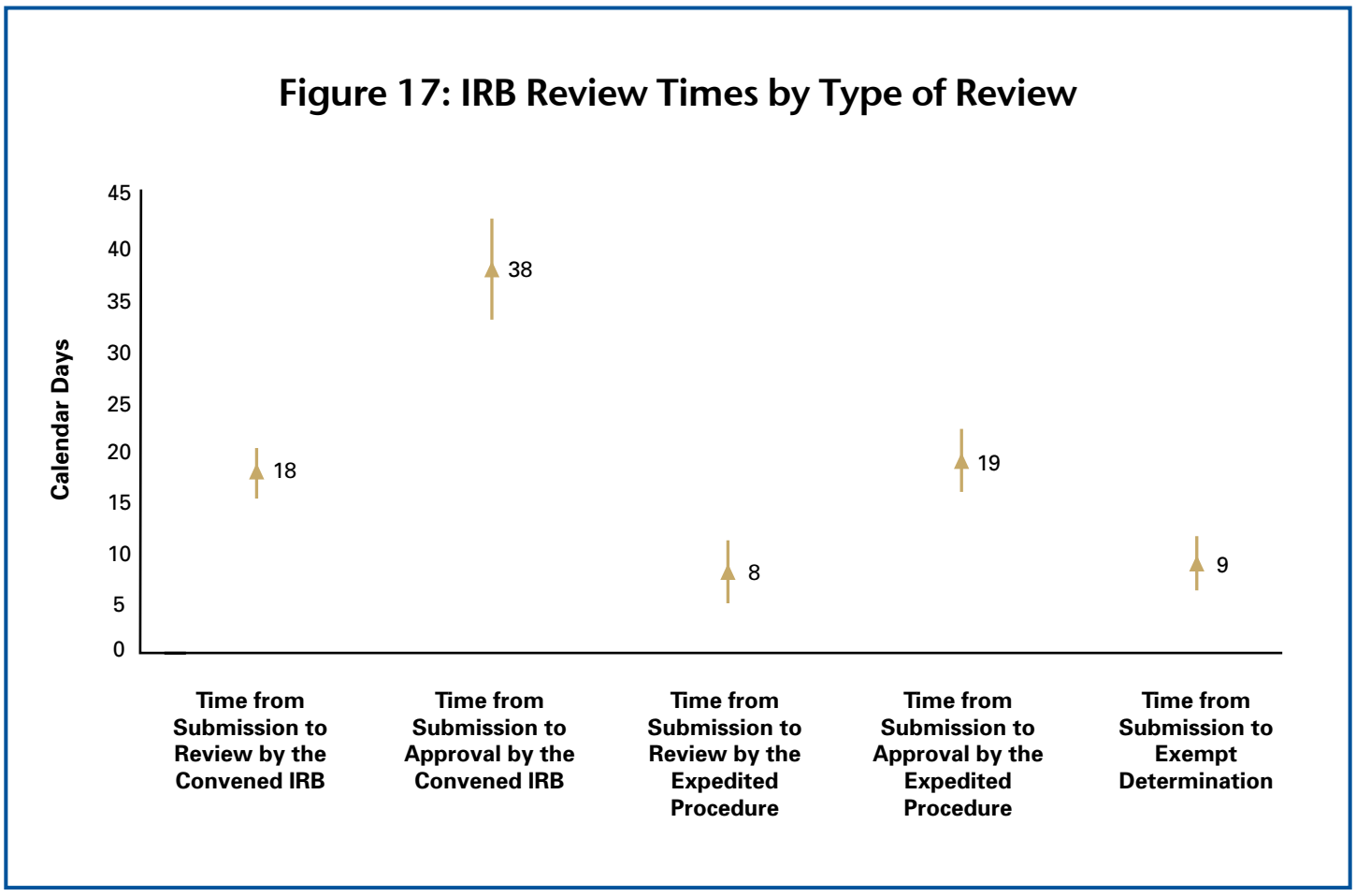

Figure 17: The time from submission to review by the convened IRB is a median of 18 calendar days, the time from submission to approval by the convened IRB is a median of 38 calendar days, the time from submission to review by the expedited procedure is a median of 8 calendar days, the time from submission to approval by the expedited procedure is a median of 19 calendar days, and the time from submission to exempt determination is a median of 9 calendar days.

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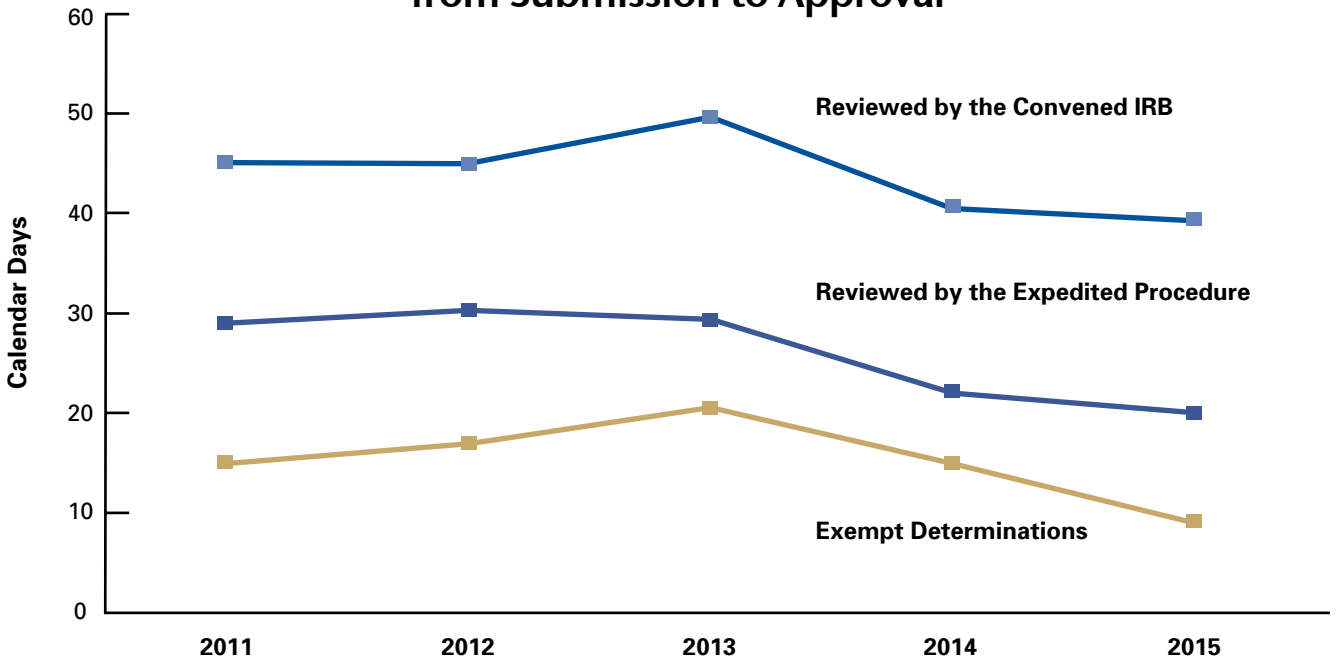
Although IRB review time is not considered a measure of quality, review times do correlate with investigator and sponsor satisfaction. The following graph shows a general trend of decreased review times across the board since 2011.

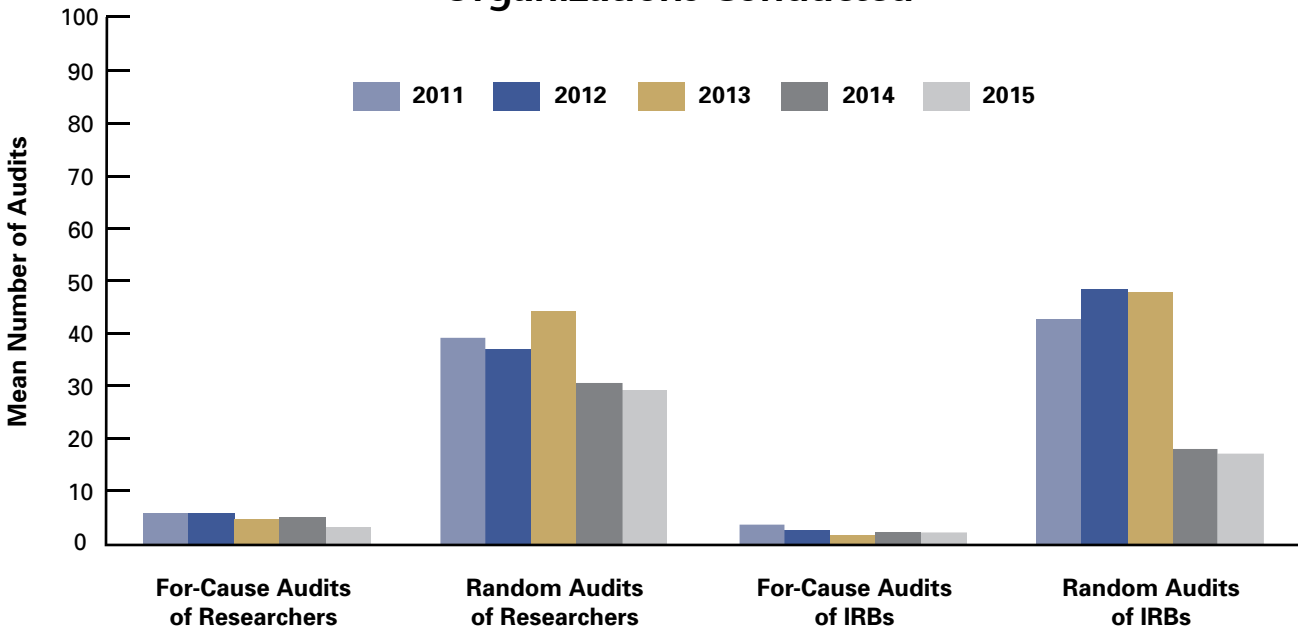
Figure 18: Five-Year Trends of Mean IRB Review Times from Submission to Approval



Audit Trends

Decreases in for-cause audits are widely regarded as evidence of quality improvement. Random audit data indicate robust programs to monitor researcher and IRB compliance.

Figure 21: Five-Year Trends in Mean Number of Audits Organizations Conducted



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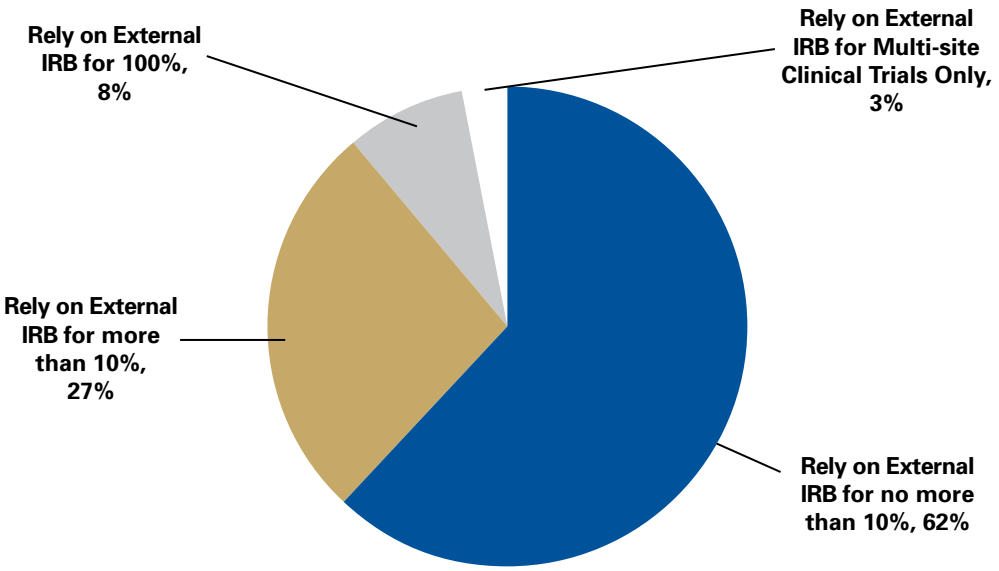
Use of External IRBs

More than one-third, or 35 percent, of AAHRPP-accredited organizations rely on external IRBs to review at least 10 percent of research studies. That's up from 21 percent in 2010. AAHRPP expects this trend to continue as the research enterprise moves toward single IRB review for multisite studies.

Figure 10. Use of External IRBs



Robert Hood, PhD, AAHRPP Director of Accreditation and Operations, and Sarah Kiskaddon, JD, MA, AAHRPP Vice President, Global Development and Public Affairs, will cover the metrics in greater detail during webinars on July 26 and 28. Webinar participants will also have a chance to weigh in on the type of data AAHRPP should collect.

Fred Hutch and Vanderbilt Reaccredited with Distinction

Two organizations—Fred Hutchinson Cancer Research Center (Fred Hutch; accredited since 2008) and Vanderbilt University (accredited since 2004)—are the first to earn Reaccreditation with Distinction, a designation introduced this year to acknowledge areas of excellence among organizations seeking reaccreditation. The distinction designation has long been available for newly accredited organizations.

Fred Hutch met Standard 1.4 with distinction through the organization's Outreach, Diversity, and Inclusion Program, which helps ensure that Seattle communities understand the mission of the cancer research center. The program has increased community involvement in research, built bridges between researchers and the community, and improved the diversity of the IRB.

Standard I.4 requires organizations to respond to the concerns of research participants, enhance understanding of human research, and promote community involvement in the design and implementation of research and the dissemination of results.

Vanderbilt met Standard II.2.H. with distinction by facilitating single IRB review of multisite studies and supporting Vanderbilt researchers who serve as the lead investigators for such studies. To simplify data reporting from multiple research sites, Vanderbilt has given researchers and research teams easy access to RedCap, an open-source statistical and database system. Vanderbilt also provides technical support to research teams. To help streamline the IRB review process, Vanderbilt hosts the online **IRBchoice** system, which offers a variety of options for single IRB review and allows organizations to customize reliance preferences on a study-by-study basis.

Standard II.2.H. covers the management of multisite research and the related responsibilities. Vanderbilt was recognized for developing innovative best practices to meet this standard.

From the President and CEO

ELYSE I. SUMMERS, J.D.

A resource, convener, and partner

Nearly 400 research professionals joined us in Long Beach, California, for the 2016 AAHRPP Conference. Those of you who attend the annual event know that it is a wonderful opportunity to get the latest perspectives on research protections from some of the best and the brightest in our field. Of course, the conference is also the go-to event for information on AAHRPP accreditation and reaccreditation.

This year, we heard from leaders in government, medicine, industry, and academia on topics including the changing landscape of research oversight, internet research, streamlining IRB review, and ethical issues in big data and genomic research. In keeping with our increasingly global influence, we held special sessions for our international clients. We also recognized our newly accredited organizations and celebrated our quinceañera, the 15th anniversary of AAHRPP's founding. We've included some conference photos on the next page.

The conference reflects AAHRPP's role in the research enterprise, as a global accrediting body, resource, and convener:

- **Global accrediting body:** In the years since our founding, AAHRPP accreditation has become the gold standard for high-quality research protections, and we have made significant progress toward our goal of achieving one standard worldwide for research protections. We recognize that there are many different ways to meet both AAHRPP and regulatory requirements, so we take a flexible approach. If organizations are committed to accreditation but are struggling, we work with them to help fill the necessary gaps. It's not enough to set the standards; we also want to help others meet them.

- **Resource and convener:** For the first time in decades, we expect some changes to U.S. regulations governing research involving humans. Like many of you, AAHRPP has submitted comments on the notice of proposed rulemaking (NPRM). We also stand ready to help interpret any changes that result. Equally important, we will continue to connect you with others throughout the research community to share information, suggestions, and solutions.

Most of all, we see ourselves as your partner. That's how it's been since the beginning, when seven organizations recognized the value of accreditation and joined forces to establish AAHRPP. In the years since, we've accomplished much together. And I look forward to more of the same in the months and years to come.

Finally, I ask you to save the dates of our 2017 conference, which will be held from May 9 to 11 in Detroit. Although we're still in the planning stages, it's reasonable to expect lively, informative discussions on any changes to the Common Rule. This is one conference you won't want to miss.

Elyse I. Summers, J.D.
AAHRPP President and CEO

Highlights from the 2016 AAHRPP Conference: Long Beach, CA

Enjoying lunch at the conference. From the University of Miami, from left: Jeanette Mestepey, MA; Kenia Viamonte, MA; and Dushyantha T. Jayaweera, MD (aka Dr. Jay).

From left: Elyse I. Summers, JD, AAHRPP President and CEO, with Judy Matuk, MS, of Stony Brook University, member of AAHRPP's Council on Accreditation.

Celebrating the 15th anniversary of AAHRPP's founding.

AAHRPP President and CEO Elyse I. Summers, JD, (left) presents a certificate of accreditation to Haihong Zhang, PhD, Office of Human Research Protection Program, Peking University.

See you in Detroit May 9-11 for our 2017 conference!