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Reaching Beyond Regulations

The Pursuit of Accreditation for Human Research Protection Programs

Human research protection programs (HRPPs) are constantly struggling to achieve and maintain a platform of credibility within their own institutions, across the nation, and most importantly with the human participants that volunteer in their research protocols. One of the ways to accomplish this is through the pursuit of accreditation. The pursuit itself is a complex and educational undertaking. Once it is achieved, the organization will have reached a level of excellence denoting a *di minimus* compliance with the federal regulations established by the Office for Human Research Protections (OHRP) within the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration (FDA). But achieving accreditation goes beyond baseline regulatory compliance to meet the higher bar set by the standards of a voluntary accreditation program. This article addresses the definition and history of accreditation, and suggests ways to successfully navigate the accreditation process while avoiding its common pitfalls.

What is Accreditation?

According to the Institute of Medicine (IOM), accreditation is a mark of excellence that goes beyond regulatory compliance and may provide accredited organizations a competitive advantage over nonaccredited organizations.[1] This advantage might come in the form of increased support from industry sponsors and other funding agencies, more favorable peer reviews, and recognition within the organization's community, including prospective research participants. The IOM also suggests that a voluntary accreditation program could reduce the burden of regulatory agencies, which would then be in a better position to focus on those organizations that are still striving to achieve regulatory compliance.[1]

The value of accreditation is already recognized by OHRP. In the registration process of an institutional review board (IRB), OHRP now asks whether the IRB or the organization is accredited. Ivor Pritchard, acting director of OHRP, said at an Association for the Accreditation of Human Research Protection Programs (AAHRPP) conference in February 2008 that for "QA not-for-cause" inspections, OHRP places AAHRPP-accredited organizations toward the bottom of the list.[2]

The pursuit of accreditation offers the organization an opportunity to educate itself about the current state of its HRPP, and the improvements necessary to achieve accreditation. This educational process occurs during the organization's self-assessment in preparation for applying for accredi-

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The History of Accreditation

Accreditation for HRPPs became a reality in April 2000, when the Department of Veterans Affairs (VA) awarded a five-year, $5.8 million contract to the National Committee for Quality Assurance (NCQA) to develop accreditation standards and evaluate all Veterans Affairs Medical Centers (VAMCs) across the nation involved in human participant research.[3] In the last quarter of 2001, AAHRPP opened its doors to offer accreditation to any organization that conducts or reviews human participant research.

In early 2002, AAHRPP began testing its accreditation standards, and it accredited its first organization, the University of Iowa, in April 2003. By that time, NCQA was experiencing problems with its program, as only nine of the 23 VAMCs evaluated had achieved accreditation.

In early 2003, NCQA partnered with the Joint Commission on Accreditation of Healthcare Organizations and formed the Partnership for Human Research Protections. However, this partnership lasted only until August 2005. By the end of that year, NCQA had accredited 51 VAMCs, and the VA contract was due to expire. Both NCQA

and AAHRPP submitted bids for the new contract.

In December 2005, AAHRPP was awarded the new five-year, $4.9 million contract. As of March 2008, AAHRPP had accredited 107 organizations with 445 total entities represented.[4] There are still 33 VAMCs accredited by NCQA that will be required to achieve AAHRPP accreditation by the end of the year, or their accreditation status will expire.

Since AAHRPP is now the only operational accreditation program for HRPPs, the remainder of this article will discuss the AAHRPP program. As a former accreditation director with AAHRPP, I have a unique vantage point from which to make observations about what it takes to successfully navigate the accreditation process.

What Does it Take to Achieve Accreditation?

AAHRPP accreditation is fundamentally achievable. It takes a commitment to quality, hard work, and dedication toward the goal of accreditation. Above all, the protection of human research participants should be paramount in an organization's research mission. This important mission must be supported by individuals at the highest levels of the organization, and requires an investment of staff and funds allocated to this effort. How much of either depends on the size and complexity of the organization.

The pursuit of accreditation should not be the task of one person. It will take the expertise of many groups and individuals within the organization if it is to be successful. All stakeholders in the HRPP will be involved in the accreditation process, including organizational officials, IRB management and staff, research investigators and study teams, and sponsored projects personnel. Various ancillary groups also will play an important role, such as pharmacy personnel, legal counsel, and ancillary review committees that focus on radiation safety, biosafety,

conflict of interest, and privacy. These components must demonstrate open communication and collaboration that result in an efficient and effective program that protects human research participants, which is critical to a successful outcome.

Once the organization has established itself as a client of AAHRPP, usually by prepaying the fee for accreditation, the organization may consult with AAHRPP staff during the self-assessment and throughout the accreditation process. The organization should take advantage of all the tools AAHRPP provides to its clients, such as the tip sheets, frequently asked questions, evaluation instrument, and other educational resources available on the AAHRPP website.[5] AAHRPP also offers annual conferences and frequent workshops designed to assist new clients in preparing for the application process. Once the self-assessment is completed and the final application is submitted, the AAHRPP staff member assigned to the organization will provide a comprehensive evaluation of the application, and make any necessary recommendations to improve it. If the organization heeds this advice, it will be well on its way to a successful accreditation determination.

The Value of the Self-Assessment

Many research professionals from accredited organizations have indicated that the self-assessment was the most beneficial part of the accreditation process. Through self-assessment the organization learns the most about its HRPP, especially the areas on which it needs to focus its attention and efforts to ensure regulatory compliance and work toward the higher standards necessary to achieve AAHRPP accreditation. During the self-assessment processes, policies and procedures will be reviewed and revised as necessary.

Some of the policies and procedures reviewed are in the areas of appropriate oversight of the HRPP and authority granted to the IRB, the research

review process, the regulatory criteria for approval, sponsored contract negotiation, training and education, investigator oversight, appropriate delegation to study team personnel, research compliance, and participant outreach. Gaps will be identified, which may require the creation of new policies and procedures. Research applications, forms, and checklists will be reviewed to ensure that all of the appropriate information regarding the regulatory criteria for approval are being collected and considered when research protocols are reviewed.

An organization must first focus on areas that are identified as noncompliant with federal regulations. In order for AAHRPP accreditation to be achieved, the organization must be in regulatory compliance with OHRP and FDA regulations. Once regulatory compliance is met, the organization should work toward meeting the higher bar of the AAHRPP standards and elements.

It is important to allow plenty of time for this task to be completed. The amount of time needed varies, due to factors such as complexity of the organization, the size of the team working on the effort, and the amount of work to be done once the problem areas have been identified. The amount of time needed could be anywhere from several months to more than a year.

Completing the self-assessment process adds value to the HRPP, immediately making it a stronger program, regardless of the final accreditation decision. This is likely the reason why research professionals have said it is the most beneficial part of the process.

What Stands in the Way of Achieving Accreditation?

There are a number of roadblocks to accreditation that organizations might encounter. Noncompliance with OHRP and FDA regulations is perhaps the most obvious. No favorable accreditation decision can be achieved unless all of the accreditation elements based on regulatory compliance with OHRP and FDA are met. A "qualified" accred-

itation can be achieved if a few administrative portions of elements remain to be met, but no regulatory elements can be left unmet.

Lack of institutional support from the top down will quickly sink an organization's efforts to achieve accreditation. At the highest levels of the organization, there must be a commitment to achieving a high-quality HRPP. Without this, it is unlikely that the appropriate staff and resources will be dedicated to the program. Programs that do not have qualified and experienced research professionals in key positions, and those that are unable to keep up with the demanding workload of an HRPP, rarely complete the accreditation process successfully. Additionally, some organizations are unwilling to embrace the higher bar necessary to achieve voluntary AAHRPP accreditation. This may occur when the philosophy of the organization is to maintain regulatory compliance without committing to standards that go above and beyond those required by the federal regulations.

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Another roadblock is not establishing a realistic working timeline and target completion date for the self-assessment, which enables organizations to spend too much time "preparing" to send in their application without actually getting it done. These

goals must be set in keeping with day-to-day responsibilities.

A lack of communication and an unwillingness to work together across the parts of the organization that make up the HRPP can also stand in the way of achieving accreditation. An organization cannot have contradictory policies and procedures for the protection of human research participants, or research personnel that will not work together in a professional and competent manner. This is a difficult problem to solve unless the organization is willing to make the necessary personnel changes to get the program back on track.

The Site Visit

Once the final application for accreditation has been submitted to AAHRPP, an organization can take a number of steps to make the forthcoming site visit a successful one. The organization should adhere, as much as possible, to the AAHRPP-proposed agenda. Although there is some flexibility, it is best to request only minimal changes to the roster of individuals targeted for interviews, as AAHRPP uses specific criteria when choosing interviewees. The organization should ensure that the individuals are prepared to appear for their interviews at the appointed time, and that the daily schedule is strictly kept. The site visitors will meet with many individuals and groups each day of the site visit; they cannot afford to let the interviews go beyond the time allotted to them.

The organization should notify AAHRPP immediately if any changes in the agenda become necessary. There should be no surprises once the site visitors arrive. If key personnel selected by AAHRPP are unavailable during the site visit, this could jeopardize the organization's accreditation.

The organization should provide adequate space for AAHRPP site visitors to perform their record review and interviews. The space required varies depending upon the size of the organization and the number of site visitors. All records requested for review by

AAHRPP should be pulled, arranged in an organized fashion in the room to be used for record review, and available for review by the site visitors at the start of the visit.

The organization should arrange transportation to and from the site for the site visitors each day, and provide options for lunch that allow the site visitors to continue their record review during the lunch period. Although these suggestions may seem trivial, they go a long way to help the site visit run smoothly.

Thirty days after the site visit, the organization will receive a draft site visit report, for which the organization has 30 days to submit a response. This deadline is absolute. Missing it means the application will go to the AAHRPP Council without the benefit of the applicant's response. The organization should work with AAHRPP staff during the response period to craft the best possible response.

The AAHRPP Council will review the draft site visit report in conjunction with the organization's response and make an accreditation decision. For new applicants, the council may declare:

- Full AAHRPP Accreditation,
- Qualified AAHRPP Accreditation,
- Accreditation Pending, or
- Accreditation Withheld.

Only Full and Qualified AAHRPP Accreditation decisions are posted on the AAHRPP website. Organizations in the Accreditation Pending mode continue to work with AAHRPP to make necessary improvements to their programs toward achieving full accreditation. The council makes an Accreditation Withheld determination only when an organization demonstrates that it is not willing to commit to undertaking corrective action or is otherwise unable to meet Full or Qualified status within a reasonable time.

Professional Recognition

The human research protection profession recognizes the achievements of IRB administrators and staff who hold

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certifications as certified IRB professionals (CIP) and certified IRB managers (CIM), as well as investigators and study team members who achieve certifications such as certified clinical research associate (CCRA), certified clinical research coordinator (CCRC), certified physician investigator (CPI), and certified clinical trial investigator (CCTI), all from the Association of Clinical Research Professionals, and the certified clinical research professional (CCRP) designation from the Society of Clinical Research Associates. The profession is now recognizing those organizations that achieve the voluntary accreditation of their HRPP, and the numbers of accredited organizations are growing.

Each quarter, the AAHRPP Council announces a new group of accredited organizations, whose names can be found on the AAHRPP website. These organizations display the seal of AAHRPP accreditation on their organizational websites. The majority of AAHRPP site visitors are employed by AAHRPP-accredited organizations, which further demonstrates the credibility and high standards of the association.

Conclusion

Voluntary accreditation for HRPPs is a standard of excellence that goes beyond requirements for compliance with federal regulations. The benefits of the process begin as early as the self-assessment that is undertaken to prepare an application for accreditation. Each time areas that need improvement are identified and corrective action is taken, value is being added to the HRPP. A successful accreditation outcome requires an organizational commitment to a high-quality research program with the appropriate resources and support. All components of the HRPP must work together to achieve this common goal.

AAHRPP helps its clients through this process by offering many educational resources and providing constructive feedback. Understanding and avoiding common roadblocks to accreditation are additional keys to success. An organization that makes a concerted effort to improve its program through the self-assessment, that works closely with AAHRPP staff throughout the application process and site visit, and that incorporates AAHRPP's recommendations into its program will soon find itself on the growing list of organizations that have achieved AAHRPP accreditation. **ACRP**

References

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