AAHRPP

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

December 10, 2024

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

Presenters

- Heather Bridge
  - Director Policy & Accreditation, Office of Human Subjects Research Protections, Office of the Director, National Institutes of Health
- Megan Kasimatis Singleton
  - Associate Dean for Human Research Protections and Director of the Human Research Protections Program at Johns Hopkins University School of Medicine, and vice chair for the AAHRPP Council on Accreditation
- Robert Hood
  - Director of Accreditation and Global Development, AAHRPP

Moderator

- Lori Kravchick
  - Director of Administration, AAHRPP

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

What is “Ask AAHRPP”?

- Bimonthly (six times per year) webinar 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

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

FYIs

- Please provide feedback by completing the survey
- A link to the webinar will be sent to those who registered for the session when it is posted
  - Including links to prior “Ask AAHRPP” sessions
- If you have any questions during the session, please use the Q&A icon to submit them

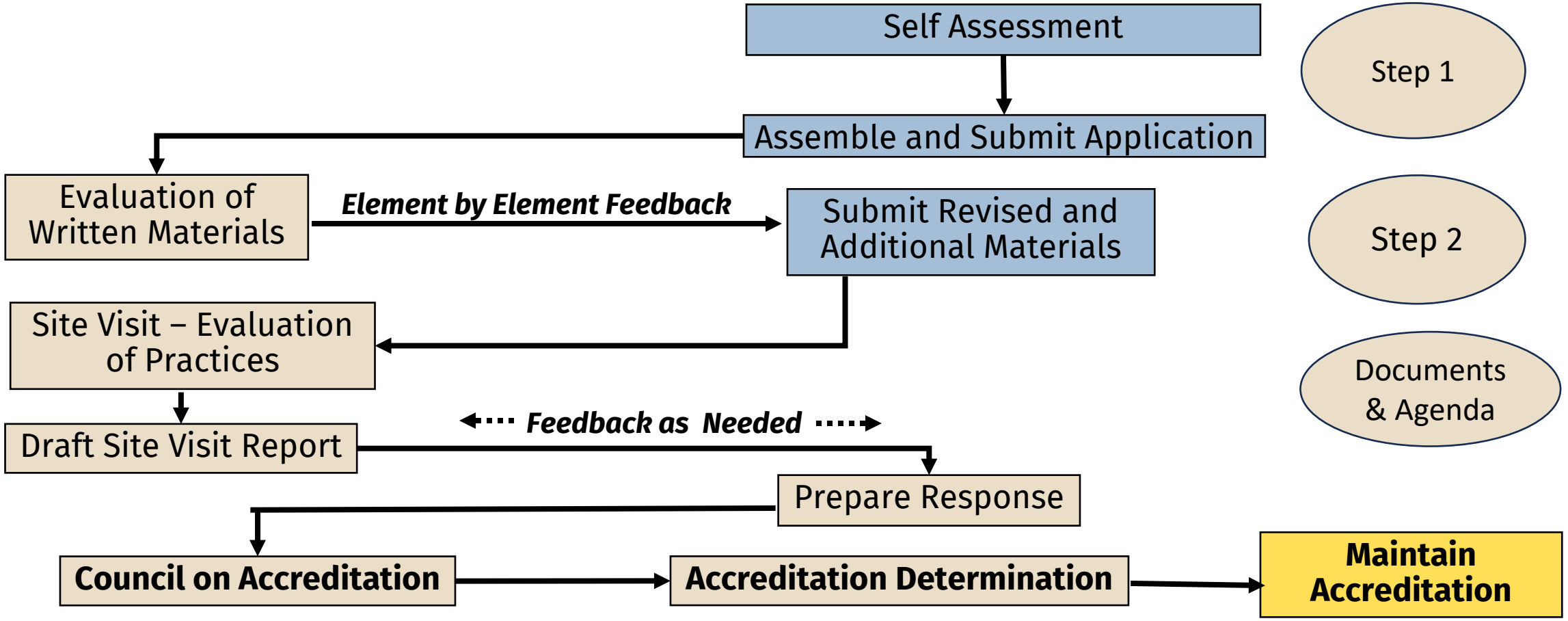
AAHRPP
Association for the Accreditation of Human Research Protection Programs, Inc.®

Maintaining Accreditation

https://aahrpp.org/accreditation/maintain-accreditation/applying-for-reaccreditation

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

Accreditation Process



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

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

Maintaining Accreditation Learning Objectives

- Respond to Council on Accreditation requests
  - Status Reports
- Understand the difference between AAHRPP's three reporting requirements:
  - Annual Reports – submit **yearly**
  - Notification of substantive program changes – submit **within 30 days**
  - Notification of other reportable events – submit as soon as possible but **within 48 hours**
- Course review – examples of the Step 1 report, Draft Site Visit Report, and Council's final report

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

Responding to Council Requests

- Council may request confirmation that program improvements continue to be implemented with:
  - Status Reports
  - Improvement Plans
- Three key elements of a Status Report or an Improvement Plan:
  1) Describe how the change meets the Standard/Element,
  2) Describe any education as a result of the change, and
  3) Describe how the change was/is being monitored
- Review instructions for submitting a Status Report: https://www.aahrpp.org/resources/for-accreditation/additional-resource/instructions-for-preparing-a-status-report

Education: In general, Organizations should provide all the information in items 1-6 below for each Standard or Element for which an Area of Concern was identified	
1. What was the topic of education or training and how does the education or training address the Area of Concern identified? 2. Specify the role of the person(s) who conducted the education or training (e.g., IRB manager, QA manager etc.). 3. Provide a specific date(s) when the education or training occurred. Education or training in general should start prior to sending the Response to the Response to Requests from the Council on Accreditation. 4. Specify who was educated or trained (e.g., IRB members, contracts staff)? 5. Identify any additional education or training planned, if applicable. 6. Attach supporting documentation (e.g., list of persons educated or trained, dates when education occurred, agenda for education or training sessions).	<u>Example:</u> *To address the request for a status report to confirm planned education had been completed, documentation that education was provided for staff who write minutes, and the IRB chair and IRB members, on substantive versus minor changes. Four sets of minutes (all IRB meetings since the Council request) were monitored, and confirm education was effective, and that substantive changes are now returned to the convened IRB.* <u>Examples of supporting documentation:</u> Document 1: List of EC members who completed education (page xx) Document 2: Confirmation of education of chairs and staff (page xx) Document 3: Agenda for education sessions (page xx) Document 4: Copies of relevant sections minutes showing requests for major and minor changes, and that major changes (substantive changes) are being returned to the convened IRB for approval.

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

Purpose of Annual and Other Notification Reporting

- To notify AAHRPP of the status or changes related to the organization's Human Research Protection Program (HRPP)
  - AAHRPP staff will review the Annual Report to determine whether any action is indicated.
  - In some circumstances, the Council on Accreditation will be advised of the status of an organization and be asked to determine whether further action is needed, such as additional reporting or a Limited Site Visit.
- **Did you know?** Information collected from Annual Reports is used as the basis for metrics
- Learn more about all AAHRPP reporting requirements in the Accreditation Procedures:

  https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting

Annual Reports – Inform AAHRPP about Organizational changes

For example, changes in:

- Entity type or corporate structure
- Name of the Organization
- Ownership or control of the Organization (e.g., from mergers or acquisitions)
- Leadership or governance of the Organization (e.g., President or Chief Executive Officer)
- The organizational official
- Leadership of the HRPP (i.e., the individual responsible for the day-to-day operation)
- The application contact

https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting

Annual Reports – Inform AAHRPP of Any Changes in Resources

For example, significant:

- Change (10% or more) in active research protocols or research portfolio
- Change (10% or more) in resources in the past 12 months and the consequences to the HRPP (e.g., reduction in staffing, addition or dissolution of a committee or other function)

https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting

Annual Reports – Notify AAHRPP of Any Changes in Program Scope

For example,

- Addition of new research program, such as a type of research not previously conducted or reviewed by the Organization (e.g., planned emergency research, research involving children, or gene transfer research)
- Addition, removal, or modification of functions, committees, or IRBs/ECs.

https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting

When Are Annual Reports Due?

- Due yearly based on when your organization was awarded accreditation, for example:
  - Accreditation in September 2024 – Annual Report due in September 2025
  - Reaccreditation in December 2024 – Annual Report due in December 2025
- You **do not** have to submit an Annual Report the year your accreditation Step 1 application is due nor the year that your accreditation package is reviewed at Council. For example,
  - If your Step 1 Application is due December 2024, then you will not need to submit an Annual Report in December 2024 nor in December 2025.

How to Submit the Annual Report

- AAHRPP will send a reminder approximately 60 days before your Annual Report is due.

- Annual Reports are submitted via a SurveyMonkey link
  - Check your spam and junk folder

- Review most recent the Annual Report Guidance:
  - https://www.aahrpp.org/resources/for-accreditation/additional-resource/annual-report-guidance

Coming Soon – Online Accreditation system

Annual Reports – Notify AAHRPP of Any Other Changes

For example,

- Changes in method of providing services, such as use of external IRBs or contracting for services from another organization
- Catastrophic event that results in an interruption or discontinuance in a part of or the entire Human Research Protection Program

https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting

What Happens if We Do Not Submit the Annual Report?

Failure to submit an Annual Report within 30 days of the due date may result in revocation of accreditation.

https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting

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

Other Notifications To AAHRPP

- Use the AAHRPP Reporting Form to notify AAHRPP of:
  - Major program changes **within 30 days**
  - Prompt reporting of other critical events as soon as possible but **within 48 hours**

Reporting Major Organizational Changes

For example, promptly report a change:

- In corporate structure
- Of ownership or leadership
- Of legal organization name

- Use the Reportable Events Form

https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting

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

Reporting Major Events

An Organization must report any of the following to AAHRPP - within 48 hours

- Negative actions by a government oversight office
- Litigation, arbitration, or settlements
- Negative press coverage

Use the Reportable Events Form submit to: reporting@aahrpp.org

https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting

Report as Soon as Possible, but Within 48 Hours

- Any negative actions by a government oversight office (e.g., OHRP Determination Letters, FDA Warning Letters, FDA 483 inspection reports with Official Action Indicated (OAI), FDA restrictions placed on IRBs or Investigators), or any corresponding compliance actions taken under non-US authorities related to human research protections
- Any litigation, arbitration, or settlements initiated related to human research protections
- Any negative press coverage (including but not limited to radio, TV, newspaper, online publications) regarding the Organization's HRPP

Unsure Whether to Report?

Please contact AAHRPP at reporting@aahrpp.org

Summary

Negative Government Actions

48 Hours

- OHRP Determination Letters
- FDA Warning Letters
- FDA 483 Official Action Indicated
- FDA Restrictions on IRBs or Investigators,
- Compliance actions taken by non-US authorities

Legal Issues Related to HRPP

48 Hours

- Litigation
- Arbitration
- Settlements

Negative Press Coverage Related to HRPP

48 Hours

- Radio
- TV
- Newspaper
- Online Publications

Major Organizational Change

30 days

- Name Change
- Change in Corporate Structure
- Change of Ownership or Leadership

How it all fits together

2024 sessions described the entire process from self-assessment to review by Council.

- The following examples review the process (Step 1 Report > Draft Site Visit Report > Response and Council determination)
  - **Step 1 Report** – the review of written materials to ensure they meet AAHRPP requirements, laws, regulations, and guidance
  - **Draft Site Visit Report (DSVR)** – observations and/or areas of concern based on interviews and review of documents during the site visit
  - **Response and Final Site Visit Report** – after the site visit, organizations have an opportunity to respond to the DSVR; the DSVR and the organization's response is reviewed by Council

Review of three examples

- **Domain I:** Emergency preparedness and response to ensure continuity of operations to ensure protection of human participants during an emergency (Element I.1.H.)
  - **Step 1** required creation of policies; site visitors observed people were not knowledgeable; the response confirmed protections are now implemented
- **Domain II:** IRB/EC members consider the ethical criteria for approval of research, and determine the criteria are met (Standard II-3)
  - **Step 1** found policies were acceptable; site visitors observed people were not knowledgeable; and response described improvements and confirmed protections were now implemented in practice; Council requested status report
- **Domain III:** Researchers report conflicts of interests, and conflicts are managed (III.1.B.)
  - **Step 1** found policies were acceptable; site visitors observed researchers were not knowledgeable; the response showed improvements had started but were not complete; Council requested status report

Step 1 Report - Emergency Preparedness and Response

- Add to written materials:
  - An emergency preparedness and response plan, which addresses how continuity of operations will be maintained to ensure human participant protections during an emergency.
- Describe in written materials:
  - The process to evaluate the emergency preparedness and response plan. The description may include, for example:
    - Who is responsible for conducting the evaluation.
    - How frequently such an evaluation will occur.
    - The process for using the results, when necessary, to make adjustments to the plan to ensure continuity of operations.
  - The process to provide education about the organization's emergency response and preparedness plan for IRB/EC members and staff, researchers.

Draft Site Visit Report - Emergency Preparedness

Observations

- The organization had an emergency preparedness and response plan that addressed how continuity of operations will be maintained to ensure human participant protections during an emergency.

Areas of Concern

- HRPP staff had **not evaluated** the emergency preparedness and response plan. HRPP staff were not knowledgeable about who was responsible to annually evaluate the emergency preparedness and response plan, what was supposed to be evaluated, and how the results were to be used to make improvements if necessary.
- **Education had not occurred** annually as required in policies. HRPP staff, IRB/EC members, and researchers and research **staff were not knowledgeable** about the specific actions required by their roles required to maintain continuity of operations and protect participants in the event of an emergency. (Element I.1.H.)

Final Site Visit Report - Emergency Preparedness

Areas of Concern

HRPP staff had not evaluated the emergency preparedness and response plan. HRPP staff were not knowledgeable about who was responsible to annually evaluate the plan.

Education of members of the HRPP was planned but had not occurred. HRPP staff, IRB/EC members, and researchers and research staff were not knowledgeable about the specific actions required by their roles required to maintain continuity of operations and protect participants in the event of an emergency. (Element I.1.H.)

Response

The HRPP Director, IRB/EC chairs, and medical director **completed an evaluation** within 30 days. The response described the results of the evaluation, which identified the need to update the plan when staff changed. **Policies were clarified** to indicate the HRPP director is responsible for updating the plan. **Education had been completed** for members of the HRPP.

Council Determination

Standard is met

Step 1 Report - Ethical criteria for approval

Step 1 review determined policies were satisfactory – policies describe the IRB/EC requirements to evaluate and determine whether:

- risks are minimized and risks are reasonable in relation to benefits, if any, in the research
- provisions for monitoring data to ensure safety of participants are adequate
- there are plans for equitable participant selection
- there are adequate provisions to protect the privacy interests of participants and the confidentiality of data
- whether the process and plan for documentation of consent met regulatory criteria

Draft Site Visit Report - Ethical Criteria for approval

Areas of Concern

- A checklist for IRB/EC members to use during IRB/EC meetings to determine the ethical criteria for approval was present; policies required IRB/EC members to complete education prior to joining the IRB/EC.

Areas of Concern

- IRB/EC members were not knowledgeable about ethical criteria for approval of research. For example, members could not describe the need to evaluate whether risks were minimized and risks were reasonable, and did not consider different kinds of risks (e.g., social, behavioral, economic risks). Members did not discuss ethical criteria during IRB/EC meetings. Members were not knowledgeable about and did not use the checklist.

Final Site Visit Report - Ethical criteria for approval

Areas of Concern

IRB/EC members were not knowledgeable about ethical criteria for approval of research. For example, members could not describe the need to evaluate whether risks were minimized and risks were reasonable, and did not consider different kinds of risks (e.g., social, behavioral, economic risks). Members did not discuss ethical criteria during IRB/EC meetings. Members were not knowledgeable about and did not use the checklist.

Response

IRB/EC members **completed 20 hours of education** on the ethical criteria for approval. The HRPP Director, IRB/EC chairs, and medical director, who were newly to their positions in the last six months after staff departed, **completed 20 extra hours of education**. At the time of the site visit the organization had approximately 200 studies. 50 studies were re-reviewed within 30 days. 150 studies were transferred to accredited external IRBs/ECs for re-review within 30 days. Four compliance and quality assurance staff vacancies were filled with experienced staff from accredited organizations. **Auditing** of all studies and IRB/EC applications and meeting minutes in the last year (since the last continuing review) was started, with a plan to complete the audits within 60 days.

Step 1 Report - Researcher conflict of interest

The Step 1 review determined policies were satisfactory. Policies describe:

- the criteria and process for researchers and research staff to disclose conflicts of interest annually and to confirm disclosures upon submission of each new research study.
- the process to determine whether disclosed interest constituted a financial interest. Policies described how conflicts would be managed, and the communication of management plans to the IRB/EC.

Draft Site Visit Report - Researcher conflicts of interest

Areas of Concern

Researchers were generally not knowledgeable about criteria requiring disclosures of potential conflicts of interest.

Researchers and research staff were generally not knowledgeable about requirements to complete a conflict of interest disclosure form.

Some researchers reported their staff might complete conflict of interest disclosure forms on their behalf when submitting IRB/EC applications.

In practice, conflicts of interest were not identified or managed.

Final Site Visit Report - Researcher conflict of interest

Response

Four hours of continuing **education was completed** within 30 days for all researchers and research staff and IRB/EC members and staff on requirements for disclosure of conflicts of interest in research.

Policies were reviewed, and IRB/EC staff created a worksheet to confirm conflict of interest disclosures were complete.

Researchers started to complete disclosures for all research (including approved studies), with a plan to complete all disclosures within 30 days. IRB/EC review of any studies with a conflict of interest were planned to be completed within 60 days to ensure conflicts were appropriately managed. Compliance auditors, who had not previously assessed conflict of interest disclosures, started to include **monitoring** of conflict of interest disclosures, and had completed 30 audits, and planned to audit the remainder of open studies with 60 days.

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

Questions and comments

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) for more information and registration links

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

2025 Accreditation Workshop
May 20, 2025

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

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

Contact AAHRPP

Questions About the AAHRPP Standards/Elements:

Robert Hood, Ph.D.
Director of Accreditation and Global Development
rhood@aahrpp.org

Questions About the Application Process/Timeline:

Jemelle Williams, BS, PMP
Assistant Director of Operations
jwilliams@aahrpp.org