



October 14, 2025



- **Council on Accreditation**

- **Martha Jones, MS, CIP**

- Vice President, Human Research Affairs
Mass General Brigham

- **AAHRPP Staff**

- **Robert Hood, PhD**

- Director of Accreditation and Global Development

- **Nichelle Cobb, PhD CIP**

- Senior Advisor for Strategic Initiatives



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



2025 Schedule

- Remaining session:
 - 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 webinar will be sent to those who registered
 - [Including links to prior “Ask AAHRPP” webinars](#)
- If you have any questions during the sessions, please use the Q&A function to submit them

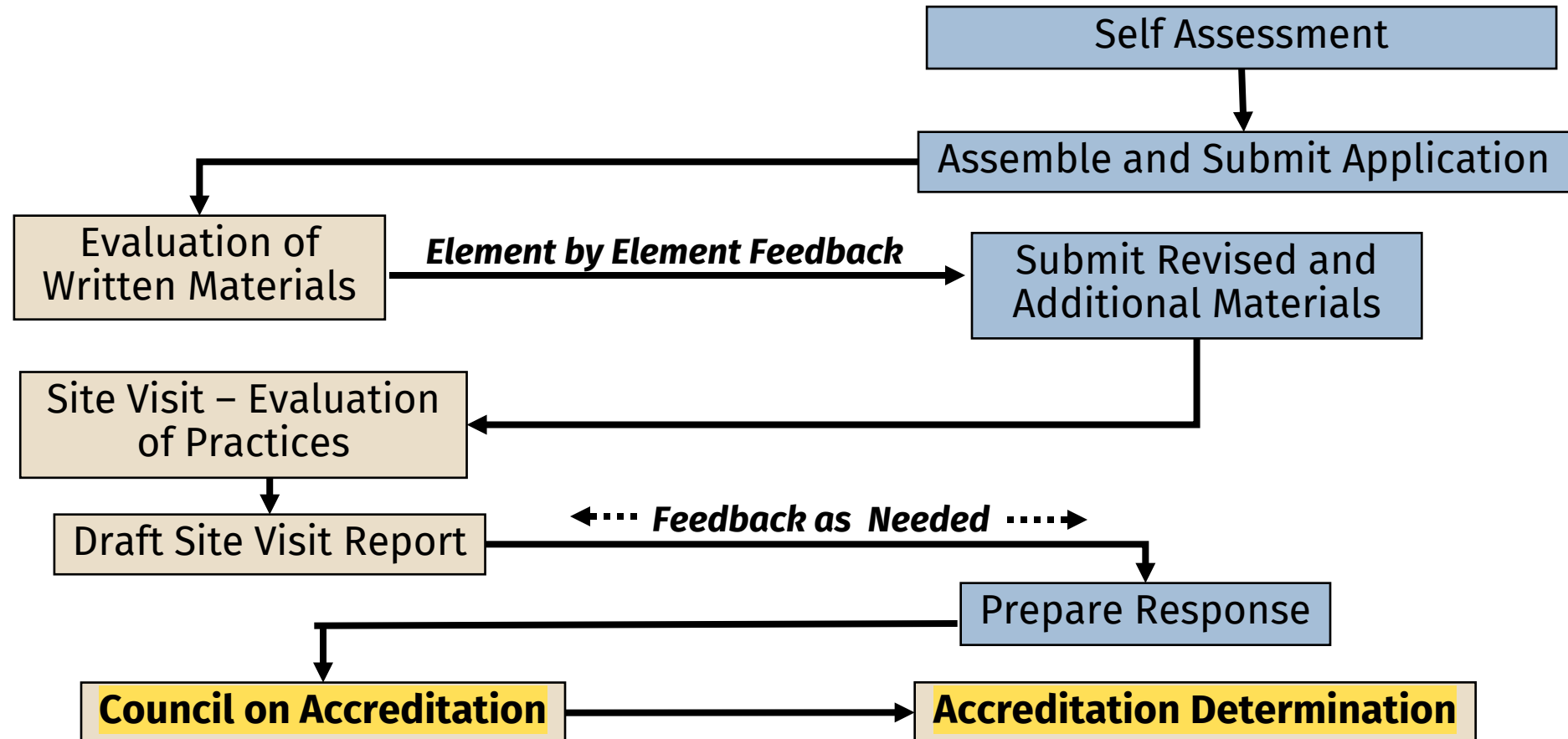


Council on Accreditation Review

<https://aahrpp.org/accreditation/get-accredited/part-5-council-on-accreditation-review>



Accreditation Process



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

Council on Accreditation

- Reviews application materials and reports (applications, Draft Site Visit Reports, responses to Draft Site Visit Reports, and evaluations)
- Makes determinations regarding accreditation status
 - The Board of Directors retains ultimate authority over determinations (e.g., in the case of appeals)
- Meets no less than four times per year (March, June, September, December)

Membership - Council on Accreditation

- Elected by Board of Directors
- Experienced Site Visitors from different backgrounds:
 - Members representing the human research protection perspective e.g., program managers (IRB/EC administrators) or IRB/EC chairs
 - Members representing the research perspective e.g., researchers familiar with federal regulations
 - Organizational officials – senior leadership familiar with federal regulations, e.g., Vice Presidents for Research, Provosts, Deans, or Directors of Science

Council on Accreditation Membership (2025)

- Kristin Rochford, EdD, MPH, CIP (Chair)
- Megan Kasimatis Singleton, JD, MBE, CIP (Vice-Chair)
- John Andrew Bertolatus, MD
- Wesley Byerly, PharmD
- Stephanie deRijke, RN, MSN
- Bruce Gordon, MD
- Martha Jones, MA, CIP
- Monika Markowitz, PhD, MSN, RN, MA
- Jonathan Miller, MPPA, CIP
- Jodi Roberts, PhD

<https://aahrpp.org/about/meet-our-team/meet-our-team---council-on-accreditation>

Categories of Accreditation

- New applicants
 - Full Accreditation
 - **All Standards Met (May require Status Reports)**
 - Qualified Accreditation
 - **All regulatory Standards met, Some AAHRPP-specific Standards not Met**
 - Accreditation-Pending
 - **Some regulatory Standards not met**
 - Accreditation Withheld
 - **Not common (Organization unable or unwilling to meet AAHRPP Standards)**
- Renewing applicants
 - Full Accreditation
 - **All Standards Met (May require Status Reports)**
 - ~~Qualified Accreditation~~
 - **Not available – Renewing applicants must meet all Standards**
 - Reaccreditation-Pending
 - **Some Standards not met**
 - Probation
 - Accreditation-Revoked

If there were areas of concern, based on the organization's response, Council may determine:

- Standard is met (Council does not require additional information to confirm a Standard is met)
- Standard is met with request for additional Status Report
 - Council requires confirmation that program improvements continue to be implemented (skips one Council to allow organizations time to confirm)
- Standard is not met
 - Council will request an Improvement Plan – due at the next Council

Based on the response to areas of concern in the DSVR: Standard is met (no additional information required)

- In general, program improvements have been implemented before Response to Draft Site Visit Report is due:
 - Education – complete
 - Monitoring – demonstrates program improvements are already implemented and meet the Standard; organization describes plans for ongoing monitoring to confirm
 - Revisions to written materials, if any
 - Approved and implemented
 - Education about revised written materials completed
 - Monitoring confirms adherence to organization's revised written materials

Based on the response to areas of concern in the DSVR: Standard is met and Status Report requested

- In general, used to confirm the organization continues to implement program improvements, or where the organization has had only a few examples to confirm program improvements are implemented
 - Skips one Council to allow organizations time to confirm
- In general, may be requested twice
 - If, after two cycles of status reports, there is still not enough evidence to confirm that an organization meets AAHRPP Standards, Council may place an organization into Pending Status (non-punitive, non-prejudicial) with request for an Improvement Plan

Based on the response to areas of concern in the DSVR: Standard is not met

- The response does not describe program improvements to meet AAHRPP requirements in a timely manner:
 - Not submitting a response
 - Not responding to all Standards and Elements with Areas of Concern
 - Not planning on implementing program improvements until far after Council
- If one or more Standards are not met, the Organization is placed into Accreditation-Pending or Reaccreditation-Pending status
 - Means the organization needs more time to implement program improvements to meet all AAHRPP Standards
 - Accreditation-Pending and Reaccreditation-Pending status are confidential
 - For organizations applying for reaccreditation, organization continues to be listed on AAHRPP's website as a Fully Accredited organization

Brief Examples

- The following scenarios are examples for illustration purposes.
- Council considers, among other things:
 - The totality of the organization's application, any Areas of Concern, and program improvements described in the Response to the Draft Site Visit submission
 - Specific facts about the organization's HRPP, such as:
 - Similar Areas of Concern across multiple accreditation cycles
 - Having been placed into Reaccreditation-Pending in the last reaccreditation cycle
 - Implementation of new types of research (e.g., organization starts conducting/reviewing biomedical research or international research)
 - Organizational changes (mergers/acquisitions, substantial HRPP reorganization)
 - Major changes in policies (e.g., replacing all policies with different ones)
 - Sanctions taken by a government oversight office, such as OHRP Determination Letters, FDA Warning Letters, and FDA Restrictions Placed on IRBs or Investigators and similar actions in other countries; and any lawsuits related to human research protection

How might Council decide?

- Area of Concern: Evaluations not conducted (examples: Standard I-2 (resources), and Elements 1.4.B. (outreach), II.1.B. (IRB/EC members and chairs))
- Response to Draft Site Visit Report:
 - Prior to sending Response to DSVR:
 - Evaluations completed
 - Policy reviewed, no changes indicated
 - Education completed and list of people educated provided
 - Organization reviewed the results of the evaluations and decided no changes needed; summary provided with Response to DSVR
 - Evaluations for next year scheduled

How might Council decide?

- Area of Concern: IRB members, chairs, and staff were not knowledgeable about requirements for review of research involving prisoners (Element II.4.A.)
- Response to the Draft Site Visit Report:
 - Prior to sending Response to DSVR organization describes prisoner research:
 - Policy, reporting forms, and reviewer forms reviewed; no changes indicated
 - Education of IRB members, chairs, staff completed and list of people provided
 - No new studies involving prisoners since the site visit, no open studies of research involving prisoners
 - Plan to have IRB members review a mock prisoner study scheduled for the next two IRB meetings, provided but has not started
 - Plan for prospective monitoring for six months provided but not started

How might Council decide?

- Area of Concern: Substantive modifications were not returned to the convened IRB for review (“substantive modifications” mean clarifications or modifications directly relevant to criteria for approval specified in regulations; see Commentary, Element II.1.B.)
- Response to the Draft Site Visit Report:
 - Policy, reporting forms, and reviewer forms reviewed, no changes indicated
 - Need to confirm education – completed for four of five IRBs and list of people educated provided
 - Minutes for the last six months were reviewed and this confirmed substantive changes were not always returned to the convened IRB.
 - One IRB meeting occurred before the response was due. Minutes from that meeting were provided, but minutes continued to show substantive changes were not returned to the convened IRB.

How might Council decide?

- Area of Concern: When reviewing FDA- or DHHS-regulated research, the IRB / EC conducted review without IRB quorum. A nonscientist was listed on the roster, but did not always attend meetings. An unaffiliated member was listed on the roster, but had not attended any meetings in the prior two years. Scientific members were listed on the roster, but sometimes the IRB met without a scientific member. (Element II.2.D.)
 - The organization
 - Agreed with the Area of Concern
 - Reported clinical call duties sometimes made it impossible for scientific members to attend
 - Had been trying to recruit nonscientists and unaffiliated members, but had been unsuccessful.
 - Was concerned about IRB approval expiring; response indicated that they planned to continue to review research without quorum, until IRB/EC membership could be improved
 - Did not provide a detailed timeline for making program improvements

Summary

- Start to implement program improvements prior sending the Response to the Draft Site Visit Report
 - Describe education
 - Describe monitoring
 - If applicable, describe changes to written materials
- Instructions for Responding to the Draft Site Visit Report:
<https://www.aahrpp.org/resources/for-accreditation/additional-resource/instructions-to-prepare-a-response-to-the-draft-site-visit-report>

Upcoming Webinars



**Save the date for the upcoming
“HRPP Innovations” webinar:**
Tuesday, November 18, 2025, 1:00pm ET
**Innovative Practices by
AAHRPP-Accredited Organizations:
Community Outreach and Collaboration”**



**Save the date for the remaining
2025 “Ask AAHRPP” webinar:**
Tuesday, December 9, 2025, 3:00pm ET:
**Responding to Council Review and
Maintaining Accreditation**

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



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.**

Contact AAHRPP

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Questions about the application process:

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Thank You!

