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

Ask... AAHRPP®

June 13, 2023

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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

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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

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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

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Evaluation of Written Materials

Responding to AAHRPP's review of your organization's written materials as described in the "Step 1 Report"

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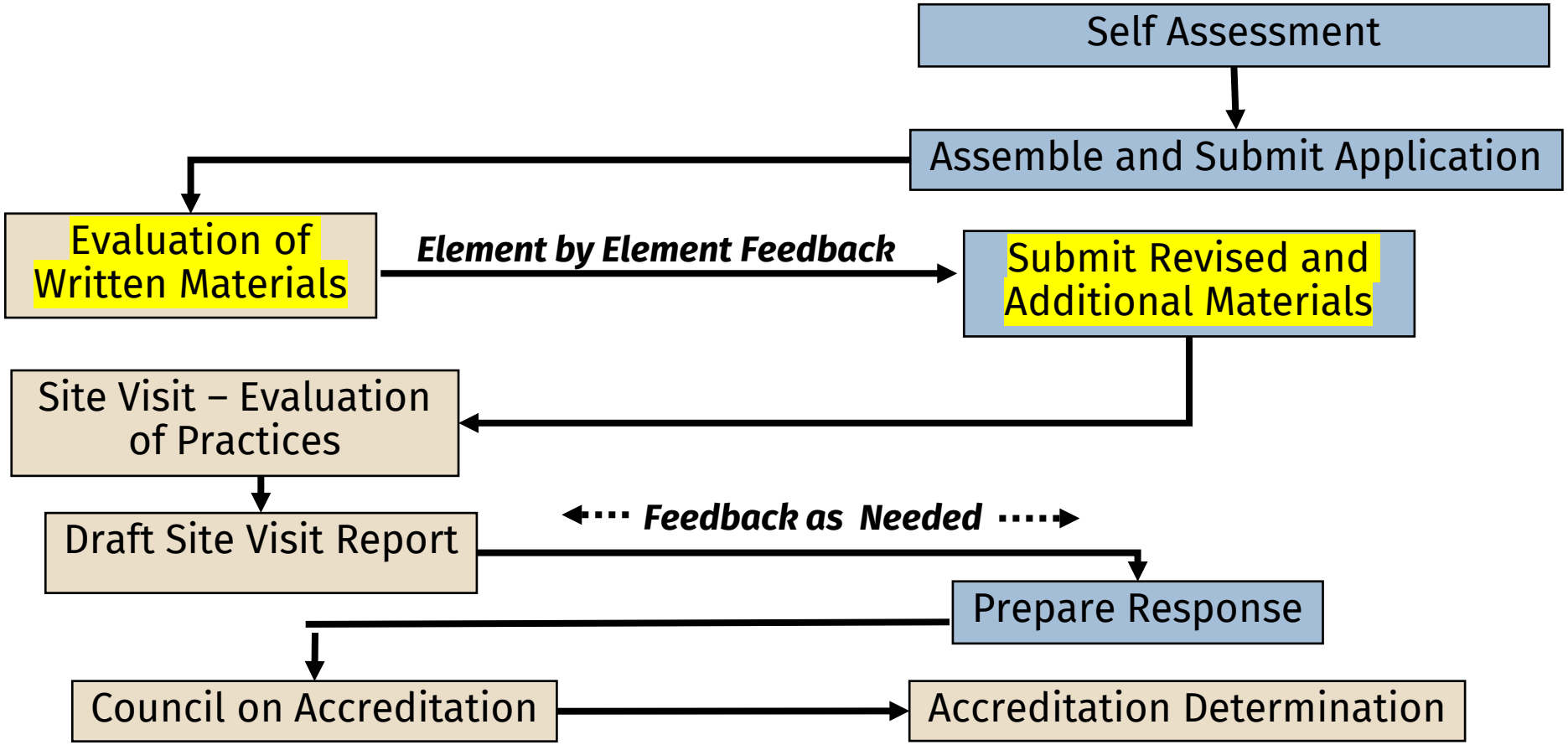
Accreditation Process



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

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Evaluation of the Step 1 Application

- Peer reviewers are from AAHRPP-accredited organizations review the initial application or have prior experience with AAHRPP accreditation
  - Reviewers are trained to recognize that different organizations may adopt different approaches to meeting AAHRPP Standards, which can all be acceptable
- AAHRPP issues a “Step 1 Report” within about 90 days (about 9 weeks) providing Element-by-Element feedback
- Organization’s response / revisions are due in about 40 calendar days (or six weeks)

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What do peer reviewers evaluate?

- *Evaluation Instrument* is used to evaluate all written materials.
- AAHRPP uses the generic term “policies and procedures” to refer to all types of written materials:
  - Standard operating procedures
  - Policy statements, procedures descriptions
  - Checklists, guidelines
  - Forms, templates
  - Job descriptions
  - Applications (screenshots if electronic)
  - Rosters
  - Any other materials used to operate your program
  - Includes all parts of the HRPP: pharmacy policies, contracts, etc.
- See Instructions to Apply for Initial Accreditation and Reaccreditation on AAHRPP’s website:
  - https://www.aahrpp.org/resources/for-accreditation/additional-resource/application-for-initial-accreditation-and-reaccreditation-instructions

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Types of requests in the Step 1 Report

- Add specific information to written materials
  - Copy and paste from the Step 1 Report to your written materials
- Describe a process in more detail
  - Provide additional information
    - Who is responsible; what has to be done; when process occurs; supporting tools (applications, checklists); how the process is evaluated for compliance and quality, efficiency, effectiveness
- Remove/replace information that is inconsistent with requirements in the Evaluation Instrument
  - Example: Delete obsolete information (e.g., based on requirements in prior Common Rule)
- Reconcile inconsistent information

Example: Add information…

- If specific information is missing from your application, the Step 1 Report will ask you to:

- Add to the policy, “Ethics Committee Operations Policy” (page 357):
  - The organization grants the IRB the authority:
    - To observe, or have a third party observe, the consent process and the conduct of the research.

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Response to request for Element I.1.C.

Attach the revised policy, with changes highlighted:

The research ethics committee manager is responsible for ensuring the implementation of the following:

1. The research ethics committee has authority
2. To approve, require modifications to secure approval, and disapprove all research activities overseen and conducted by the organization.
3. To approve, require modifications to secure approval, and disapprove all research activities overseen and conducted by the organization.
4. To suspend or terminate IRB approval of research not being conducted in accordance with the IRB's requirements or that had been associated with unexpected serious harm to participants.
5. To observe, or have a third party observe, the consent process and the conduct of the research.
6. To have final authority to approve researcher and research staff conflict of interest management plans. (See conflict of interest policy)

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Example: Describe in written materials…

If the written materials do not address Elements I.5.A. and I.5.B., the Step 1 report will ask you to:

Describe in written materials: A quality improvement plan that periodically assesses compliance of the HRPP.

- State the goals of the quality improvement plan with respect to achieving and maintaining compliance.
- Define at least one objective to achieve or maintain compliance.
- Define at least one measure of compliance.
- Describe the methods to assess compliance and make improvements.

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Response: Description of a process for Element I.5.A. and Element I.5.B.

Attach revised policy for Elements I.5.A. and I.5.B.

Annually in March, the HRPP Director, the Associate Director, and the Quality Assurance Manager and IRB/EC chair(s) are responsible for:

- Identifying at least one objective for to ensure the effectiveness of the compliance program, as determined by the group
  - Identifying at least one measure of the effectiveness of the compliance program
- Identifying at least one objective for enhancing quality, efficiency, or effectiveness, based on needs identified by the group.
  - Identifying at least one measure of quality or efficiency or effectiveness
- The HRPP Director records the objectives and goals in the QA Worksheet
- The HRPP Director schedules a meeting quarterly in June, September, December, and March to review the results and identify whether program improvements are needed and records the results in the QA worksheet.
- Examples of compliance goals include:
  - 100% of minutes document whether a change is a minor change or a major change
  - 100% of continuing review applications are submitted on time
- Examples of assessing quality, efficiency and effectiveness include:
  - IRB members are knowledgeable about ways of identifying and managing conflicts of interest
  - Time from application to submission to approval will be less than described in AAHRPP metrics

(Note goals are not in policy – policy describes a process)

Example: Remove/Replace…

Example II.2.E.: If policies still require continuing review for minimal risk research eligible for the expedited procedure (prior to the 2018 Common Rule), the Step 1 Report will ask you to:

- Remove the following statement from the policy, “Continuing Review” (page 437): “When following DHHS regulations, continuing review is required for all research.”
- Describe in the policy, “Continuing Review”: When the IRB/EC is not required to conduct continuing review, how records will provide a rationale for any decisions to conduct continuing review of research otherwise eligible for review using the expedited procedure.

Response to request to remove/replace for Element I.1.C.

The research ethics committee manager is responsible for ensuring the implication of the following:

- When following DHHS regulations, and for research not otherwise covered by regulations requiring continuing review: Continuing review is not required for minimal risk research.
  - If for some reason the expedited reviewer or convened IRB believes continuing review by the IRB is still required, the reviewer must document in the IRB Electronic System (IRBWise), in the reviewer comment worksheet for expedited review, section II.2. a specific rationale for why continuing review is required.

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Example: Reconcile written materials for Element I.6.B…

If two policies are in conflict, the Step 1 report will ask you to reconcile policies / make them consistent.

Reconcile researcher and research staff disclosure requirements in the policy “Review of conflicts of interest”(1) and the policy “Researcher disclosure of conflicts of interest”(2) and the “Researcher Manual”(3)

- Policy 1 uses a $5000 disclosure threshold for PHS-regulated research
- Policy 2 uses a $10,000 disclosure threshold
- Policies 3 uses a $0 disclosure threshold

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Response to request to reconcile materials for Element I.6.B.

Provide the revised document (e.g., Word file) with changes highlighted

Provide a summary in email:

- Deleted disclosure criteria from Policy 2, and Policy 3.
  - See attached policies with markup showing deletions
- Revised policy 1 to specify that we require a $0 disclosure threshold for financial interests in research
  - See attached policy 1 with markup showing revisions

Tracking revisions to written materials

Use a spreadsheet to track all documents in your HRPP:

- Document Title
- Owner (person responsible for maintaining)
- Version
- Revision date
- Date for the next compliance monitoring / quality, efficiency, effectiveness assessment (e.g., annually)

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Instructions for sending responses

- Detailed instructions provided with Step 1 Report
- Overview:
  - Send one email per Element
    - Or one per Standard 1-2, 1-3, and I-9
  - Send email to:
    - response@aahrpp.org AND
    - Email address of the assigned step 1 reviewer
  - Attach the relevant portion of the revised written materials with changes tracked or highlighted
    - do not paste changes into an email without attaching a document

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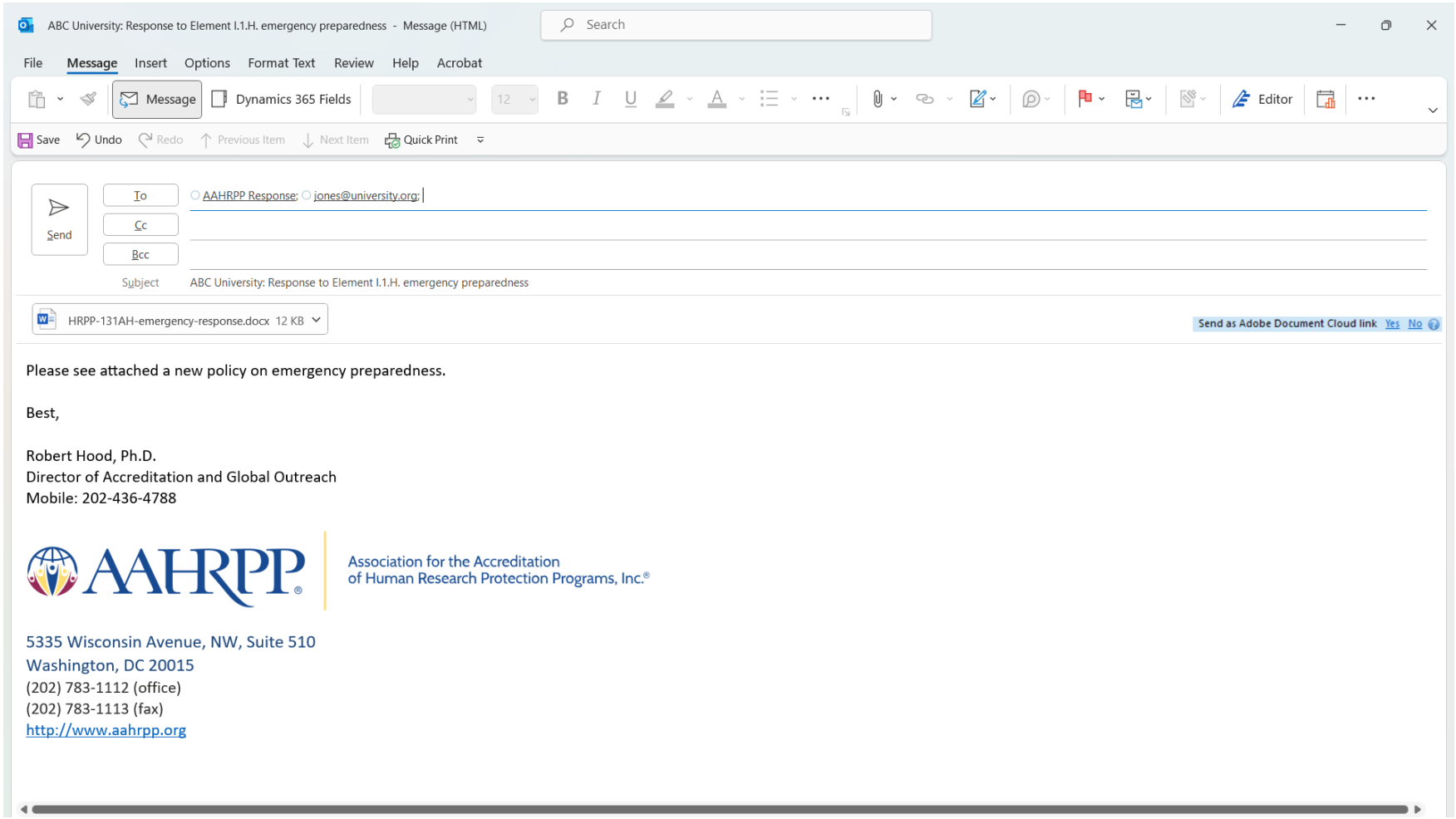
Sample email



Updating written materials

- Send each response as soon as it is completed
  - If you send each response as soon as you complete it, the peer-reviewer can:
    - Confirm that the way you are responding addresses our requests
    - Advise you on whether you can improve your revisions and clarifications to written materials
- Once revised materials are approved, plan education
- Please do not make changes to written materials after they are approved (after the Step 2 application is sent and until after Council review)

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Thank You!

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

- Look for future dates on the AAHRPP website:
  - August 8, 2023: Evaluation of Practice
  - October 10, 2023: Council on Accreditation Review
  - December 12, 2023: Response to Council Review

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- **The Importance of Diversity in Genetic Studies**
- **Omar Abdul-Rahman, MD**, Weill Cornell Medicine & NewYork-Presbyterian Komansky Children's Hospital; **Bruce Gordon, MD**, University of Nebraska Medical Center; **Ivy Tillman, EdD, CCRC, CIP** Director of Research Operations, Mayo Clinic
- **July 26, 2023: 1:00 - 2:30 ET**

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Contact AAHRPP

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Questions about the application process:

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