



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

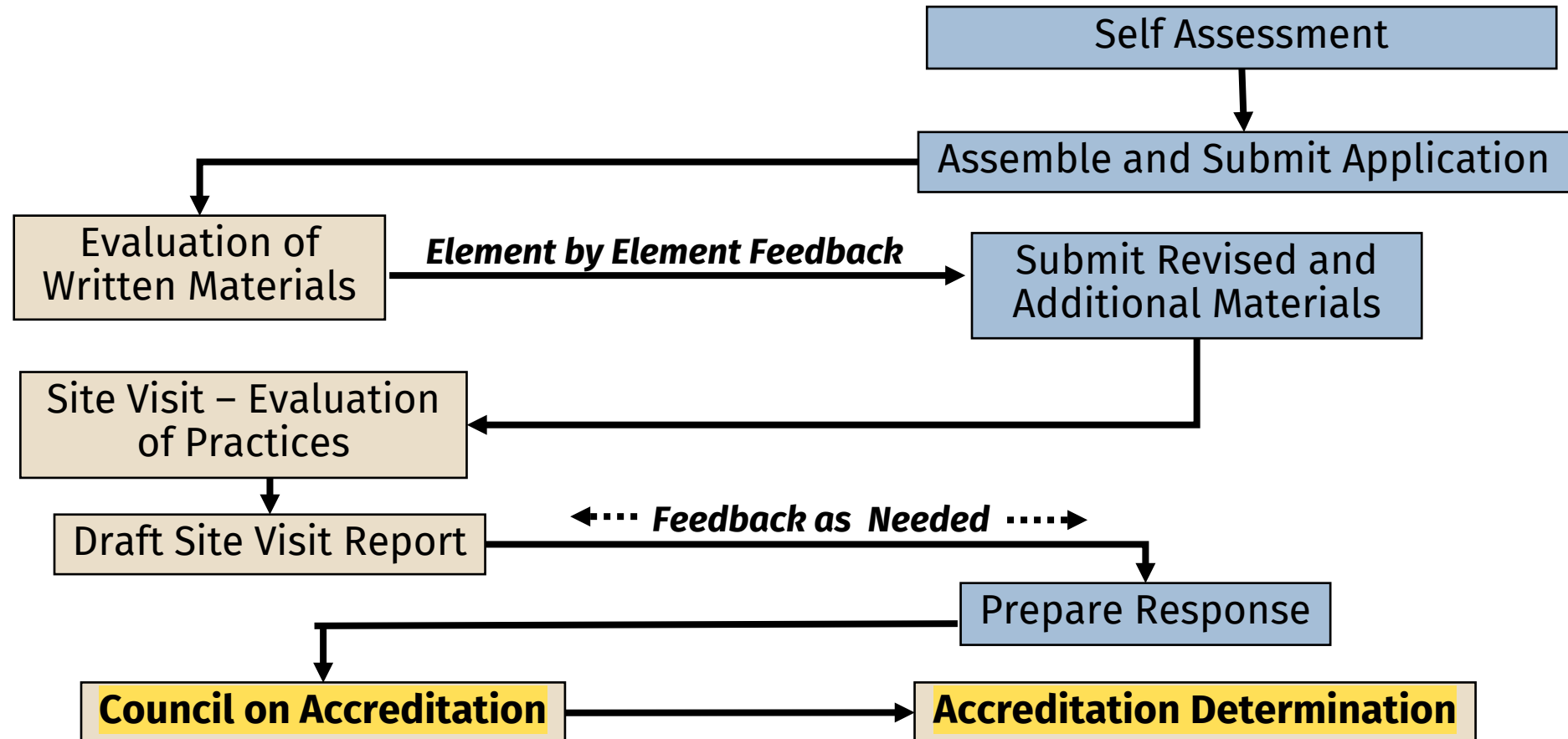


Council on Accreditation Review

<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>

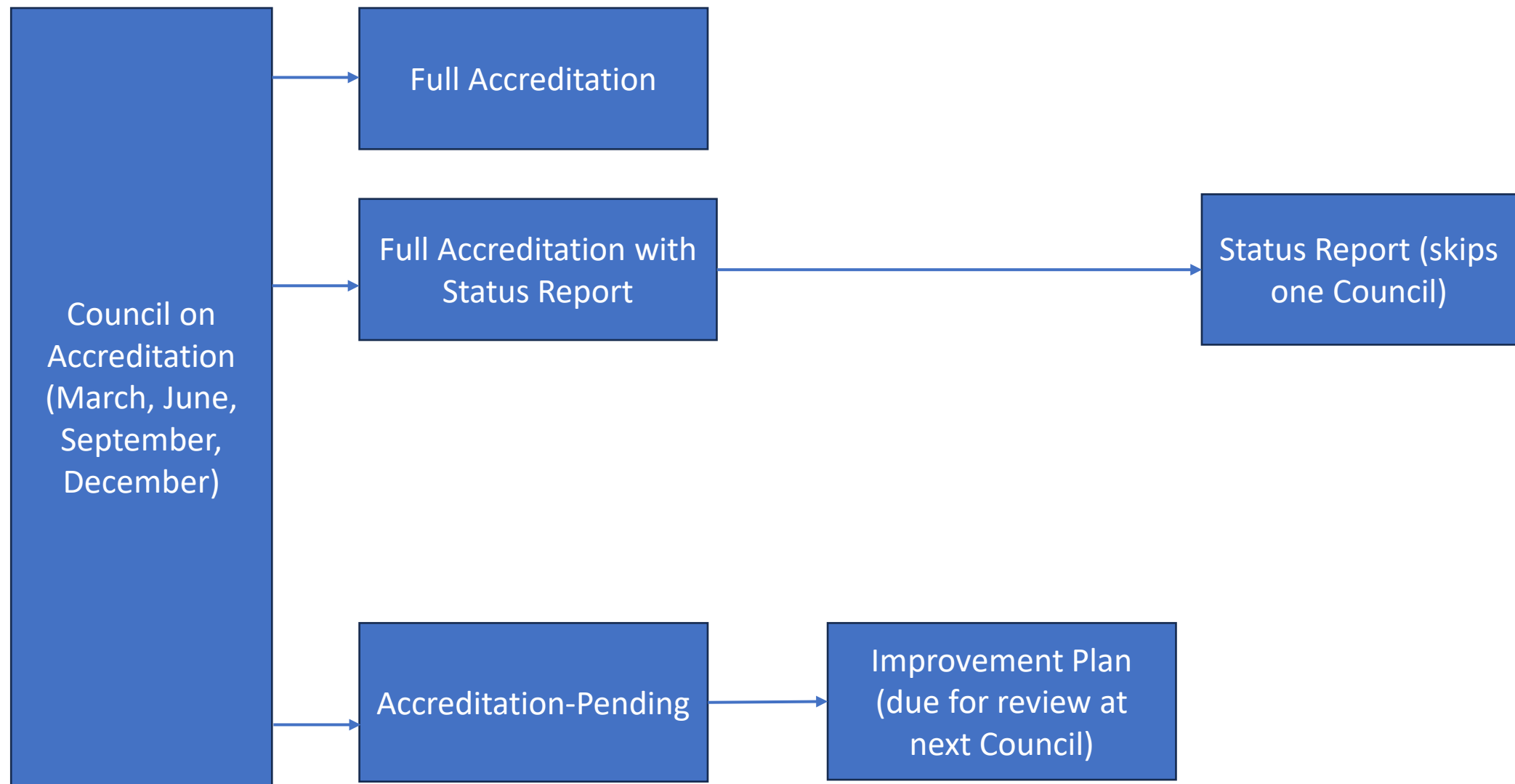
Question: What is the Council on Accreditation's philosophy for how to evaluate HRPPs?

Categories of Accreditation

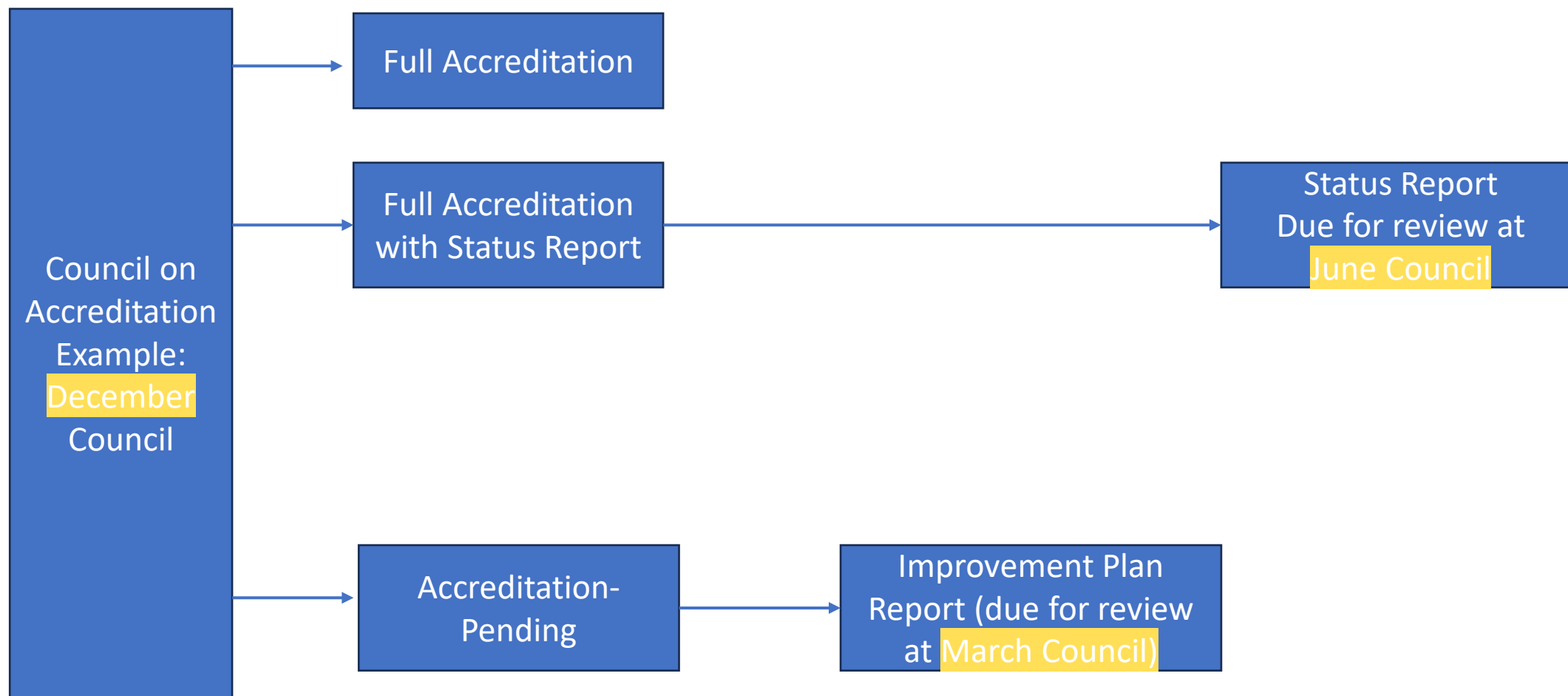
- New applicants
 - Full Accreditation
 - **All Standards Met (May require Status Reports)**
 - Qualified Accreditation
 - **All regulatory Standards met, Some AAHRPP-specific Standards not Met**
 - Accreditation-Pending
 - **Some regulatory Standards not met**
 - Accreditation Withheld
 - **Not common (Organization unable or unwilling to meet AAHRPP Standards)**
- Renewing applicants
 - Full Accreditation
 - **All Standards Met (May require Status Reports)**
 - ~~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 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 meets AAHRPP Standards, Council may place the organization into Reaccreditation-Pending status with request for an Improvement Plan. Reaccreditation-Pending status is confidential, and the organization's name stays on AAHRPP's website.

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?

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

Robert Hood, Ph.D.

Director of Accreditation and Global Development

rhood@aahrpp.org

Questions about the application process:

Jemelle Williams, BS, PMP

Assistant Director of Operations

jwilliams@aahrpp.org

