



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



**October 8, 2024**



- **Chair, Council on Accreditation**

- **Kristin Rochford, EdD, MPH, CIP (Council Chair)**

- **Senior Director, Office of the Human Research Protection Program (OHRPP)**
- **University of California Los Angeles**

- **AAHRPP Staff**

- **Robert Hood, PhD**
  - **Director of Accreditation and Global Development, AAHRPP**
- **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



# 2024 Schedule

- January 9, 2024: Conduct a Self-Assessment (using the Evaluation Instrument for Accreditation)
- April 9, 2024: Build and Develop an Application
- June 11, 2024: Evaluation of Written Materials
- August 13, 2024: Evaluation of Practice (“site visit”)
- **October 8, 2024: Council on Accreditation Review**
- December 10, 2024: Respond to Council Review and maintain accreditation



# FYIs

- Please provide feedback by completing the survey
- 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 chat function or Q&A function to submit them

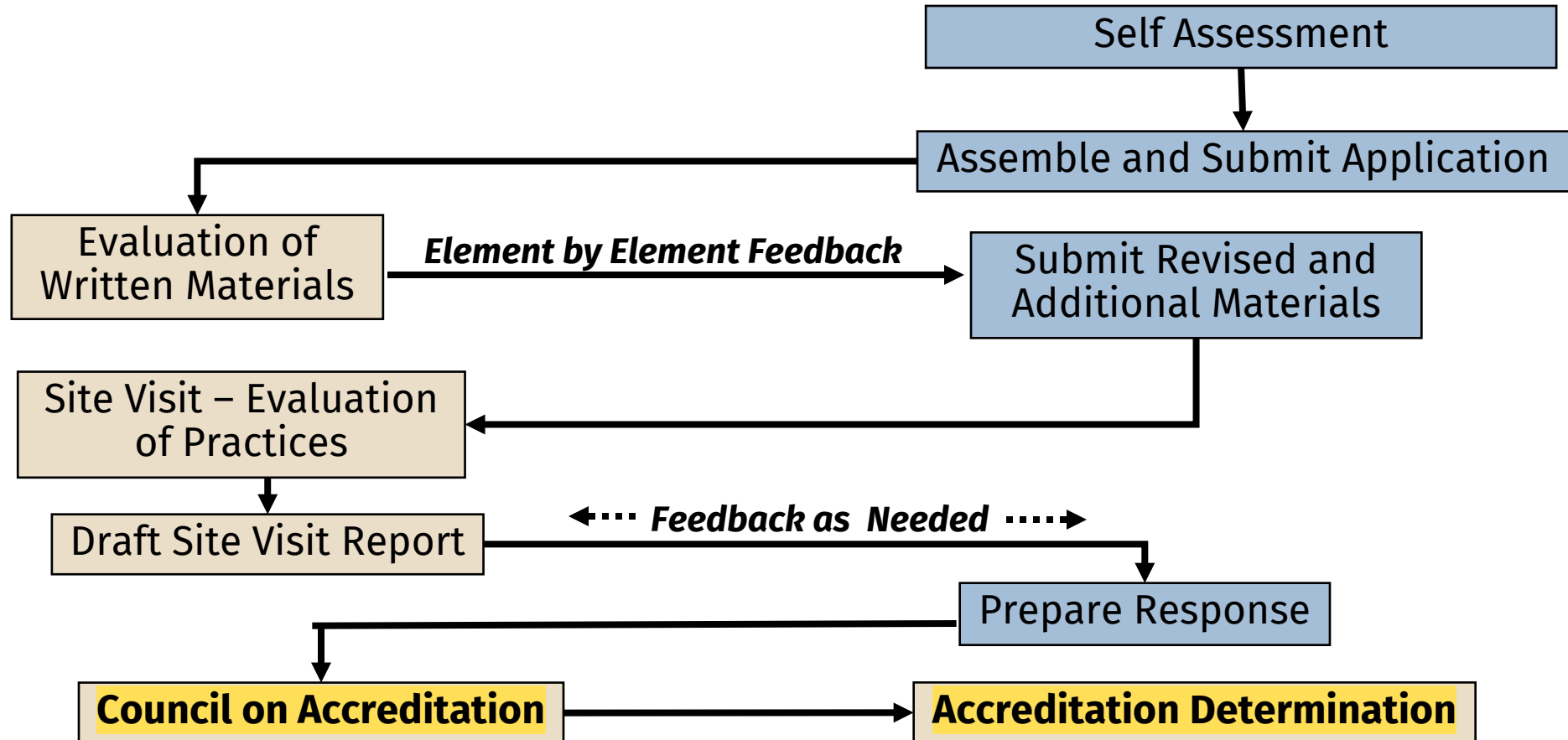


# Council on Accreditation Review

<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 (2024)

- 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**

# How does Council determine if a Standard is met?

- Standard is met (Council does not require additional information to confirm a Standard is met)
- Standard is met with request for additional Status Report
  - Confirmation in three months that program improvements continue to be implemented (skips one Council)
- Standard is not met

## 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
  - Revisions to written materials, if any
    - Approved and implemented
    - Education about revised written materials completed
    - Monitoring confirms adherence to organization's revised written materials

## Standard is met with Status Report

- Due in four months (skips one Council)
- 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
- May be requested twice
  - If, after two cycles of status reports, there is still not enough information to determine that an organization is doing what it needs to be doing, Council may place an organization into Reaccreditation-Pending Status (non-punitive, non-prejudicial) with request for an Improvement Plan

## Standard is not met

- The response does not describe program improvements that will allow the organization 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
  - Pending status is confidential
  - For renewing organizations, organization continues to be listed on AAHRPP's website as an 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
  - The specific facts of the organization's HRPP, including but not limited to things like:
    - Size of the HRPP
    - Types of research
    - Location of research (in state vs global)
    - Complexity of the HRPP (e.g., multiple locations, distributed HRPPs)
    - Repeated Areas of Concern across multiple accreditation cycles
    - Organizational changes (mergers/acquisitions, substantial HRPP reorganization)
    - Regulatory actions



## How might Council decide?

- Area of Concern: Evaluations not conducted (examples: Standard I-2, and Elements 1.4.B., II.1.B.)
- 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.):
  - 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 but not started
    - Plan for prospective monitoring for six months provided but not started

## How might Council decide?

- Area of Concern: Substantive changes were not returned to the convened IRB, but were reviewed by staff (Element II.2.E.):
  - 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
  - Monitoring to confirm practice has changed: Minutes for four of five IRBs were reviewed for the last six months to see whether the IRB needed to review substantive changes
  - Monitoring: Prospective monitoring for started for two IRBs, was planned but had not started remaining IRBs (meetings had not yet occurred)
  - Minutes from one IRB meeting after the site visit highlighting examples demonstrating substantive concerns were approved pending review by the convened IRB

## How might Council decide?

- Area of Concern: When reviewing FDA- or DHHS-regulated research, the IRB / EC conducted review without quorum. A nonscientist was listed on the roster, but did not always attend meetings. An unaffiliated member was listed on the roster, but had never 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, so 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

# Upcoming Webinars



Save the date for the remaining  
2024 "Ask AAHRPP" webinar:  
- December 10, 2024



Save the date for the remaining  
2024 "HRPP Innovations" webinars:  
- November 12, 2024

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



# 2025 Ask AAHRPP



## Save the date for 2025 "Ask AAHRPP" webinars (tentative):

- January 14: Conducting a Self-Assessment and building an Application
- April 8: Evaluation of Written Materials
- June 10: Evaluation of Practice – what to expect for site visit
- August 12: Responding to the Draft Site Visit Report
- October 14: Understanding the Council on Accreditation Review
- December 9: Responding to Council Review and maintaining accreditation

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

# 2025 Accreditation Workshop May 20, 2025

Comprehensive course in how  
to achieve accreditation or  
reaccreditation featuring  
experts from accredited  
organizations



**SAVE THE  
DATE!**

**2025 AAHRPP ANNUAL CONFERENCE:  
*HRPP Dedication, Dialogue and  
Discovery in Denver***

**MAY 20-22, 2025** |  **GRAND HYATT DENVER**  
1750 WELTON STREET  
DENVER, CO 80202

# Thank You!

- A link to the talk will be sent to those who registered for the talk when it is posted



# Contact AAHRPP

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Questions about the application process:

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