



December 12, 2023



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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



2023 Schedule

- January 10, 2023: Conduct a Self-Assessment (using the Evaluation Instrument for Accreditation)
- March 14, 2023: Build and Develop an Application
- June 13, 2023: Evaluation of Written Materials
- August 8, 2023: Evaluation of Practice (“Site Visit”)
- October 10, 2023: Council on Accreditation Review
- December 12, 2023: Respond to Council Review and Maintain Accreditation



FYIs

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

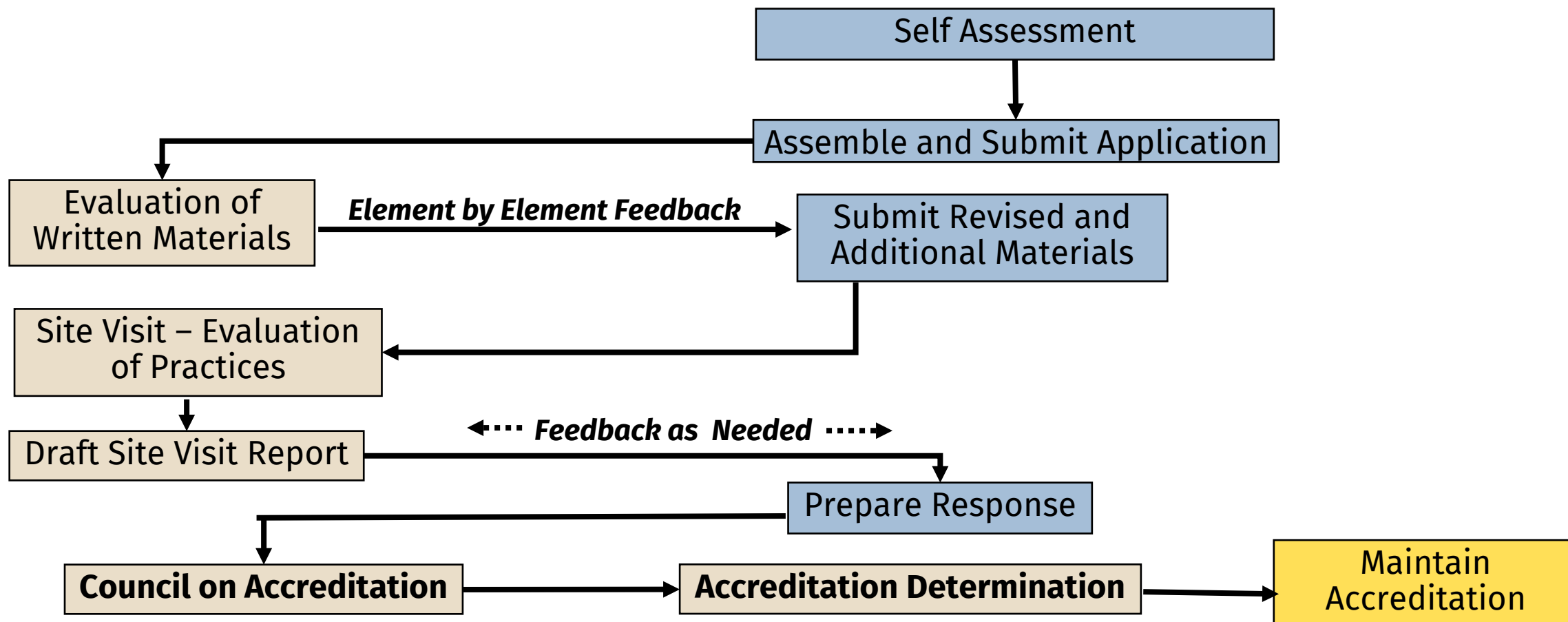


Maintaining Accreditation

<https://aahrpp.org/accreditation/maintain-accreditation/applying-for-reaccreditation>



Accreditation Process



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

Learning Outcomes: Maintaining Accreditation

- How to Respond to Council on Accreditation Requests
- Understand the Difference between AAHRPP's Three Notification Requirements:
 - Annual Reports – submitted annually
 - Notification of substantive program changes – submitted within 30 days
 - Notification of other reportable events - as soon as possible but within 48 hours
- Complete the Annual Report Using the Annual Report Form
 - Failure to submit an Annual Report within 30 days of the due date may result in revocation of accreditation.
- Use the AAHRPP Reporting Form to Notify AAHRPP of:
 - substantive program changes within 30 days
 - other reportable events as soon as possible but within 48 hours

Responding to Council Requests

- Council May Request Confirmation that Program Improvements Continue to be Implemented with:
 - Status Reports
- Use the Instructions for Submitting a Status Report
 - <https://www.aahrpp.org/resources/for-accreditation/additional-resource/instructions-for-preparing-a-status-report>
- Instructions Describe How to Submit a Complete and Accurate Status Report

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 Response to Requests from the Council on Accreditation.
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).

Example:

To address the request for a status report to confirm planned education had been completed, documentation that education was provided for staff who write minutes, and the IRB chair and IRB members, on substantive versus minor changes. Four sets of minutes (all IRB meetings since the Council request) were monitored, and confirm education was effective, and that substantive changes are now returned to the convened IRB.

Examples of supporting documentation:

Document 1: List of EC members who completed education (page xx)

Document 2: Confirmation of education of chairs and staff (page xx)

Document 3: Agenda for education sessions (page xx)

Document 4: Copies of relevant sections minutes showing requests for major and minor changes, and that major changes (substantive changes) are being returned to the convened IRB for approval.

Purpose of Annual and Other Notification Reporting

- **Notifying AAHRPP of Changes** Related to or that Might Affect the Organization's Human Research Protection Program
 - AAHRPP staff will review information regarding the Human Research Protection Program determine whether any action is indicated.
 - In some circumstances, the Council on Accreditation will be advised of the situation and requested to determine whether further action is needed, such as further reporting or a Limited Site Visit.
- **Questions Asked are Used as the Basis for Metrics**
- Learn About All AAHRPP Reporting Requirements in the Accreditation Procedures:

<https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting>

When Are Annual Reports Due?

- Due annually based on when your organization was awarded accreditation
 - Accreditation in December 2023 – Annual Report due in December 2024
- You do not have to submit an Annual Report the year your reaccreditation/accreditation application is due and the year that your reaccreditation/accreditation package is reviewed at Council.
 - If your Step 1 Application is due December 2023, then you will not need to submit an Annual Report in December 2023 or December 2024.

How Do I Submit My Annual Report?

- AAHRPP will send a reminder approximately 60 days before your Annual Report is due.
- Annual Reports are submitted via a SurveyMonkey link
 - Check spam and junk folder

Guidance

- [Summary of Changes to the 2023 Annual Report](#)

This document identifies the changes made to the 2023 Annual Report Form and the guidance below.

- [Guidance on Completing the 2023 Annual Report](#)

This document provides question-by-question guidance for the current Annual Report.

- [Annotated 2023 Annual Report](#)

This document contains a list of all the questions that you *might* be required to answer in the 2023 Annual Report. The online form's logic will skip some questions depending upon your previous answers. This document notes some main sections that only apply to certain organizations.

Annual Reports – Notify AAHRPP of Any:

1. Organizational Changes, Including but Not Limited To:
 - Change in entity type or corporate structure
 - Change in name of the Organization
 - Change in ownership or control of the Organization
 - Any mergers or acquisitions
 - Change in leadership or governance of the Organization (e.g., President or Chief Executive Officer)
 - Change in the organizational official
 - Change in the leadership of the Human Research Protection Program (i.e. the individual responsible for the day-to-day operation)
 - Change in the application contact

<https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting>

Annual Reports – Notify AAHRPP of Any:

2. Changes in Resources:

- Significant change (10% or more) in the balance of resources and active research protocols
- Significant reduction (10% or more) in resources in the past 12 months and the consequences on the Human Research Protection Program, such as reduction in FTE or dissolution of an IRB/EC, committee or other function

<https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting>

Annual Reports – Notify AAHRPP of Any:

3. Changes in Program Scope:

- Addition of new research program, including but not limited to a type of research not previously conducted or reviewed by the Organization such as planned emergency research, research involving children, or gene transfer research)
- Addition, removal, or modification of functions, committees, or IRBs/ECs. Significant change (10% or more) in the balance of resources and active research protocols

<https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting>

Annual Reports – Notify AAHRPP of Any:

4. Other Changes:

- Changes in method of providing services, such as use of external IRBs or contracting for services from another organization
- Catastrophic event that results in an interruption or discontinuance in a part of or the entire Human Research Protection Program

<https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting>

Importance of Annual Reports

Failure to submit an Annual Report within 30 days of the due date may result in revocation of accreditation.

<https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting>



Reporting Substantive Changes Within 30 days

When an accredited Organization or its Human Research Protection Program has a substantive change, including but not limited to:

- a change in corporate structure
- a change of ownership or leadership
- or a change of name

<https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting>

Other Notifications

An Organization must report the following to AAHRPP as soon as possible - within 48 hours





Events That Must be Reported As Soon As Possible but Within 48 Hours:

- Any **negative actions by a government oversight office**, including, but not limited to OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections
- Any **litigation, arbitration, or settlements** initiated related to human research protections
- Any **press coverage** (including but not limited to radio, TV, newspaper, online publications) **of a negative nature** regarding the Organization's Human Research Protection Program

Unsure Whether to Report?

If it is unclear whether a particular item is reportable, please contact AAHRPP

reporting@aahrpp.org

Summary

Negative Government Actions

48 Hours

- OHRP Determination Letters
- FDA Warning Letters
- FDA 483 Official Action Indicated
- FDA Restrictions on IRBs or Investigators,
- Compliance actions taken under non-US authorities

Legal Issues Related to HRPP

48 Hours

- Litigation
- Arbitration
- Settlements

Negative Press Coverage Related to HRPP

48 Hours

- Radio
- TV
- Newspaper
- Online Publications

Substantive Change to Organization

30 days

- Name Change
- Change in Corporate Structure
- Change of Ownership or Leadership.

How to Notify AAHRPP of Substantive Changes and Other Events

- Complete the Reportable Events Form:
 - <https://www.aahrpp.org/resources/for-accreditation/additional-resource/reportable-events-form>
- Contact reporting@aahrpp.org with questions

Reportable Events			
Organization Information			
Name of Organization: <small>Click or tap here to enter text.</small>			
Organization address line 1 <small>Click or tap here to enter text.</small>			
Organization address line 2 <small>Click or tap here to enter text.</small>			
Organization address line 3 <small>Click or tap here to enter text.</small>			
City: <small>Click or tap here to enter text.</small>	State: <small>Click or tap here to enter text.</small>	Country: <small>Click or tap here to enter text.</small>	Zip/Postal Code: <small>Click or tap here to enter text.</small>
Contact Information			
A. Person Submitting this Form			
Name: <small>Click or tap here to enter text.</small>			
Degree(s): <small>Click or tap here to enter text.</small>			
Title: <small>Click or tap here to enter text.</small>			
Department: <small>Click or tap here to enter text.</small>			
Address, if different from above: <small>Click or tap here to enter text.</small>			
Telephone (including country code): <small>Click or tap here to enter text.</small>			
Fax: <small>Click or tap here to enter text.</small>			
Email: <small>Click or tap here to enter text.</small>			
Instructions			
Use this form to provide a summary of the issue(s) that require reporting. If applicable, include: <ul style="list-style-type: none">• Immediate actions taken to protect participants, if applicable• Planned corrective actions with timeline, if applicable			
If it is unclear whether a particular item is reportable to AAHRPP, please contact the AAHRPP office.			
Email this form and PDF copies of supporting documents to: <ul style="list-style-type: none">• reporting@aahrpp.org• esummers@aahrpp.org• mfeige@aahrpp.org• rhood@aahrpp.org			
Supply copies of supporting documents, including but not limited to: <ul style="list-style-type: none">• letters from a government oversight agency• information about litigation, if public• press coverage			

Thank You!

- A link to the webinar will be sent to those who registered
- Tentative dates for 2024 Ask AAHRPP webinars:
 - **January 9:** Conducting a Self-Assessment and Building an Application
 - **April 9:** Evaluation of Written Materials
 - **June 11:** Evaluation of Practice – What to Expect for the Site Visit
 - **August 13:** Responding to the Draft Site Visit Report
 - **October 8:** Council on Accreditation Review
 - **December 10:** Maintaining Accreditation

SAVE THE DATE:

2024 AAHRPP Annual Conference: *Science and Standards in San Diego*

May 21-23 | Sheraton San Diego Hotel & Marina



Visit the AAHRPP Website for Conference Details: [AAHRPP Annual Conference](#)

Contact AAHRPP

Questions About the AAHRPP Standards/Elements:

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Questions About the Application Process/Timeline:

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