



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



**April 14, 2026**



# 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



# 2026 Ask AAHRPP



Save the date for 2026 "Ask AAHRPP" webinars:

- **January 13:** Conducting a Self-Assessment and building an Application
- **April 14:** Evaluation of Written Materials
- **June 9:** Evaluation of Practice – what to expect for site visit
- **August 11:** Responding to the Draft Site Visit Report
- **October 13:** Understanding the Council on Accreditation Review
- **December 8:** Responding to Council Review and maintaining accreditation

Visit [Webinars \(aahrpp.org\)](https://www.aahrpp.org) for more information and registration links

## FYIs

- Please provide feedback by completing the survey after the session
- A link to the webinar will be sent to those who registered
  - Including links to prior “Ask AAHRPP” sessions
- If you have any questions during the session, please use the Q&A function



# Presenters

- **Sujatha Sridhar, MBBS, MCE**
  - Associate Vice President, Research Compliance  
The University of Texas Health Science Center at  
Houston
- **Robert Hood, PhD**
  - Director of Accreditation and Global Outreach
  - AAHRPP

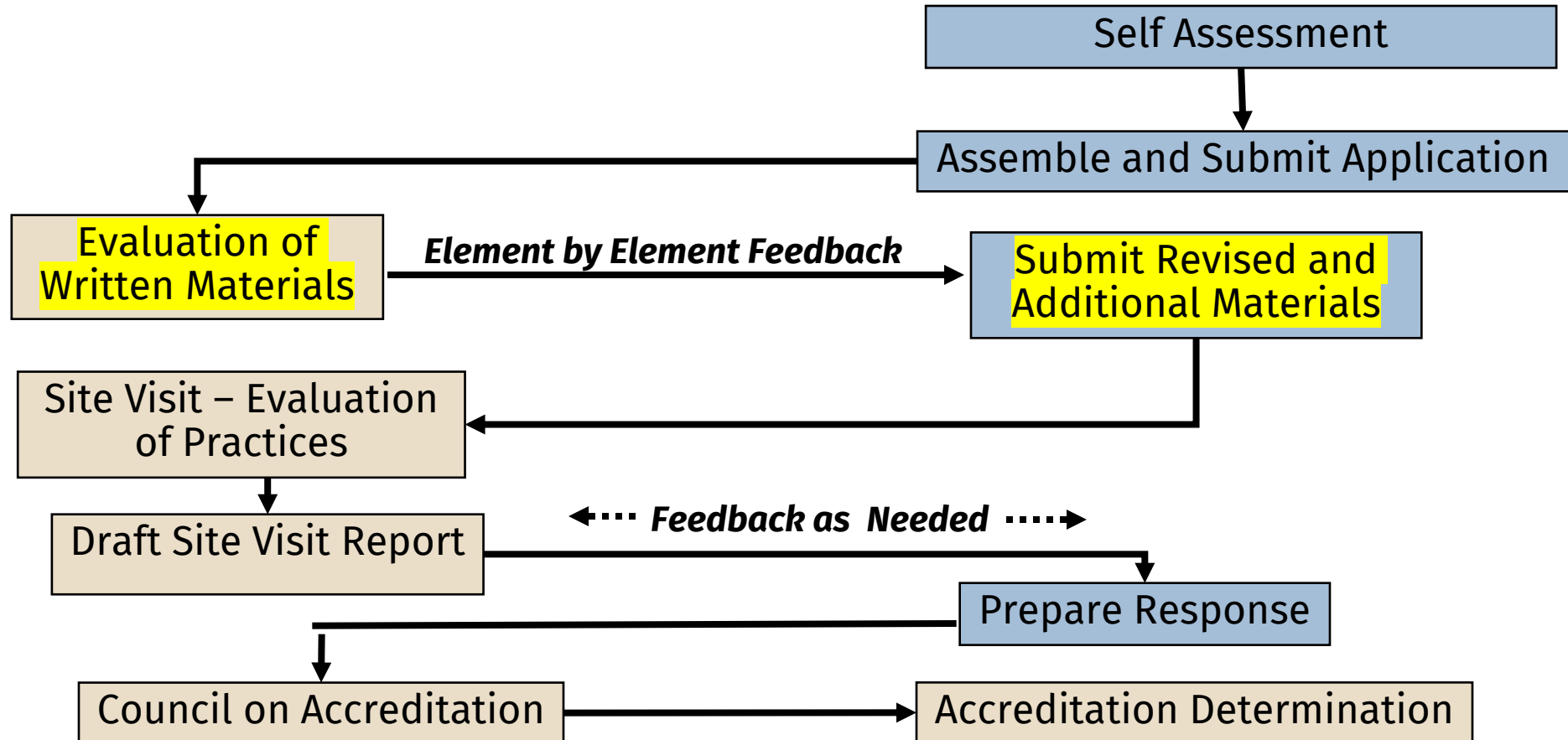


# Evaluation of Written Materials

Responding to AAHRPP's review of your organization's written materials as described in the "Step 1 Report"



# Accreditation Process



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

# Evaluation of the Step 1 Application

- Peer reviewers are from AAHRPP-accredited organizations, or have prior experience with AAHRPP accreditation
  - Reviewers are trained to recognize that different organizations may adopt different approaches to meeting AAHRPP Standards, which can all be acceptable
- AAHRPP issues a “Step 1 Report” approximately 9 weeks providing Element-by-Element feedback
- Organization’s response / revisions are due in about 40 calendar days (or six weeks)



# What Do Peer Reviewers Evaluate?

- *Evaluation Instrument* is used to evaluate all written materials.
- AAHRPP uses the generic term “policies and procedures” to refer to all types of written materials:
  - Standard operating procedures
  - Policy statements, procedures descriptions
  - Checklists, guidelines
  - Forms, templates
  - Job descriptions
  - Applications (screenshots if electronic)
  - Rosters
  - Any other materials used to operate your program
  - Includes all parts of the HRPP: pharmacy policies, contracts, etc.
- See Instructions to Apply for Initial Accreditation and Reccreditation on AAHRPP’s website:
  - <https://www.aahrpp.org/resources/for-accreditation/additional-resource/application-for-initial-accreditation-and-reccreditation-instructions>



# Types of Requests in the Step 1 Report

- Add specific information to written materials
  - Copy and paste from the Step 1 Report to your written materials
- Describe a process in more detail
  - Provide additional information
    - Who is responsible; what has to be done; when process occurs; supporting tools (applications, checklists); and how the process is evaluated for compliance and quality, efficiency, effectiveness
- Remove/replace information that is inconsistent with requirements in the Evaluation Instrument
  - Example: Delete obsolete information (e.g., based on requirements in prior Common Rule)
- Reconcile inconsistent information



## Example: Add Information...

- If specific information is missing from your application, the Step 1 Report will ask you to:
- Add to the policy, “Ethics Committee Operations Policy” (page 357):
  - The organization grants the IRB the authority:
    - To observe, or have a third party observe, the consent process and the conduct of the research.



# Response: Add to policy for Element I.1.C.

Attach the revised policy, with changes highlighted:

The research ethics committee manager is responsible for ensuring the implementation of the following:

1. The research ethics committee has authority
2. To approve, require modifications to secure approval, and disapprove all research activities overseen and conducted by the organization.
3. To approve, require modifications to secure approval, and disapprove all research activities overseen and conducted by the organization.
4. To suspend or terminate IRB approval of research not being conducted in accordance with the IRB's requirements or that had been associated with unexpected serious harm to participants.
5. To observe, or have a third party observe, the consent process and the conduct of the research.
6. To have final authority to approve researcher and research staff conflict of interest management plans. (See conflict of interest policy)



## Example: Describe a process ...

- If specific information is missing from your application, the Step 1 Report will ask you to:
  - Describe a process...
  - The process should explain:
    - Who is responsible
    - When the task occurs
    - What tools (worksheets/electronic systems) used
    - What the program does with the results (if applicable)
- Describe in written materials - A quality improvement plan that periodically assesses the effectiveness of the HRPP's compliance program.



# Response: Description of a Process for Element I.5.A. and Element I.5.B.

## Attach revised policy for Elements I.5.A. and I.5.B.

Annually in March, the HRPP Director, the Associate Director, and the Quality Assurance Manager and IRB/EC chair(s) are responsible for:

- Identifying at least one objective for to ensure the effectiveness of the compliance program, as determined by the group
  - Identifying at least one measure of the effectiveness of the compliance program
- Identifying at least one objective for enhancing quality, efficiency, or effectiveness, based on needs identified by the group.
  - Identifying at least one measure of quality or efficiency or effectiveness
- The HRPP Director records the objectives and goals in the QA Worksheet
- The HRPP Director schedules a meeting quarterly in June, September, December, and March to review the results and identify whether program improvements are needed and records the results in the QA worksheet.
- **Examples** of compliance goals include:
  - 100% of minutes document whether a change is a minor change or a major change
  - 100% of continuing review applications are submitted on time
- **Examples** of assessing quality, efficiency and effectiveness include:
  - IRB members are knowledgeable about ways of identifying and managing conflicts of interest
  - Time from application to submission to approval will be less than described in AAHRPP metrics

**(Note goals do not have to be in a policy – policy describes a process)**



## Example: Reconcile...

- If policies are inconsistent, the Step 1 Report will ask you to make the policies consistent:
  - Same definitions
  - Same criteria, e.g., disclosure criteria for conflicts of interest
  - Same persons responsible
  - Delete inconsistent information from one policy and refer to the correct information in another policy



## Response to Request to Reconcile Materials for Element I.6.B.

Provide the revised document (e.g., Word file) with changes highlighted

Provide a summary in email:

- Deleted disclosure criteria from Policy 2, and Policy 3.
  - See attached policies with markup showing deletions
- Revised policy 1 to specify that we require a \$0 disclosure threshold for financial interests in research
  - See attached policy 1 with markup showing revisions



# Tracking Revisions to Written Materials

Use a spreadsheet to track all documents in your HRPP:

- Document Title
- Owner (person responsible for maintaining)
- Version
- Revision date
- Date for the next compliance monitoring / quality, efficiency, effectiveness assessment (e.g., annually)



# Instructions for Sending Responses

- Detailed instructions provided with Step 1 Report
- Overview:
  - Send one email per Element
    - And one email for Standard 1-2, one for Standard 1-3, and one for Standard I-9
  - Send email to:
    - [response@aahrpp.org](mailto:response@aahrpp.org) AND
    - Email address of the assigned step 1 reviewer
  - Attach the relevant portion of the revised written materials with changes tracked or highlighted
    - Do not paste changes into an email without attaching a document



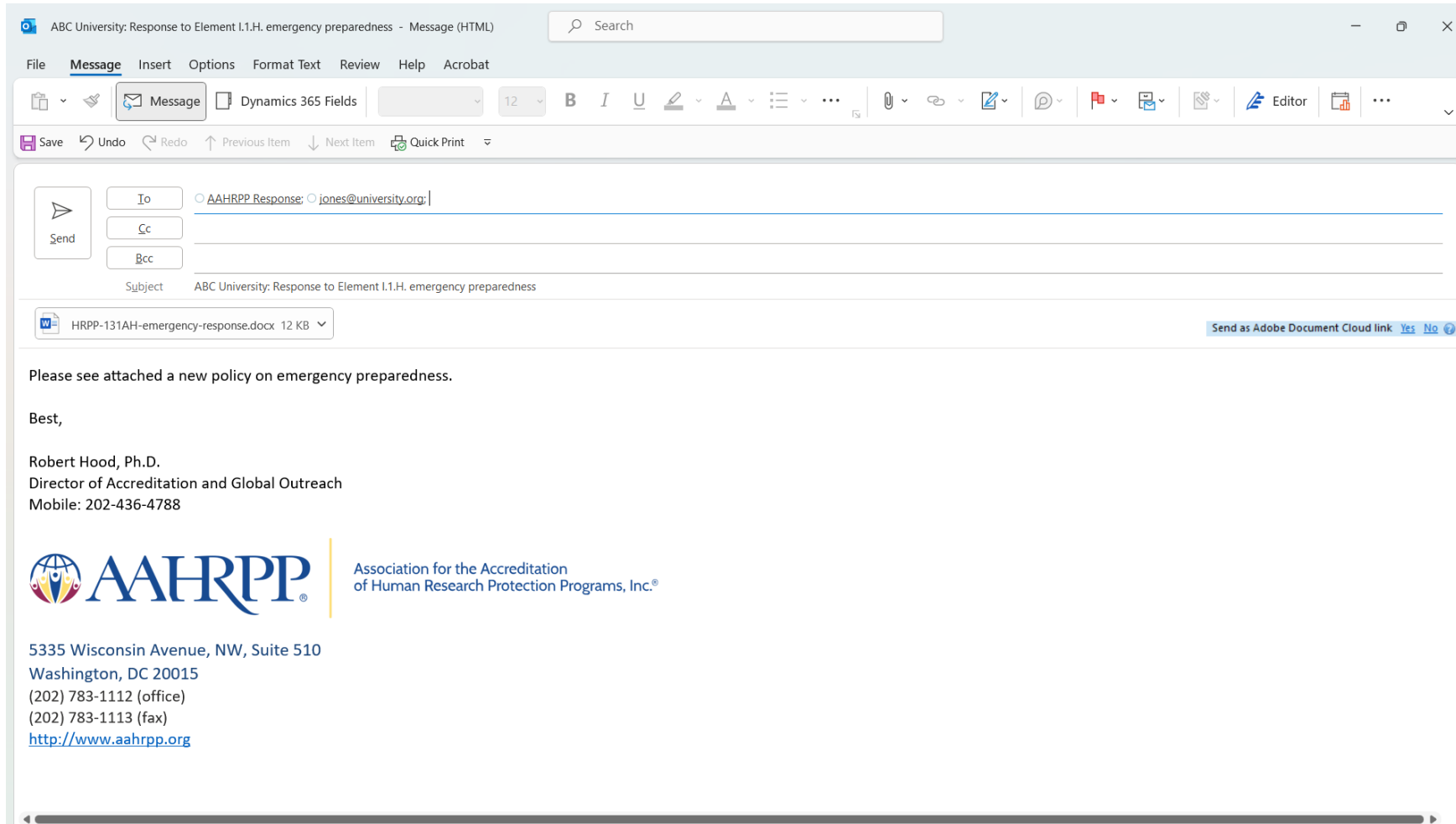
# **Please Send One Email Per Element**

**Please send responses as soon as you complete them**

**Please do not hold responses to send all just before the deadline**



# Sample Email



ABC University: Response to Element I.1.H. emergency preparedness - Message (HTML)

File Message Insert Options Format Text Review Help Acrobat

Message Dynamics 365 Fields 12 B I U A ...

Save Undo Redo Previous Item Next Item Quick Print

To AAHRPP Response; jones@university.org

Cc

Bcc

Subject ABC University: Response to Element I.1.H. emergency preparedness


HRPP-131AH-emergency-response.docx 12 KB

Send as Adobe Document Cloud link Yes No

Please see attached a new policy on emergency preparedness.

Best,

Robert Hood, Ph.D.  
Director of Accreditation and Global Outreach  
Mobile: 202-436-4788



Association for the Accreditation  
of Human Research Protection Programs, Inc.<sup>®</sup>

5335 Wisconsin Avenue, NW, Suite 510  
Washington, DC 20015  
(202) 783-1112 (office)  
(202) 783-1113 (fax)  
<http://www.aahrpp.org>



# Updating Written Materials

- Send each response as soon as it is completed
  - If you send each response as soon as you complete it, the peer-reviewer can:
    - Confirm that the way you are responding addresses our requests
    - Advise you on whether you can improve your revisions and clarifications to written materials
- Once revised materials are approved, plan education
- Please do not make changes to written materials after they are approved (after the Step 2 application is sent and until after Council review)
  - If you have questions about changes to policies contact AAHRPP immediately



# AAHRPP Educational Activities



## Webinars:

Ask AAHRPP  
Ask AAHRPP  
International  
HRPP Innovations



## Conference:

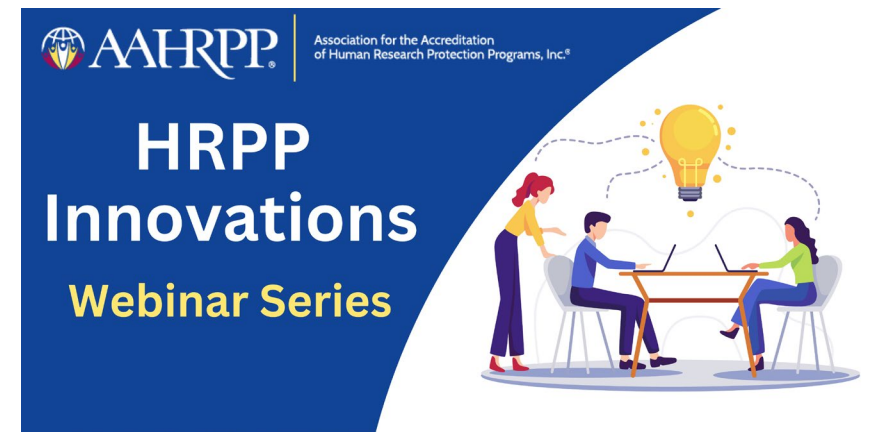
2026 Annual  
Conference - Detroit



## News:

Advance Newsletter  
AAHRPP Website

# 2026 Webinars...



Visit [Webinars \(aahrpp.org\)](https://www.aahrpp.org/webinars) for more information



Association for the Accreditation  
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# 2026 AAHRPP ANNUAL CONFERENCE:

# GREAT LAKES, GREAT MINDS MEET 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.**

# AAHRPP News

## AAHRPP Website

(available 24/7)

## Advance Newsletter

(two times per year)

Spring –April

Fall – October



## Contact AAHRPP

Robert Hood, Ph.D.

Director of Accreditation and Global Outreach

[rhood@aaahrpp.org](mailto:rhood@aaahrpp.org)

Jemelle Williams, BS, PMP

Assistant Director of Operations

[jwilliams@aaahrpp.org](mailto:jwilliams@aaahrpp.org)



# Thank You!

Please complete the  
survey

Slides, tools, and a link  
to the recording of  
today's session will be  
provided in an email  
soon.