



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



October 11, 2022



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
- Second Tuesdays continuing in January 2023
- Open and free to everyone
- Recordings available



Looking forward to 2023...

(Tentatively):

- January 10, 2023: Conduct a Self-Assessment
- March 14, 2023: Build and Develop an Application
- June 13, 2023: Evaluation of Written Materials
- August 8, 2023: Evaluation of Practice
- October 10, 2023: Council on Accreditation Review
- December 12, 2023: Response to Council Review



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
- If you have any questions during the sessions, please use the chat function or Q&A function to submit them



Responding to the DSVR

- **Draft Site Visit Reports**
 - **Observations:** Where an organization meets a Standard
 - **Areas of concern:** Where organizations do not meet a Standard



Describe changes

- Were any revisions made to policies and procedures, or to an IRB or HRPP process?
 - For revisions to policies and procedures, highlight the revisions.
 - For revisions to electronic systems, highlight changes to forms, or provide descriptions of what specifically was changed.
 - For revisions to IRB or HRPP processes, describe the process in place at the time of the site visit, and provide detailed comparisons of changes made to the process.
- Describe how the change addresses the area of concern.
- Specify the role of the person(s) who is responsible for implementing the change.
- Provide a specific date(s) when the changes will be implemented. Changes should generally be implemented prior to sending the Response to the Draft Site Visit Report.
- Attach supporting documentation



Example: Description of changes

To address the concern that protocol-specific determinations were not documented when reviewing research involving vulnerable populations, on-line reviewer forms were changed so that the text box for reviewers to provide protocol-specific reasons was required, not optional. The system was revised to require IRB members to complete this information prior to submitting the form. Previously forms could be submitted without these fields being completed. Instructions were added to the form to remind reviewers that these fields must be completed before the reviewer form can be submitted. An error message was created if reviewers submitted forms without required information.

Examples of supporting documentation:

Document 1: Revised forms showing instructions that the fields must be completed prior to submitting the form.

Document 2: Screen shot of a pop-up error message



Describe education

- What was the topic of education or training and how does the education or training address the Area of Concern identified?
- Specify the role of the person(s) who conducted the education or training (e.g., IRB manager, QA manager etc.).
- 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 Draft Site Visit Report.
- Specify who was educated or trained (e.g., IRB members, contracts staff)?
- Identify any additional education or training planned, if applicable.
- Attach supporting documentation (e.g., list of persons educated or trained, dates when education occurred, agenda for education or training sessions).



Example: Description of education

To address the concern that substantive changes were not being returned to the convened IRB or EC, the HRPP manager conducted education for staff who write minutes on September 5, 2022. The HRPP manager started to conduct education on September 15, 2022 for the chair and EC members on substantive versus minor changes, and the requirement that substantive changes be returned for review by the convened EC. Additional education for the chair and EC members is planned for EC meetings in October and November. Education will also occur at an annual retreat scheduled for February 2023.

Examples of supporting documentation:

Document 1: List of EC members who have completed education

Document 2: Confirmation of education of chairs and staff

Document 3: Agenda for education sessions



Describe monitoring

- **Confirm the organization now meets the Standard.** What evaluation or monitoring are you conducting to show this? When there are multiple concerns under a Standard or Element, describe what was evaluated to confirm each meets the Standard.
- Who conducted monitoring to confirm the Standard is now being met in practice and, when applicable, confirming the organization is complying with applicable regulations?
- When did monitoring start to confirm the program meets the AAHRPP Standard? Confirm your organization meets the Standard prior to sending the Response to the Draft Site Visit Report, when possible; otherwise provide a specific timeline of how you will confirm the Standard is met.
- What additional monitoring is planned, if applicable?
- Who reviewed results of the monitoring and assessed whether the education, training, or other actions taken were effective?
- What changes were made, if any, as a result of the monitoring?
- Who will review the results of future monitoring to evaluate whether additional changes, if any, are required?



Example: Description of monitoring

To confirm that when the IRB requests substantive changes they are returned to the convened IRB for approval, the IRB manager conducted retrospective monitoring of IRB minutes for the prior six months to establish a baseline and started to evaluate IRB minutes prospectively beginning with the September 15, 2022 meeting (which was the only meeting that occurred prior to when the Response was due). The IRB manager planned to continue monitoring each set of minutes for six months. The IRB manager and IRB chair met on September 30, 2022 (before the Response was due) to review the monitoring that had occurred so far, and determined that no changes to policies or written materials were required, but that additional education to ensure substantive changes are returned to the convened IRB for approval for staff writing IRB minutes was required.

The IRB manager and IRB chair planned to meet monthly to review ongoing monitoring. The IRB manager and IRB chair planned to meet in six months and determine, based on planned monitoring, if any changes are required.

Examples of supporting documentation:

Document 1: Spreadsheet summarizing retrospective monitoring

Document 2: Copies of relevant portions of minutes demonstrating minutes meet AAHRPP requirements, with relevant portions highlighted



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:
 - January 10, 2023: Conduct a Self-Assessment
 - March 14, 2023: Build and Develop an Application
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Resources

- AAHRPP's website
- Accreditation Procedures
- Evaluation Instrument



Contact AAHRPP

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