



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

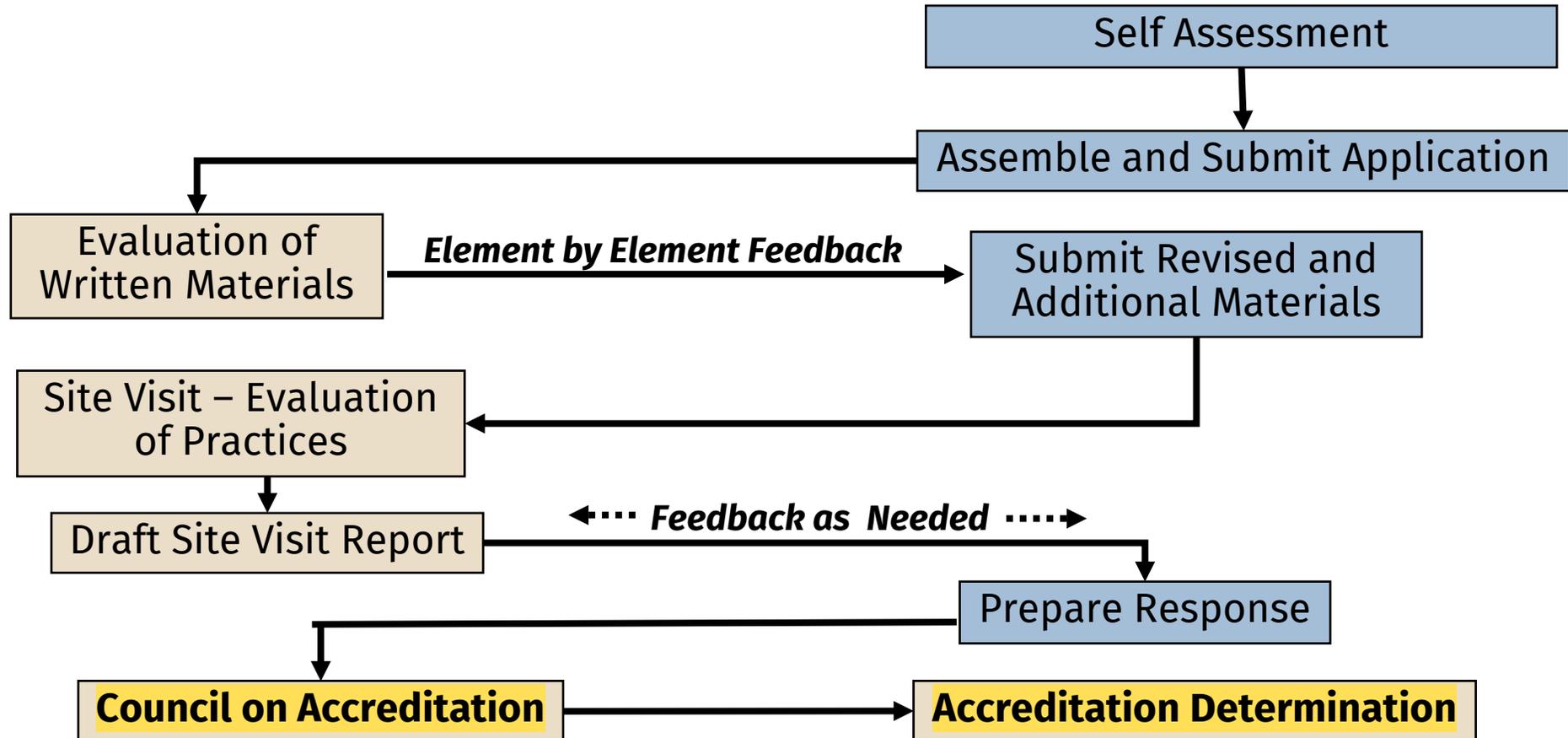


# Council on Accreditation Review

<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>

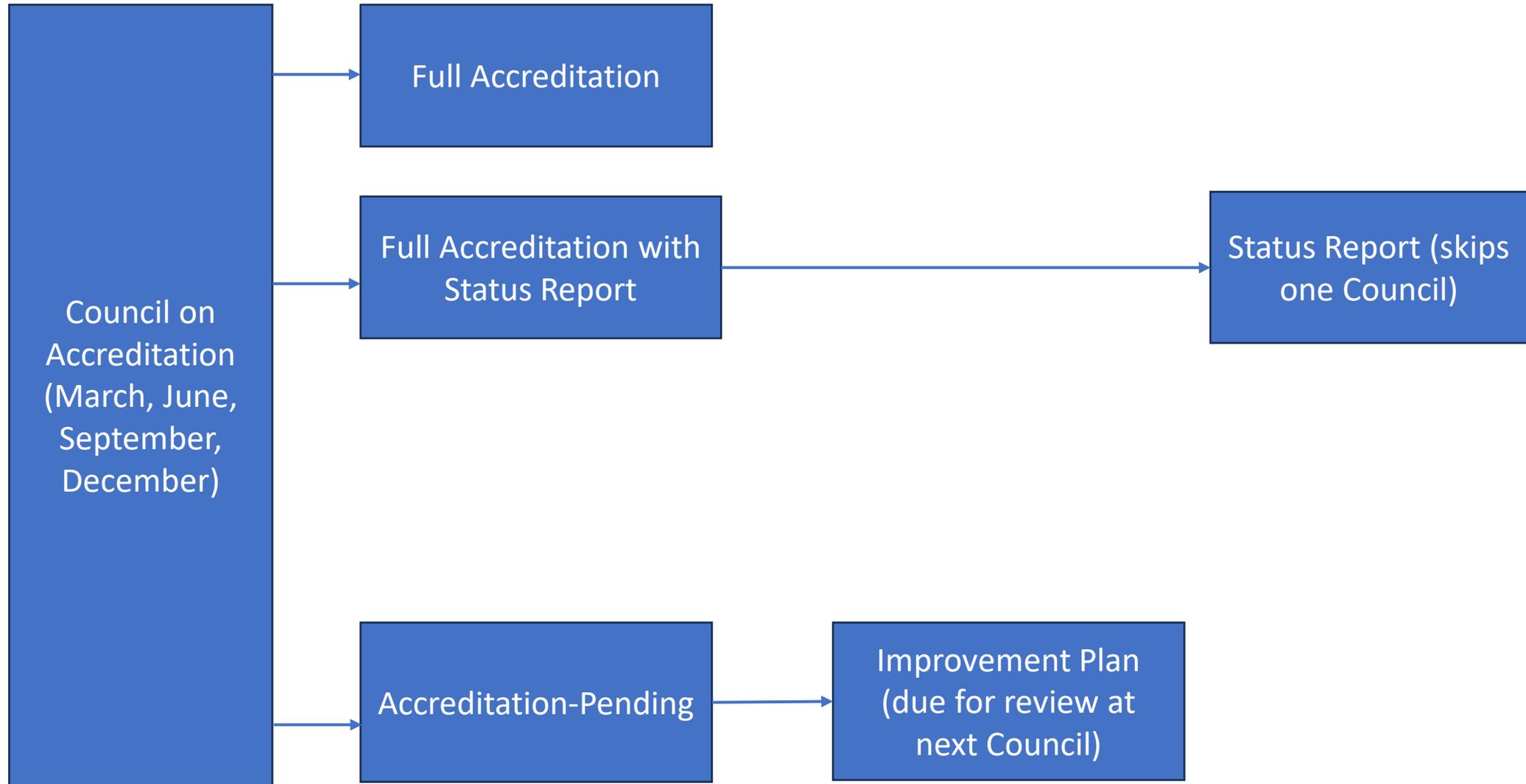
**Question: What is the Council on Accreditation's philosophy for how to evaluate HRPPs?**

# Categories of Accreditation

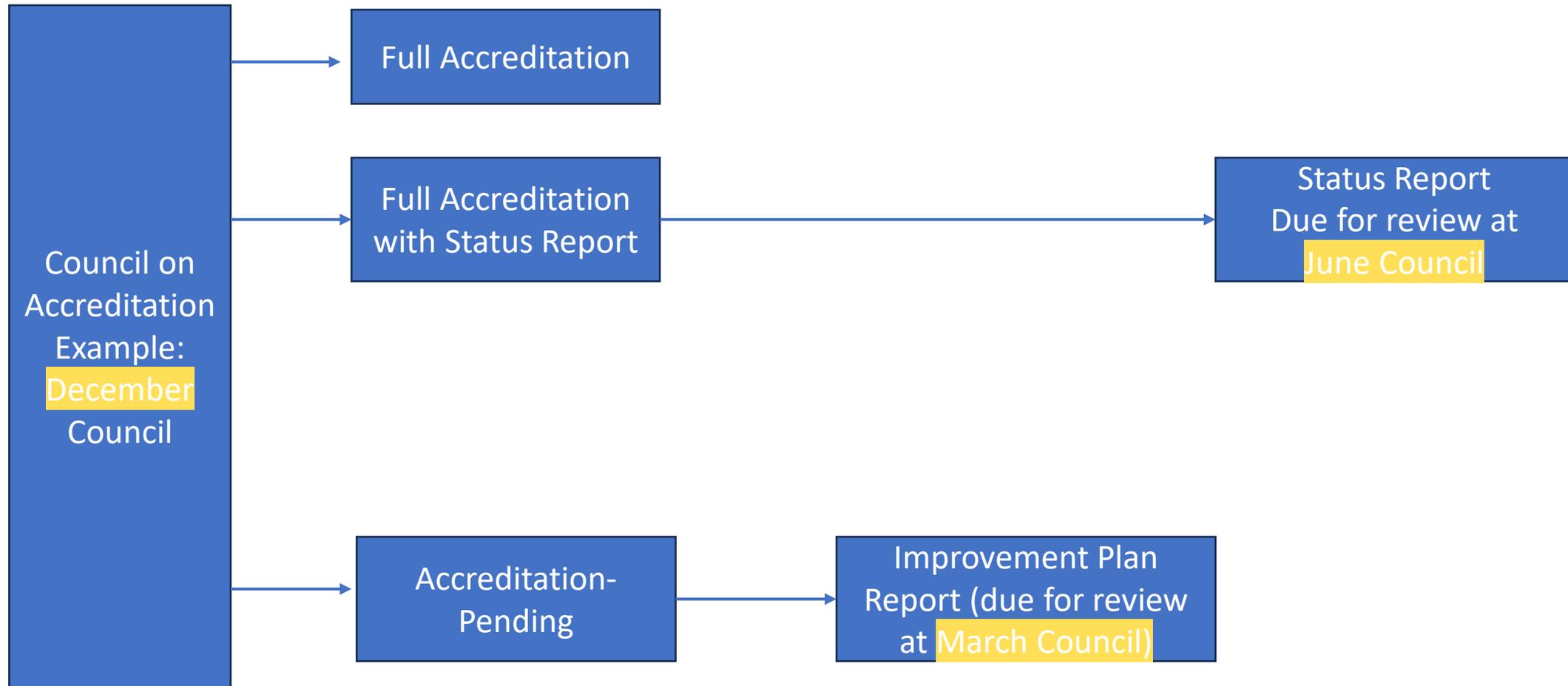
- New applicants
  - Full Accreditation
    - **All Standards Met (May require Status Reports)**
  - Qualified Accreditation
    - **All regulatory Standards met, Some AAHRPP-specific Standards not Met**
  - Accreditation-Pending
    - **Some regulatory Standards not met**
  - Accreditation Withheld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

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