Instructions to Apply for Initial Accreditation and Reaccreditation

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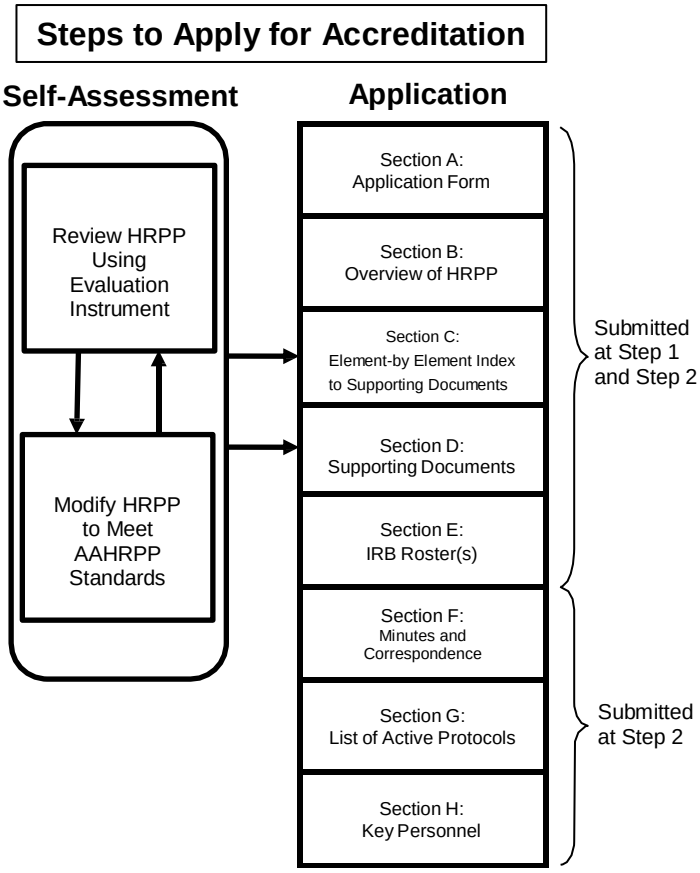
I. Overview

The application process for an Organization involves a self-assessment followed by a two-step application process.



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The self-assessment is a critical introspection of your Human Research Protection Program in which you evaluate your program according to each Element of the Accreditation Standards. Once you have submitted a Step 1 Application for Accreditation, AAHRPP staff will evaluate your policies and procedures according to the Accreditation Standards. After AAHRPP staff determines that your policies and procedures satisfy the Accreditation Standards, you will submit a Step 2 Application for Accreditation and a site visit will be conducted.

If you are applying for reaccreditation, the process is the same as the initial accreditation process. The reaccreditation application forms ask some additional questions regarding changes in the last year, which are not in the initial application form.

II. Conduct a Self-Assessment of the Human Research Protection Program

See the AAHRPP website for instructions on How to Conduct a Self-Assessment.

Separately consider and address each Element of the Accreditation Standards. Review the Element in the Evaluation Instrument for Accreditation. Use the Commentary section to gain an understanding of the Element. Consider the following questions, and if needed, take steps to improve your program:

- Do you have the Required Written Materials?
- Do you follow the practice described in the Required Written Materials?
- Do your activities achieve the Outcomes?

During your self-assessment you create a list of supporting documents, which will become Section C of your application, and submit copies of those documents as Section D. As you are conducting the self-assessment, revise your policies and procedures as necessary so that they meet the Elements, and implement any changes so that your policies and procedures match your practice. The success of your application is dependent on the depth of your self-assessment and on the actions you take to improve your Human Research Protection Program.

Make a List of Supporting Documents

For each Element, collect the policies and procedures that describe the practices your Human Research Protection Program follows to meet the Element, or indicate that the Element is not applicable to your Human Research Protection Program. When available, collect documents that verify that your Organization follows those practices. Most Elements can be supported by one to five documents. Some Elements will not have any supporting documents. In general, no more than 10 documents are necessary.

AAHRPP uses the generic term "policies and procedures" to refer to all types of written materials. Policies and procedures include any written materials that your Organization uses to define and communicate its practices, such as standard operating procedures, policy statements, procedure descriptions, checklists, guidelines, educational materials, job descriptions, memoranda, forms, templates, strategic plans, websites, charters, and mission statements. Policies and procedures are not limited to IRB policies and procedures; other organizational procedures are relevant, such as some policies related to human resources, pharmacy, contracting, student orientation, corporate compliance, or corporate ethics.

Include among supporting documents:

- Application forms
- Reviewer checklists
- Consent templates
- Organizational chart for the Human Research Protection Program
- Organizational chart for the overall Organization
- Template letters (e.g., approvals, contingent approvals, disapprovals, lapse of approval)

Do not include as supporting documents:

- Budgets
- Educational materials
- Employee manuals
- Faculty handbooks or bylaws
- Medical staff handbooks or bylaws
- Policies, procedures, and forms related to HIPAA
- Publicly available documents (e.g., Belmont Report, regulations, OHRP guidance)
- Resumes and curriculum vita
- Scientific misconduct policies
- Slide presentations
- Software manuals
- Websites or materials created by another organization
- Websites that duplicate documents provided in another form

Construct an Element-by-Element Index to the Supporting Documents

List the supporting documents for each Element. Reference the document number and provide a brief explanation. Make it easy for AAHRPP staff and site visitors to find the specific information you want them to see. Use combinations of page numbers, paragraph numbers, line numbers, item numbers, chapter titles, and section headings to pinpoint the supporting information. For example, if you wish to point out information in your investigator's manual that addresses financial conflict of interest, provide the page numbers, section numbers, and section titles as appropriate, rather than referencing the investigator's manual in its entirety. For example:

> **Element I.1.C. The Organization has and follows written policies and procedures that allow the Institutional Review Board or Ethics Committee to function independently of other organizational entities in protecting research participants.**
>
> - Board of Directors Policy "Research Involving Humans" (**Document 10**, Section V on page 3) grants the IRB authorities as required by the regulations, and outlines the IRB's independence.
> - IRB Policies and Procedures (**Document 15**, page 10, Item XI, "Undue Influence of IRB members") describes what IRB members should do if they believe they are being coerced or unduly influenced.
> - Compliance Policy (Document 14, 4th bullet on page 2) identifies the Senior Vice President for Research as the individual with the responsibility to investigate allegations of coercion and undue influence and take corrective action.

This Element-by-Element Index becomes Section C of your application.

Make a copy of each document authored by your Organization and cited in the Element-by-Element index. If a document is cited for more than one Element, include only one copy. Assign a reference number to each document. This becomes Section D of your application.

Once you have completed your self-assessment, submit all of your updated documents, finalize your Sections C and D, and complete the appropriate application form (Section A), write a description (7-page maximum) of your Human Research Protection Program to form your Step 1 application for Accreditation or Reaccreditation.

Note for organizations using Adobe Acrobat X: AAHRPP requires that submissions are enclosed as one, seamless .PDF file, allowing for each individual section of a submission to move directly to the next section without an interruption in pagination. Therefore, a submission should begin on page 1 of Section A and scroll all the way through the last page of the final Section. Organizations submitting multiple .PDF files bound as an Adobe .PDF Portfolio, will be required to resubmit.

III. Prepare the Step 1 Application

If you are unfamiliar with preparing PDF files, obtain software early in the process, become familiar with it, and allow at least a week to put together the application. Contact AAHRPP staff with questions about completing your application.

A Step 1 application for accreditation is comprised of a single .PDF with the following five sections:

- **Section A:** Step 1 Application Form for Accreditation or Reaccreditation

- **Section B:** Overview of the Human Research Protection Program
- **Section C:** Element-by-Element Index to the Supporting Documents
- **Section D:** Supporting Documents
- **Section E:** IRB Roster(s)

See section IV for a description of Sections A-E.

AAHRPP staff will review your application and send you a Step 1 Review of Application Materials, which identifies those Elements of the Accreditation Standards that require revision and provides specific instructions on what is required to address the Element satisfactorily.

Once you receive the Step 1 Review of Application Materials you will work with AAHRPP staff to update your policies and procedures so that all of the Elements are satisfactorily addressed. After this is completed, you will be provided instructions on submitting your Step 2 application for accreditation or reaccreditation.

IV. Prepare the Step 2 Application

Once AAHRPP staff informs you that you are ready to move to Step 2, you will submit the **Step 2 Application for** Accreditation or Reaccreditation.

A Step 2 application is comprised of the following eight sections:

- **Section A:** Step 2 Application for Initial Accreditation or Reaccreditation Form
- **Section B:** Overview of the Human Research Protection Program
- **Section C:** Element-by-Element Index to the Supporting Documents
- **Section D:** Supporting Documents
- **Section E:** IRB Roster(s)
- **Section F:** Minutes, Correspondence with government oversight offices, and summary of internal audits
- **Section G:** List of Active Protocols including names of researchers
- **Section H:** Key Personnel

Contact AAHRPP staff with questions about completing your application.

Once you have submitted the application in Step 2, AAHRPP staff will work with you to schedule your site visit. Do not change your policies and procedures. Site visitors will evaluate the materials submitted with the application and will not consider any revisions made between the application submission and the site visit.

Section A: Application Form

Select either the **Step 1 Application Form** or **Step 2 Application Form** to submit with the application, depending upon your Organization's stage in the accreditation process. Complete and sign the correct form and make certain that the Organizational Official and application contact sign the form. State the legal name of your Organization. Check with your legal counsel to confirm your legal name. At the bottom of page 1, list the components of your Organization as described in the explanation.

The application form contains questions that will help AAHRPP staff customize the review of your application and the site visit and provide important information about your site to the site visitors. Please complete this section as completely and accurately as possible. Please review the Guidance on Completing Tables 1 or 1a in the Application and Annual Review Forms available on our website for assistance in completing the forms.

Section B: Overview of your Human Research Protection Program

Maximum length: Seven pages. Include the following sections.

- Give a brief description of your Organization, its purpose, and how the Human Research Protection Program relates to the Organization's mission.
- Provide an organizational chart for your Organization.
- Provide an organizational chart for you Human Research Protection Program.
- Indicate the individual who is the Organizational Official. This is the individual with direct authority and responsibility for the Human Research Protection Program. (This might not be and does not have to be the same person who is the signatory for a federalwide assurance.)
- List administrative units (e.g., schools, centers, divisions, or branches) within the Organization.
- If responsibility for human research protection is decentralized, describe all responsible entities and their relationship to the Organizational Official. Reference the organizational chart(s) if appropriate. If research is conducted at multiple locations (e.g., campuses or facilities), list them
  and indicate the approximate percentage of research conducted at each location.
- List other organizations that are components of your Human Research Protection Program and indicate whether there are active research protocols being conducted at the site.
- Indicate any essential functions of the Human Research Protection Program that are conducted at other units or components (e.g., conflict of interest, IRB review, research pharmacy services, grants and contracts, education).
- If your Organization follows ICH-Good Clinical Practice (E6), indicate if all, or only portions, of the ICH-GCP guideline are followed, and if they are applied to all studies reviewed by your Organization or a defined subset of studies (e.g., international clinical trials).
- When applicable, include other relevant background that will assist AAHRPP staff and site visitors in reviewing your application.

Section C: Element-by-Element Index to the Supporting Documents

Section C is an Element-by-Element index to the supporting documents in Section D that allows AAHRPP staff and site visitors to locate the information that supports your Organization meeting each AAHRPP Element. Generate Section C by appending the lists created during your self-assessment. You should not use more than one page for each Element and you should not separate Elements by page breaks. While not required, if you have the capability to create a hyperlink from the Element-by-Element index to the revision or new policy and procedure in the PDF file, you may do so.

Additional narrative to orient the site visitors may be added to Section C, but is not required. AAHRPP does not consider procedural details described in Section C to be written policies and procedures.

The AAHRPP website includes a template you can use to create Section C (Element-by- Element Index to the Supporting Documents).

Section D: Supporting Documents

AAHRPP staff and site visitors use the information in Section D and observations made during the site visit to evaluate your Organization. Section D should include one copy of each supporting document ordered by a unique reference number. Include one copy even when the document is used to support more than one Element.

Section E: IRB Roster(s)

If your Organization has an IRB(s), include the roster for each IRB. Put together a list of IRB members in a single file using Microsoft Excel. Format the information with the following columns. Include all columns and include the following information for each IRB member:

- Name of IRB member (last name, first name)
- Earned degrees
- Scientific status (i.e., scientist or non-scientist)
- Representative capacity. Indicate the populations about which the member is knowledgeable about or experienced in working with (e.g., children, pregnant women, prisoners, economically disadvantaged, educationally disadvantaged, cognitively impaired adults, or Native Americans).
- Indications of experience. Provide a description of all relevant experiences that describe each member's chief anticipated contributions to IRB deliberations, such as professions, life experiences with research or vulnerable populations, research experiences, IRB experiences, certifications and licensures, or other information as appropriate.
- Relationship of the IRB member to the Organization (e.g., current or former employee, consultant, board of directors, volunteer, trainee, or student). If the Organization has multiple components, include both the relationship and the component with which the member has a relationship (e.g., faculty of ABC University or medical staff of DEF Hospital).
- Affiliation status. Indicate whether the IRB member or any immediate family member is affiliated with the Organization. (Note that an IRB member may have no individual relationship with the Organization, but may be affiliated because an immediate family member of the IRB member has a relationship with the Organization.)
- Position on the IRB (e.g., chair or vice chair).
- Membership status (e.g., member, alternate, or non-voting. If a member is ex officio, indicate whether the member is a voting member).
- Alternate status (e.g., list the members or class of members for whom the alternate member can substitute or otherwise leave blank).

If you have multiple IRBs, you may either list each IRB in a separate worksheet within the Excel file or add a column to the spreadsheet that lists the IRB(s) to which the member belongs.

The AAHRPP website includes a template you can use to create the IRB roster(s).

Section F: Minutes and Other Correspondence

Section F consists of a single PDF file that contains the following:

- The most current minutes for each IRB.
- Correspondence with government offices, including, but not limited to ORO, OHRP Determination Letters, FDA Warning Letters, and FDA Restrictions Placed on IRBs or Investigators from the last year.
- A summary of internal audits or reviews in the past year. (Do not include identifiable data about protocols or investigators.)

Section G: List of Active Protocols including names of researchers

Section G consists of a list of active protocols in a single Microsoft Excel file. Format the spreadsheet with the following columns:

- Title
- IRB Tracking Number (when used)
- IRB name or number (if more than one IRB)

- Name of researcher (or researcher code number)
- Date of initial approval
- Name of sponsor or funding entity (e.g., National Institutes of Health, Department of Defense, Environmental Protection Agency, American Diabetes Association, Greenwall Foundation, or General Motors Foundation)
- Type of initial review (e.g., full, expedited, or exempt)
- Indicate whether the research is biomedical or non-biomedical, if the Organization reviews both types of research and the type of research is not identifiable by the IRB that reviews it. For example, if your Organization has only one IRB that reviews all types of research or has multiple IRBs and each one reviews all types of research, indicate whether each protocol is biomedical or non-biomedical. If your Organization has multiple IRBs and each reviews a specific type of research, such as biomedical, cancer, or behavioral and social science, indicate at the type of the list what type of research each IRB reviews. If the latter case applies, be sure that each protocol is identified with the IRB that reviews it.

Include all active protocols (under continuing review) reviewed under expedited procedures or by the convened IRB. Include all exemption determinations made in the past 12 months.

If you have protocols at more than one site (e.g., different campuses), you may either list the protocols for each site on a separate worksheet within the spreadsheet or add a column to the spreadsheet that lists the group to which the protocol belongs.

Section H: Key Personnel

The AAHRPP website provides an Excel worksheet to indicate the key personnel involved in the Human Research Protection Program at your organization. Pick the worksheet that is appropriate for your organization. For each category listed, provide the title and name of the individual or individuals who fulfill that role. If a person has more than one role, they should be listed for each role. You may add more rows as needed.

V. Assembly and Mailing

Please refer to the Instructions for Submitting Materials in Support of Accreditation for information on assembly and mailing of an application for accreditation.

Please contact the AAHRPP staff at (202) 783-1112 if you have questions related to submitting an application for accreditation.

Timeline for Initial Accreditation and Reaccreditation **Please note that the time frames listed are <u>approximate</u> and unique to each organization.**	
Initial Accreditation	**Reaccreditation**
Within approximately **60 calendar days** of application, AAHRPP will send a **Step 1 Review of Application Materials.**	Within approximately 6**0 calendar days** of application, AAHRPP will send a **Step 1 Review of Application Materials.**
Organization responds in a separate email for each element until all revisions are completed. This may begin as soon as the review is received and **must be completed within one year** of receipt of the Step 1 Review of Application Materials.	Organization responds in an email for each element until all revisions are completed. This may begin as soon as the review is received. Organizations are given approximately **45 calendar days** to respond to the Elements that require revisions.
Once all of the revisions have been completed and approved by AAHRPP staff, the Organization submits the **Step 2 application**, which includes the revised policies and procedures, within **14 calendar days**.	Once all of the revisions have been completed and approved by AAHRPP staff, the Organization submits the **Step 2 application**, which includes the revised policies and procedures, within **14 calendar days.**
The **site visit** is scheduled approximately **90 calendar days** after receiving the Step 2 application.	The **site visit** is scheduled approximately **90 calendar days** after receiving the Step 2 application.
AAHRPP will send a **Draft Site Visit Report** when it is ready, and no later than **28 calendar days** after the site visit has ended.	AAHRPP will send a **Draft Site Visit Report** when it is ready, and no later than **28 calendar days** after the site visit has ended.
After receiving the Draft Site Visit Report, the Organization has up to **28 calendar days** to provide a response to the report.	After receiving the Draft Site Visit Report, the Organization has up to **28 calendar days** to provide a response to the report.
The **Final Site Visit Report** is reviewed by the Council on Accreditation.	The **Final Site Visit Report** is reviewed by the Council on Accreditation.