Instructions to Prepare a Response to the Draft Site Visit Report

Updated July 17, 2019

I. Reviewing the Draft Site Visit Report

An Organization should review the Draft Site Visit Report for errors in fact and implement changes to its Human Research Protection Program based on the Areas of Concern. Within 30 calendar days of the receipt of the Draft Site Visit Report, the Organization may provide AAHRPP with a written response describing any errors in fact, any corrective actions it has taken in response to Areas of Concern identified by the site visitors, and to report any other changes it has made to its Human Research Protection Program. For each item listed under Areas of Concern, describe the changes you have made or will make. The Council on Accreditation considers those changes when making an accreditation determination.

For Areas of Concern regarding written materials, provide the revised or added materials.

For Areas of Concern regarding practice:

- Include changes to policies or procedures, if any, with revisions highlighted.
- Include an education or training plan for the appropriate people.
  - If education or training has occurred prior to the submission of the response, provide the date(s) it occurred, the individuals who were educated or trained (e.g., IRB members or researchers), and a summary of the content of the education or training (e.g., syllabus, agenda, minutes, or table of contents).
  - If education or training has not occurred, indicate the date it will begin. Generally, the Council on Accreditation expects education and training to begin within 20 business days of the receipt of the Draft Site Visit Report (i.e., during the period while you are drafting your response), and no later than by the date of the Council meeting.
- Include monitoring related to the Area of Concern to demonstrate the change in practice to meet the Standard.
  - If monitoring is completed prior to the submission of the response, provide a summary of the results of the monitoring in narrative or statistical form. Do not submit names of researchers or protocols.
  - If monitoring has begun but was not completed or is planned, provide the plan for monitoring. Generally, the Council on Accreditation expects monitoring to begin within 30 days of the receipt of the Draft Site Visit Report (i.e., during the period while you are drafting your response), and no later than by the date of the Council meeting.
- Include evidence of implementation of practice of revised policies and procedures since the site visit (e.g., required language in contracts and funding agreements, evaluation and feedback of IRB members and chairs).
- Include other strategies to improve practice, when appropriate.

For Areas of Concern regarding knowledge:

- Include an education or training plan for the appropriate people.
  - If education or training has occurred prior to the submission of the response, provide the date(s) it occurred, the individuals who were educated or trained (e.g., IRB members, researchers), and a summary of the content of the education or training (e.g., syllabus, agenda, minutes, or table of contents).
  - If education or training has not occurred, indicate the date it will be begin. Generally, the Council on Accreditation expects education or training to begin within 30 days of the receipt of the Draft Site Visit Report (i.e., during the period while you are drafting your response), and no later than by the date of the Council meeting.

If you do not plan to educate or monitor in response to an Area of Concern, provide an explanation why education or training and monitoring are not appropriate to address the deficiencies in practice or knowledge.

Communication with AAHRPP staff is strongly encouraged during the time of preparing the response. The AAHRPP staff can be contacted at (202) 783-1112.

II. Preparing the Response to the Draft Site Visit Report

A Response to the Draft Site Visit Report should include the Submission Form and the following two sections:

Section A: Response
Section B: Supporting Documents

Section A: Response

For each item listed under Areas of Concern, provide a written response. Begin your response with a brief summary of the changes, followed by a list of the revised documents submitted. Identify the Element or Standard with which each response is associated. Below is a sample response in a suggested format.

In your response refer the supporting documents in Section B. Identify the document number and point out the relevant sections, pages, paragraphs, or lines to make it easy for AAHRPP staff and site visitors to locate in Section B the information that supports your Organization's response.

Section B: Supporting Documents

Section B should include a copy of each supporting document ordered by reference number. Include only one copy even when the document supports multiple Elements or Areas of Concern. Use highlighting or track changes to point out specific revisions. Use highlighting or track changes to indicate revisions to previously submitted documents.

III. Helpful Hints

Your response to the Draft Site Visit Report should include all of the following:

1) How you have changed or addressed a process in order to meet the Standard or Element.
2) How and whom you have educated about this change.
3) How you will monitor that the change has been effectively implemented and is being carried out.

If you do not intend to address one (or all) of the three items listed above, you should explain your reasoning in your response.

Sample Documentation of a Response

This sample is intended to show the range of actions that might be taken and how they can be documented. This sample is not meant to imply that this range of actions is required for every response to every Element. This example is provided solely to illustrate the requested style of a response. For your organization, the specific steps listed may be incomplete, inappropriate, or irrelevant. If you want, you can use the Draft Site Visit Report as follows to create a response, but this is not required.

Element II.1.B. The IRB or EC has qualified leadership (e.g., chair and vice chair) and qualified members and staff. Membership and composition of the IRB or EC are periodically reviewed and adjusted as appropriate.	*Areas of Concern:* No one evaluated the IRB chair or IRB members and provided feedback. Response: IRB policies and procedures were revised to designate that the IRB chair will annually evaluate each IRB member and provide feedback in face-to-face meetings. The Vice President for Research was designated to annually evaluate the IRB chair and provide feedback in a face-to-face meeting. Evaluation tools for IRB members and the IRB chair were developed. The IRB members were made aware of the criteria for evaluation at the March 1 IRB meeting. IRB members were evaluated and provided feedback during March. The IRB chair was evaluated on March 31 and provided feedback. A summary of the evaluations and actions that took place as a result is attached. • Document 14, IRB SOP, Page 47, Section X.3.a describes the annual evaluation of the IRB members by the IRB chair. • Document 14, IRB SOP, Page 48, Section X.3.b describes the annual evaluation of the IRB chair by the Vice President for Research. • Document 15, Evaluation Tool for IRB Members • Document 16, Evaluation Tool for IRB Chair • Document 17, Minutes of the March 1 IRB Meeting indicating the education and training session on IRB member responsibilities and evaluation. • Document 18, Summary of the Evaluation of the IRB Members and IRB Chair

III. Submission

Please refer to the Instructions for Submitting Materials in Support of Accreditation for information on assembling and submitting the Response to the Draft Site Visit Report.

Please contact the AAHRPP staff at (202) 783-1112 if you have questions related to submitting a Response to the Draft Site Visit Report.