AAHRPP®

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

Instructions to Prepare an Improvement Plan

Updated December 15, 2015

I. Instructions for an Improvement Plan

An Improvement Plan should provide a point-by-point response to each Standard that is marked as "Standard is not met." You will find Areas of Concern that indicate the deficiencies in meeting the Standard. Describe the corrective actions you have made or plan to make. If you are unable to respond to all the Areas of Concern by the time the Improvement Plan is due, provide your plan for meeting the remaining Areas of Concern and a timeline indicating when they will be addressed.

For Areas of Concern regarding practice:

- Include changes to policies or procedures, if any.
- Include an education or training plan for the appropriate people.
  - If education or training has occurred prior to the submission of the Improvement Plan, 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. The Council on Accreditation expects education or training to begin as soon as possible.
- Include monitoring related to the Area of Concern to demonstrate the change in practice has occurred in order to meet the Standard or Element.
  - If monitoring is completed prior to the submission of the Improvement Plan, 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 is not completed or is planned, provide the plan for monitoring. The Council on Accreditation expects monitoring to begin as soon as possible. Include evidence of implementation of practice of revised policies and procedures (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 plan for the appropriate people.
  - If education or training has occurred prior to the submission of the Improvement Plan, provide the date(s) it occurred, the individuals who were educated (e.g. IRB members, researchers), and a summary of the content of the education (e.g., syllabus, agenda, minutes, or table of contents).
  - If education has not occurred, indicate the date it will begin. The Council on Accreditation expects education to occur as soon as possible.

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

II. Preparing an Improvement Plan

An Improvement Plan should include the Submission Form and the following two sections:

Section A: Improvement Plan
Section B: Supporting Documents

Section A: Improvement Plan

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.

Below is an example of an Improvement Plan for Element I.1.D: The Organization has and follows written policies and procedures setting forth the ethical standards and practices of the Human Research Protection Program. Relevant policies and procedures are made available to Sponsors, Researchers, Research Staff, research participants, and the Institutional Review Board or Ethics Committee, as appropriate.

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. Assembly and Mailing

Please refer to the Instructions for Submitting Materials in Support of Accreditation for information on assembly and submitting the Improvement Plan.

Please contact the AAHRPP staff at (202) 783-1112 if you have any questions related to submitting an Improvement Plan.