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

Ask... AAHRPP®

June 10, 2025

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What is “Ask AAHRPP”?

- Bimonthly (six times per year) forum with:
  - Practical approach to achieving and maintaining accreditation
  - Brief presentations on topics relevant to organizations applying for initial accreditation or reaccreditation
  - An emphasis on Q&A on topics presented as well as questions submitted when participants register
  - Organized around the steps in the accreditation process
- Open and free to everyone
- Recordings available

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Schedule for the Remainder of 2025

- Tuesday, August 12, 2025, 3:00 pm ET: Responding to the Draft Site Visit Report
- Tuesday, October 14, 2025, 3:00 pm ET: Understanding the Council on Accreditation Review
- Tuesday, December 9, 2025, 3:00pm ET: Responding to Council Review and Maintaining Accreditation

FYIs

- Please provide feedback by completing the survey –
  - Link included in follow-up email
- A link to the talk will be sent to those who registered for the talk when it is posted
  - Including links to prior “Ask AAHRPP” talks
- If you have any questions during the sessions, please use the Q&A function to submit them

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Evaluation of Practice: The Site Visit

Site visits may be on-site or remote

https://www.aahrpp.org/accreditation/get-accredited/part-4-evaluation-of-practice

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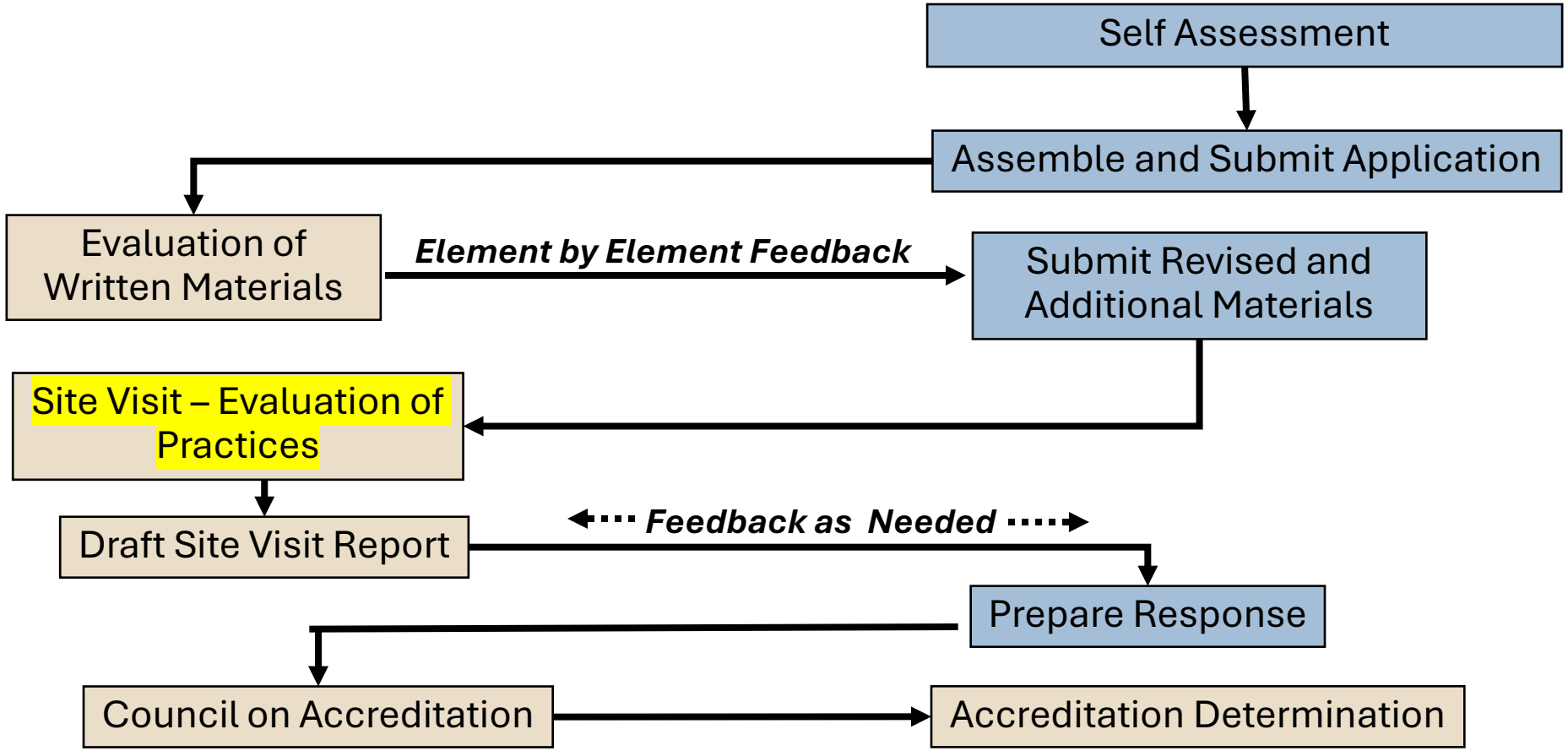
Accreditation Process



https://aahrpp.org/accreditation/get-accredited/overview

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AAHRPP Philosophy of Site Visits

- Site Visits are educational, peer-driven, collegial
- Site Visit are about evaluation, not auditing
  - The goal is to evaluate whether your organization follows policies and procedures that allow it to meet AAHRPP Standards
- AAHRPP Site Visits are flexible and outcomes-based
  - Site visitors are flexible and open to new and innovative ways of meeting the Standards

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Overview of the Site Visit

- After you submit a complete Step 2 application, AAHRPP offers several potential dates (site visits are generally two to four days)
- AAHRPP sends a list of persons who will be interviewed, along with a proposed schedule of interview times (“Draft Site Visit Agenda”)
- AAHRPP sends a list of the records and documents for review by Site Visitors (“Docs to Pull”)
- A team of individuals (generally two to four people) from accredited organizations will evaluate how HRPP policies and procedures are operationalized at your organization through:
  - interviews with key personnel
  - document review
- The Site Visit team will review their observations on the last day of the site visit
- AAHRPP will provide a Draft Site Visit Report in approximately 30 calendar days
- **https://aahrpp.org/accreditation/get-accredited/part-4-evaluation-of-practice**

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Who is interviewed? How does AAHRPP decide who will be interviewed?

- Site visitors interview key persons in your HRPP based on the information you provide:
  - Section H Template For Key Personnel, Including Research Teams asks organizations to provide information about:
    - Domain I: leadership and organizational official, persons involved in contracts, conflicts of interest, compliance, education, quality improvement, and reliance agreements;
    - Domain II: IRB/EC chairs and members and staff
    - Domain III: Researchers and research staff
  - Section H describes the roles and links to the relevant Standards and Elements

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Section H Template For Key Personnel, Including Research Teams

Knowledge Area/Responsibility	Key Personnel		
Section I			
1. Who is the person with **overall responsibility for the HRPP**? (Element I.1.B.) NOTE: This individual may be the person listed as the "institutional official" when registering with regulatory agencies	Please identify the person who has overall responsibility for the HRPP and no more than one additional person if the person responsible for overall HRPP responsibility has delegated significant HRPP oversight responsibility to them.	Person with overall responsibility for the HRPP:	First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.
		Person to whom a significant HRPP oversight responsibility has been delegated:	First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.

https://www.aahrpp.org/resources/for-accreditation/additional-resource/application-for-accreditation-or-reaccreditation-section-h-template-for-key-personnel

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What is the Site Visit Agenda?

- A list of members of your Organization who will be interviewed, along with a proposed schedule of interview times
  - You will work with AAHRPP staff to revise the agenda as needed
  - You may suggest other people to interview if the people listed in Section H are in different roles, or if you think we should interview someone else to understand your HRPP better
- Your Agenda will reflect your staff composition, and number of IRBs/ECs (if you have IRBs/ECs), and the size of your research program.

Example:
Part of an agenda

AAHRPP Site Visit			
Day 1			
Start	**End**	**Min**	
8:00 AM	8:15 AM	15	**Introductions**
8:15 AM	8:35 AM	20	**Human Research Protection Program Overview**
8:35 AM	8:55 AM	20	**Discussion of program improvements and successes**
8:55 AM	9:10 AM	15	**Organizational Questions**
9:10 AM	9:55 AM	45	**Ancillary Reviews** **Element I.1.F.> Person who oversees scientific/scholarly review [5]:** **Element I.1.F.> Person who oversees the scientific or safety review of research involving radiation [6]:** **Element I.1.F.> Person who is part of the ancillary review process related to IRB review [7]:** **Element I.7.A.> Person who provides regulatory support and/or oversees the compliance program for unlicensed test articles [18]:** **Element I.7.B.> Person who oversees the research pharmacy program or provides pharmacy support for the management and storage of investigational drugs used in human participants research [19]:** **Element I.7.B.> Person who oversees the centralized program or provides support for the management and storage of investigational devices used in human participants research [20]:**
9:55 AM	10:05 AM	10	**Executive Session**
10:05 AM	10:35 AM	30	**Key Organizational Functions Related to the HRPP** **Element I.1.G.> Person who provides legal advice [8]:** **Element I.6.A.> Person involved with the management of organizational conflicts of interest [16]:** **Standard I-8> Person who oversees industry contracts/funding agreements [21]:**
10:35 AM	10:45 AM	10	**Executive Session**
10:45 AM	11:45 AM	60	**Element II.1.A.> IRB Members (Scientific) [28]:** **1)** **2)** **3)** **Alternates:** **1)** **2)**

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Who are the Site Visitors?

- Experienced people from AAHRPP-accredited organizations with direct experience of the accreditation process
- https://www.aahrpp.org/about/meet-our-team/meet-our-team---site-visitors

What kinds of questions do site visitors ask?

- Questions are based on *Evaluation Instrument* and are designed to understand the knowledge and practice of different people in the HRPP, for example:
  - IRB members – asked about the process they go through to ensure the ethical criteria for approval are met (Standard II-3, but also Elements I.5.D., II.2.G., II.2.H., and other Elements)
  - Reliance staff – asked about the process the organization uses when researchers seek to rely upon external IRBs/ECs or want the organization to review for other organizations (Element I-9)
  - Researchers (Domain III, but also Element I.6.B. and other Elements)

Domain I: Examples of some questions – Emergency Preparedness

- Does your organization have an emergency preparedness and response plan?
  - What was the process of developing the plan?
  - Who was involved in developing the plan? What kinds of things did they consider?
  - How might IRB/EC or other HRPP functions change during an emergency?
- How was the plan communicated to persons in the HRPP?
  - How did you communicate the plan?
  - Did you communicate how the plan impacts different roles?
- Who is involved in evaluating the plan?
  - What things are considered (what criteria are used) to assess the emergency response plan?
  - What did you learn from the evaluation?
  - Did you make any changes as a result?
  - How often is the plan evaluated?

Domain II Examples of some questions: IRB/EC members

- What materials do you review to prepare for meetings?
- What kinds of things do you consider when deciding whether to approve research?
  - What are some things you consider when deciding that risks are minimized and risks are reasonable?
  - How do you decide that participant selection is equitable?
- What kinds of modifications or changes have to return to the convened IRB?
- Can you think of a time when IRB members disagreed on whether to approve a study? How did you resolve that?
- What process do you go through to evaluate unanticipated problems and noncompliance?

Domain III: Examples of some questions: Researchers

- What kind of research do you conduct?
- Do you have study staff? What is your role and what is their role?
- Are you the main person who obtains consent? How do you educate others involved in the consent process and ensure they are knowledgeable?
- What are some kinds of things you consider in terms of safety monitoring?
- Are you required to report things to the IRB office?
- Who would you ask if you had a question about IRB review?

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What documents are reviewed?

- Your Organization's most recent periodic evaluation of resources allocated to the HRPP and key functions of the HRPP (Standard I-2), and participant outreach plan (Element I.4.B.)
- Copies of the most recent review of the effectiveness of the HRPP compliance program (Element I.5.A.) and quality, efficiency, and effectiveness of the HRPP (Element I.5.B.)
- Organizational conflict of interest management plans (Element I.6.A.)
- Copies of the last notification letters sent to a US federal agency (e.g., OHRP, FDA, or other agency) or other governmental agency reporting:
  - serious or continuing noncompliance (Element I.5.D.)
  - unanticipated problems involving risks to participants or others (Element II.2.G.)
  - suspension and termination of IRB or ethics committee approval (Element II.2.H.)

What documents are reviewed? Cont.

- IRB or ethics committee meeting minutes (Element II.5.B.)
- IRB or ethics committee roster(s) (Element II.1.A.)
- Curriculum vitae or resume for IRB or ethics committee members (Element II.1.A.)
- Performance evaluation of IRB or ethics committee members and chairs; and (Element II.1.B.)
- Study files (Element II.5.A.)
- **See AAHRPP's Frequently Asked Questions: https://www.aahrpp.org/resources/for-accreditation/faq/documents-to-pull#documents-to-pull-faqs**

Discussion of Program Improvements and Successes

- Organizations have an opportunity to review program improvements and successes since the last accreditation review.
  - What are you doing well?
  - What have you improved over time?
  - Are there any program improvements that you are currently working on?
- You do not have to provide examples.
  - If you do not provide examples in this session or elsewhere during the site visit, site visitors may not be able to describe areas of strength or potential distinctions.
  - If you provide examples, Council may still determine they do not rise to the level of program strengths.

Link to FAQs

- FAQ: Documents to Pull
- FAQ: Considering Accreditation and Getting Started

https://aahrpp.org/resources/resource-library/faqs

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Upcoming Webinars

Ask... AAHRPP®

Save these dates for the remaining 2025 "Ask AAHRPP" webinars:

- August 12, 2025
- October 14, 2025
- December 9, 2025

Save the following date for the next "HRPP Innovations" webinar:

July 29, 2025 –

Innovative Practices by AAHRPP-Accredited Organizations: Researcher Education Programs

Visit [Webinars (aahrpp.org)] for more information and registration links


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2026 AAHRPP
ANNUAL CONFERENCE:
GREAT LAKES,
GREAT MINDS
MELD IN MICHIGAN
SAVE THE DATE!
MAY 19-21, 2026
DETROIT MARRIOTT
AT THE RENAISSANCE CENTER
400 RENAISSANCE DR W
DETROIT, MICHIGAN
MARK YOUR CALENDARS FOR ONE OF THE RESEARCH
COMMUNITY'S MUST-ATTEND ANNUAL EVENTS.
MORE DETAILS TO FOLLOW.

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Thank You!

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Contact AAHRPP

Robert Hood, Ph.D.
Director of Accreditation and Global Development
rhood@aahrpp.org

Questions about site visits:

Jemelle Williams, BS, PMP
Assistant Director of Operations
jwilliams@aahrpp.org