



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



October 10, 2023



- **Chair, Council on Accreditation**

- **Martha Jones, MA CIP**

- **Vice President, Human Research Affairs, Mass General Brigham (Boston MA, USA)**

- **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



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 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

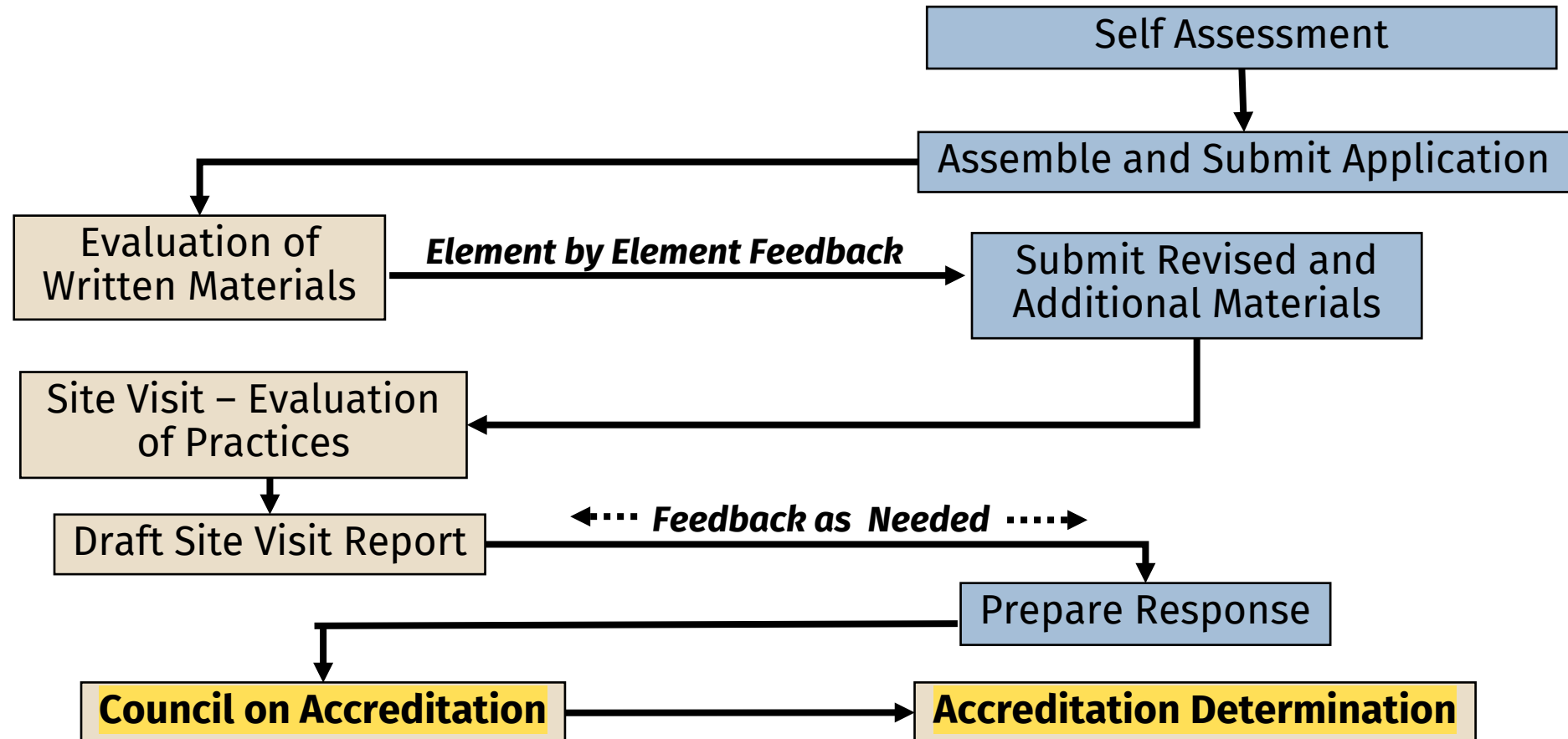


Council on Accreditation Review

<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 (2023)

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

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

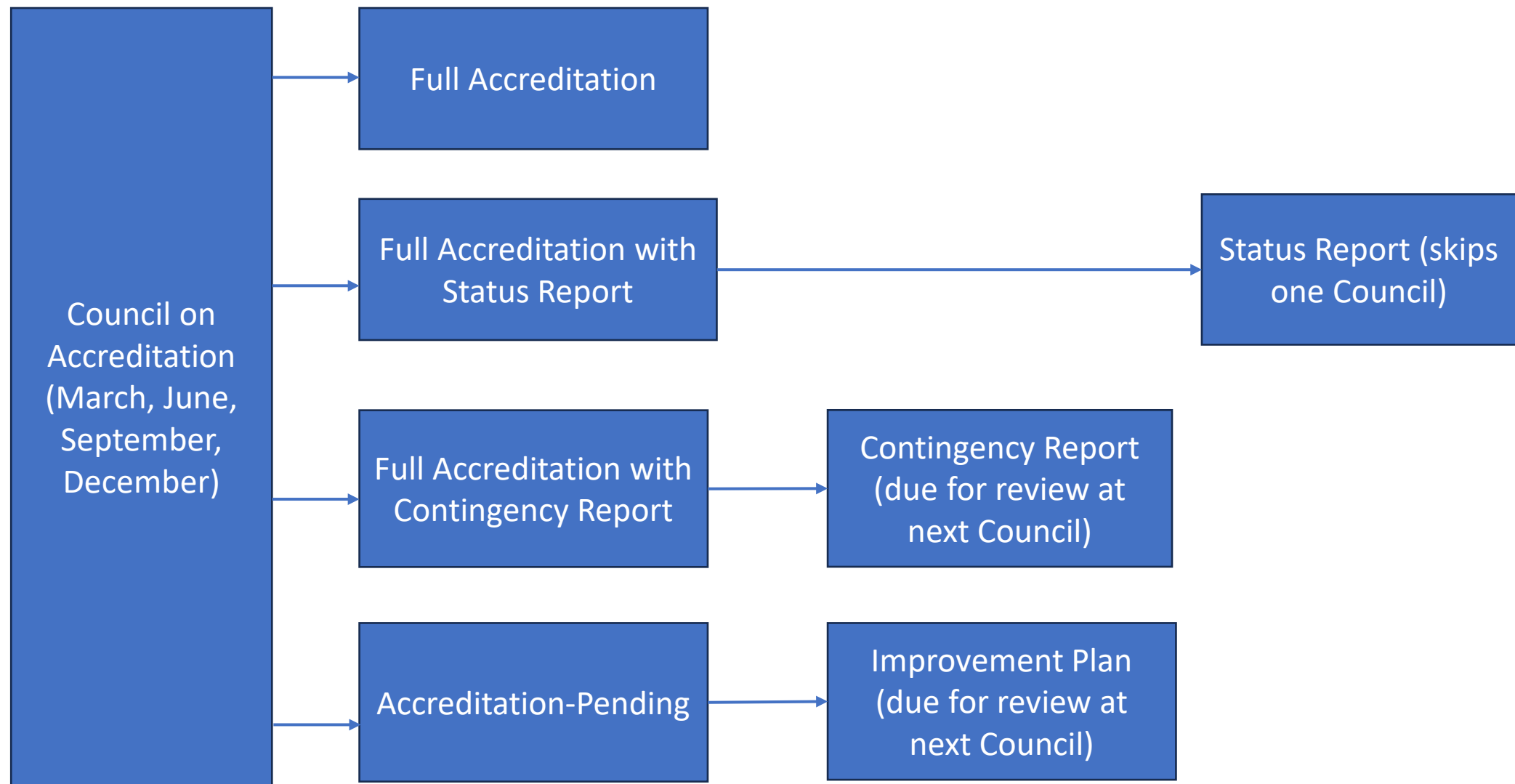
Question: What is the Council on Accreditation's philosophy for how to evaluate HRPPs?

Categories of Accreditation

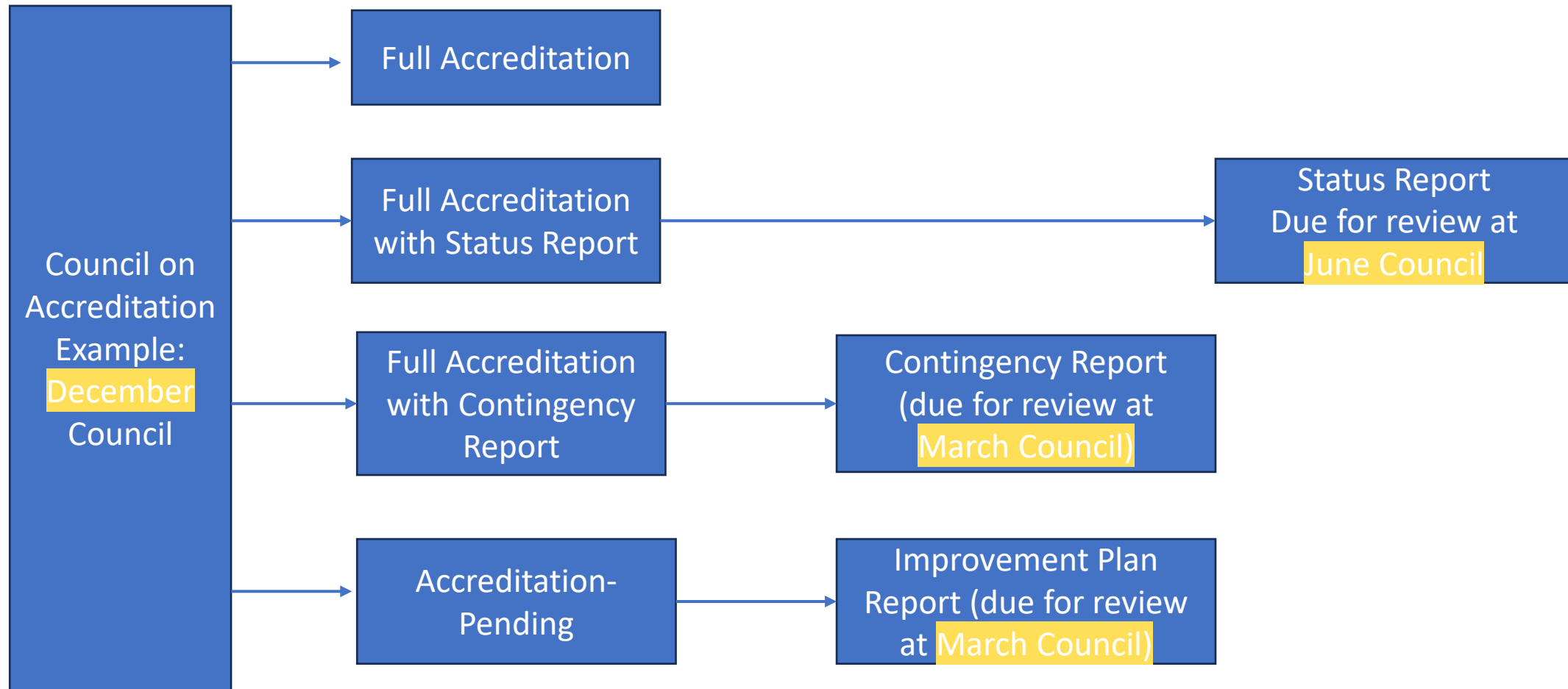
- New applicants
 - **Full Accreditation**
 - All Standards Met (May require Status Reports)
 - **Qualified Accreditation**
 - All regulatory Standards met, Some AAHRPP-specific Standards not Met
 - **Accreditation-Pending**
 - Some regulatory Standards not met
 - **Accreditation Withheld**
 - Not common (Organization unable or unwilling to meet AAHRPP Standards)
- Renewing applicants
 - **Full Accreditation**
 - All Standards Met (May require Status Reports and/or Contingency 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 (Status report not required)
- Standard is met with request for Status Report
 - Confirmation that program improvements continue to be implemented (skips one Council e.g., March -> skips June -> due for September Council)
- Standard is met with request for Contingency Report
 - Confirmation by the next Council that program improvements have been implemented (Next Council e.g., March -> due for June Council)
- Standard is not met
 - Demonstration that program improvements have been implemented (next Council e.g., March -> due for June Council)



Example: Application reviewed at December Council



Standard is met (no additional information required)

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

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
 - Documentation changes to written materials are complete and/or
 - Education is complete and/or
 - Monitoring confirms organization has sustained program improvements
- 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, an escalation, in the form of a contingency report, may be required
 - Failure to meet the request(s) stated within a contingency report within one cycle may result in Reaccreditation-Pending status with request for an Improvement Plan

Standard is met with Contingency Report

- Due at the next Council
- Typically, available to organizations applying for reaccreditation
- The organization is very close to meeting all Elements and Standards and will be required, within one Council cycle, to complete the program improvements or confirm the improvements have been implemented
 - Documentation changes are started and almost complete and/or
 - Education has started and is almost complete and/or
 - Monitoring has started but only limited information is available
- Gives an organization one final opportunity to demonstrate full adherence to all standards and elements in the context of reaccreditation
 - Failure to meet the request(s) stated within a contingency report within one cycle may result in Reaccreditation-Pending status 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
 - Pending status is confidential
 - For renewing organizations, organization continues to be listed on AAHRPP's website as an accredited organization

Question: Do you think it's an easy decision or it's always clear what Council should decide? (Whether it's a status report or contingency report?)

Brief Examples

- The following scenarios are examples for illustration purposes.
- Council considers, among other things:
 - The totality of the organization's application
 - Areas of Concern
 - Program improvements described in the Response to the Draft Site Visit submission

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:
 - Policy reviewed, no changes to written materials indicated
 - Evaluations completed
 - Education completed and list of people educated provided
 - Monitoring occurred; 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:
 - No new studies involving prisoners since the site visit, no open studies of research involving prisoners
 - Written materials evaluated (policy, reporting forms, and reviewer forms reviewed) no changes indicated
 - Initial education of IRB members, chairs, staff completed and list of people provided
 - Additional education scheduled involving review of a mock prisoner study for the next two IRB meetings (in next two months)
 - Monitoring prior prisoner studies in the last two years was completed; training of staff on monitoring of new prisoner studies for six months planned 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
 - Education of the core staff that support all IRBs started but not complete – completed 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 (minister / attorney) was listed on the roster, but did not always attend meetings. Scientific members were listed on the roster, but sometimes the IRB met without a scientific member. (Element II.2.D.)
 - The organization
 - Disagree with the Area of Concern
 - Reported clinical call duties sometimes made it impossible for scientific members to attend
 - Had been trying to recruit nonscientists 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

Join Us for Upcoming AAHRPP Webinars:

November 14, 2023, 1:00 pm – 2:30 pm ET:

HRPP Innovations Webinar: Innovative Practices by AAHRPP-Accredited Organizations

Speakers: Representatives from three AAHRPP-accredited organizations will present their “Areas of Distinction”

December 12, 2023, 3:00 pm – 4:00 pm ET:

Ask AAHRPP Webinar: Response to Council Review – Last of the six-part series

Speakers: Robert Hood, AAHRPP; AAHRPP Consultants/Operations Team Members

Moderator: Nichelle Cobb, AAHRPP

Thank You!

- A link to the talk will be sent to those who registered for the talk when it is posted
- 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 site visit
 - **August 13:** Responding to the Draft Site Visit Report
 - **October 8:** Understanding the Council on Accreditation Review
 - **December 10:** Responding to Council Review and maintaining accreditation

Contact AAHRPP

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