AAHRPP®

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

Ask... AAHRPP®

August 12, 2025

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

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

FYIs

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

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Responding to Draft Site Visit Report

Instructions for Responding to the Draft Site Visit Report

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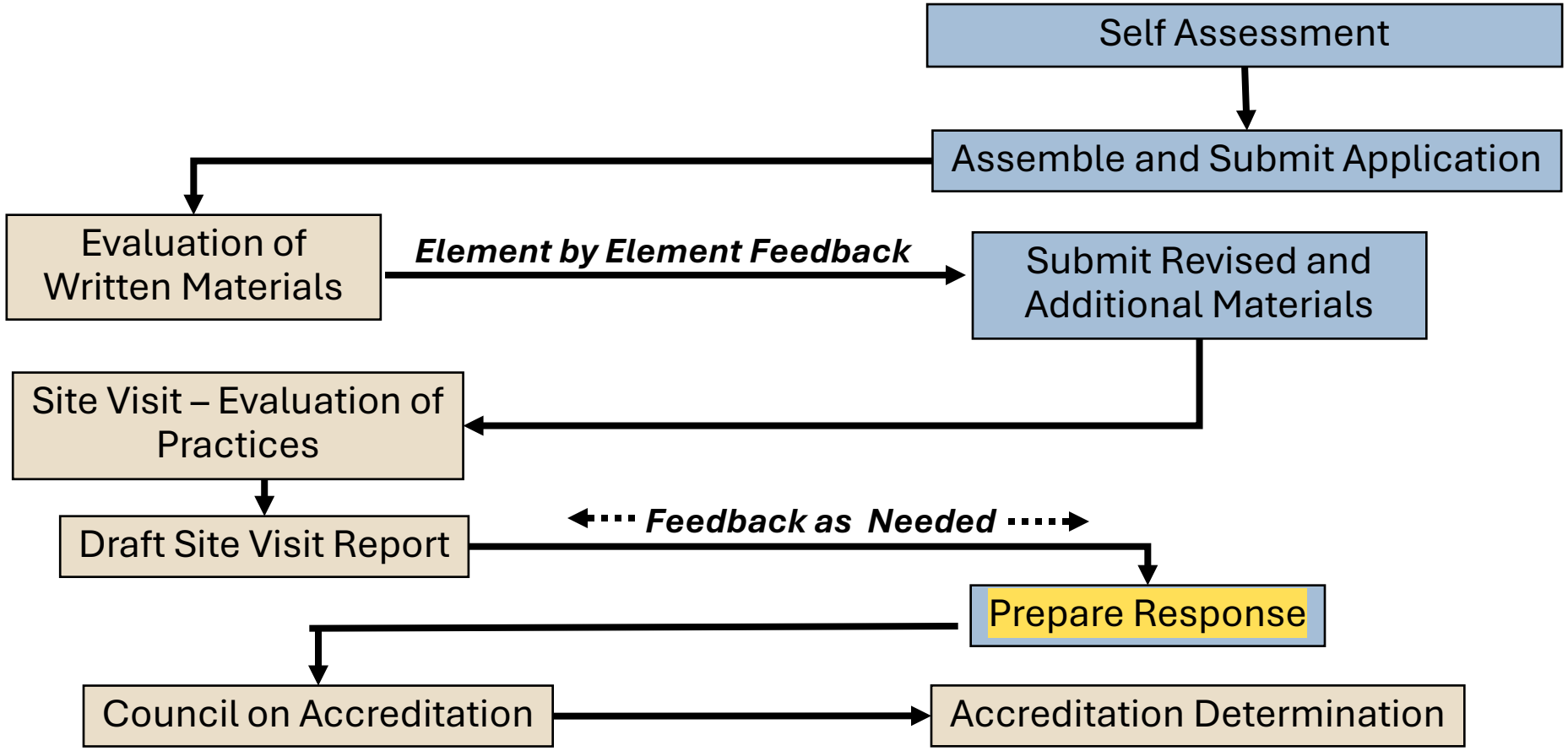
Accreditation Process



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

Responding to the Draft Site Visit Report

- Program improvements should be completed before Response to Draft Site Visit Report is due:
  - **Education** – confirms educational activities are complete so that people understand their responsibilities
  - **Monitoring** – confirms program improvements are already implemented and meet the Standard
  - **Revisions to written materials**, if any: Approved and implemented, education on revised written materials completed, monitoring confirms adherence to organization's revised written materials. Generally not necessary, because AAHRPP found materials meet AAHRPP Standards during the Step 1 review

Form with detailed instructions

Response to the Draft Site Visit Report
I. Organization Information
Legal name of Organization applying for accreditation (please consult with your general counsel): Click or tap here to enter text.
Organization name that should appear on AAHRPP's website, if different from above: Click or tap here to enter text.

Education: In general, Organizations should provide all the information in items 1-6 below for each Standard or Element for which an Area of Concern was identified	
1. What was the topic of education or training and how does the education or training address the Area of Concern identified? 2. Specify the role of the person(s) who conducted the education or training (e.g., IRB manager, QA manager etc.). 3. Provide a specific date(s) when the education or training occurred. Education or training in general should start prior to sending the Response to the Draft Site Visit Report. 4. Specify who was educated or trained (e.g., IRB members, contracts staff)? 5. Identify any additional education or training planned, if applicable. 6. Attach supporting documentation (e.g., list of persons educated or trained, dates when education occurred, agenda for education or training sessions).	<u>Example:</u> *To address the concern that substantive changes were not being returned to the convened IRB or EC, the HRPP manager conducted education for staff who write minutes on September 5, 2022. The HRPP manager started to conduct education on September 15, 2022 for the chair and EC members on substantive versus minor changes, and the requirement that substantive changes be returned for review by the convened EC. Additional education for the chair and EC members is planned for EC meetings in October and November. Education will also occur at an annual retreat scheduled for February 2023.* <u>Examples of supporting documentation:</u> Document 1: List of EC members who have completed education (page xx) Document 2: Confirmation of education of chairs and staff (page xx) Document 3: Agenda for education sessions (page xx)

Monitoring to confirm the organization meets the Standard	
1. What evaluation or monitoring are you conducting to show this? When there are multiple concerns under a Standard or Element, describe what was evaluated to confirm each meets the Standard. 2. Who conducted monitoring to confirm the Standard is now being met in practice and, when applicable, confirming the organization is complying with applicable regulations? 3. When did monitoring start to confirm the program meets the AAHRPP Standard? Confirm your organization meets the Standard prior to sending the Response to the Draft Site Visit Report, when possible; otherwise provide a specific timeline of how you will confirm the Standard is met. 4. What additional monitoring is planned, if applicable? 5. Who reviewed results of the monitoring and assessed whether the education, training, or other actions taken were effective? 6. What changes were made, if any, as a result of the monitoring? 7. Who will review the results of future monitoring to evaluate whether additional changes, if any, are required?	Example: *To confirm that when the IRB requests substantive changes they are returned to the convened IRB for approval, the IRB manager conducted retrospective monitoring of IRB minutes for the prior six months to establish a baseline and started to evaluate IRB minutes prospectively beginning with the September 15, 2022 meeting, which was the only meeting that occurred prior to when the Response was due. The IRB manager planned to continue monitoring each set of minutes for six months. The IRB manager and IRB chair met on September 30, 2022 to review the monitoring that had occurred so far, and determined that no changes to policies or written materials were required, but that additional education to ensure substantive changes are returned to the convened IRB for approval for staff writing IRB minutes was required.* *The IRB manager and IRB chair planned to meet monthly to review ongoing monitoring. The IRB manager and IRB chair planned to meet in six months and determine, based on planned monitoring, if any changes are required.* <u>Examples of supporting documentation:</u> Document 1: Spreadsheet summarizing retrospective monitoring (page xx) Document 2: Copies of relevant portions of minutes demonstrating minutes meet AAHRPP requirements, with relevant portions highlighted (page xx) Document 3: Summary of meeting to review results, listing who attended (page xx)

Changes to policies, and procedures, processes, if applicable:	
AAHRPP approved the organization's policies and procedures during the Step 1 review and response. Consequently, changes to policies and procedures are generally not required.	
1. What was the change in policies and procedures, or the change to an IRB or HRPP process, if any? If there are revisions to policies and procedures, highlight the revisions. If there are revisions to electronic systems, highlight changes to forms, or provide descriptions of what specifically was changed. If there are revisions to IRB or HRPP processes, describe the process in place at the time of the site visit, and provide detailed comparisons of changes made to the process. 2. Describe how the change addresses the area of concern. 3. Specify the role of the person(s) who is responsible for implementing the change. 4. Provide a specific date(s) when the changes will be implemented. Changes should generally be implemented prior to sending the Response to the Draft Site Visit Report. 5. Attach supporting documentation (e.g., copies of revised policies with changes highlighted, copies of revised application forms with changes highlighted, descriptions of revised IRB/EC or HRPP processes with comparisons between the process prior to the site visit and the revised process. For changes not yet implemented provide highlighted documents showing planned changes. For changes not yet implemented, provide documentation of how the organization will address the area of concern while the planned changes are being implemented.	Example: *To address the concern that protocol-specific determinations were not documented when reviewing research involving vulnerable populations, online reviewer forms were changed so that the text box for reviewers to provide protocol-specific reasons was mandatory, not optional. The system was revised to require IRB members to complete this information prior to submitting the form. Previously forms could be submitted without these fields being completed. Instructions were added to the form to remind reviewers that these fields must be completed before the reviewer form can be submitted. An error message was created if reviewers submitted forms without required information.* <u>Examples of supporting documentation:</u> Document 1: Revised forms showing instructions that the fields must be completed prior to submitting the form. (page xx) Document 2: Screen shot of a pop-up error message showing the system requires reviewers to complete the fields prior to submitting the review form. (page xx) Example: *To address the concern that researchers were not informed that IRB approval expired, a database query was changed to correctly identify the date of IRB approval and pull the list of expired studies on the correct date and send notifications to researchers on the correct date.* <u>Examples of supporting documentation:</u> Document 1: Example of a report showing how the revised electronic system will report out expired studies on the date IRB approval expires. (page xx) Document 2: Example of a notification sent to a researcher (redacted) showing the notification is sent on the correct date of study expiration. (page xx)

If the Draft Site Visit Report identifies potential regulatory noncompliance, noncompliance should be reported to government agencies per regulatory requirements. Organizations must follow AAHRPP requirements for reporting to AAHRPP as described in the Accreditation Procedures available on the AAHRPP website at www.aahrpp.org.

Program improvements should be completed prior to when Response is submitted…

- In general, program improvements should be complete before Response to Draft Site Visit Report is due:
  - Education – complete
  - Monitoring – demonstrates program improvements are already implemented program improvements and meet the Standard
  - Revisions to written materials, if any: Approved and implemented, education completed, monitoring confirms adherence to organization's revised written materials

Responding to the Draft Site Visit Report

DOMAIN I: ORGANIZATION
Standard I-1: The organization has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants. Individuals within the organization are knowledgeable bout and follow the policies and procedures of the Human Research Protection Program.
Element I.1.A. The Organization has and follows written policies and procedures for determining when activities are overseen by the Human Research Protection Program.
Area of Concern (paste here):
Changes to policies and procedures, or processes, if applicable:
Education and training:
Confirmation of change in practice (monitoring)

Example

- Area of Concern: Evaluations not conducted (examples: Standard I-2, and Elements 1.4.B., II.1.B.)
- Sample response to Draft Site Visit Report
  - Prior to sending Response to DSVR the organization:
    - Completed evaluations
    - Reviewed written materials, and determined no changes needed
    - Completed education, and provided list of people educated provided
    - Reviewed the results of the evaluations and decided no changes needed, and provided a summary with the Response to DSVR
    - Scheduled evaluations for next year

Example

- Area of Concern is about a type of research the organization sees infrequently (prisoner research, drug research at a majority-social science organization)
  - For example: "IRB members, chairs, and staff were not knowledgeable about requirements for review of research involving prisoners"
- Sample response to Draft Site Visit Report
  - Prior to sending Response to DSVR the organization:
    - Reviewed policies, reporting forms, and reviewer forms, and made minor changes
    - Completed education of IRB members, chairs, staff, and provided a list of people educated
    - Checked and found no new studies involving prisoners since the site visit, no open studies of research involving prisoners
    - Planned to have IRB members review a mock prisoner study scheduled within 60 days, but the mock prisoner review had not started
    - Planned prospective monitoring for six months provided; currently no studies involving prisoners were active and no new studies had been submitted

Example

- Area of Concern (Element I.1.H.): Although policies described the creation and evaluation of an Emergency Preparedness Plan, site visitors observed a plan had not been created or evaluated.
- Response indicated:
  - Working group created to develop plan, but had not met and no schedule was provided
  - Education planned, but not started. Who would be trained not specified, no schedule provided.
  - Monitoring (evaluation) had not occurred and no schedule was provided

Best practices

- Start as soon as you receive the Draft Site Visit Report
- Study the instructions and examples in the Response to the Draft Site Visit Report form
- Divide up the work
- Complete program improvements prior to sending your response, to the extent possible
- Contact consultants for assistance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2026 AAHRPP
ANNUAL CONFERENCE:
GREAT LAKES,
GREAT MINDS
MEET IN MICHIGAN
SAVE THE DATE!
MAY 19-21, 2026
DETROIT MARRIOTT
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DETROIT, MICHIGAN
Visit the Annual Conference Page for more information
MARK YOUR CALENDARS FOR ONE OF THE RESEARCH
COMMUNITY'S MUST-ATTEND ANNUAL EVENTS.
MORE DETAILS TO FOLLOW.

AAHRPP
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