

Instructions for Submitting Materials in Support of Accreditation

The following are formatting requirements which must be applied to submissions to AAHRPP. Please ensure that you are using the most recent version of each form available on our website. For additional assistance in submitting documents electronically, please do not hesitate to contact AAHRPP staff at reporting@aahrpp.org.

The formatting requirements below apply to the following materials:

Step 1 Application

1. One PDF file containing:
 - [Section A](#) (Signatures required)
 - [Section B](#) (Overview of HRPP)
 - [Section C](#) (Element by Element Index to the Supporting Documents)
 - [Section D](#) (Supporting Documents)
2. One Excel Spreadsheet containing [Section E](#) (IRB/EC Roster)

Response to the Draft Site Visit Report

1. One PDF file containing:
 - [Response to the Draft Site Visit Report Form](#)
 - Supporting documents, if applicable

Step 2 Application

1. One PDF file containing [Sections A-D](#)
2. One Excel Spreadsheet containing [Section E](#) (IRB/EC Roster)
3. One PDF containing [Section F](#) (Minutes, Correspondence with government oversight offices, and summary of internal audits)
4. One Excel Spreadsheet containing [Section G](#) (Active protocols including name of researchers)
5. One PDF containing [Section H](#) (Key Personnel and Research Team)

Response to Council Requests

For Status Reports, Contingency Reports, and Improvement Plans

1. One PDF containing:
 - [Response to Council Requests Form](#)
 - Supporting documents, if applicable

Change in Application Contact, Organizational Official, or Legal Name of Organization

1. One PDF file containing [Section A](#), Section I only (Signatures required)

Guidance for submitting Microsoft Excel files:

Section E: IRB/EC Roster:

Organizations with multiple IRBs/ECs should either list each IRB/EC in a separate worksheet within the Excel file **or** add a column to the spreadsheet that lists the IRB(s)/EC(s) to which the member belongs.

Section G: List of Active Studies:

Organizations that keep protocols at more than one location (e.g., different campuses) should either list the protocols for each site on a separate worksheet within the Excel file **or** add a column(s) to the spreadsheet that lists the location where the protocol is maintained.

Forms and Supporting Documents:

A. Must be submitted as a Portable Document Format (PDF), except where Microsoft Excel files are requested.

<p>PDFs must be:</p> <ul style="list-style-type: none"> ▪ One, combined file ▪ Paginated ▪ Bookmarked ▪ Searchable (OCR-enabled) <p>Multiple PDF files bound as an Adobe PDF Portfolio will not be accepted.</p> <p>In order to facilitate the most efficient review possible, it is encouraged, but not required, to hyperlink references to documents to jump to the corresponding supporting documents within your PDF.</p> <p>For specific Adobe instructions, please visit the following web pages:</p> <p>How to combine files into one PDF How to paginate your PDF How to add bookmarks to your PDF How to create hyperlinks within your PDF</p>	<p>Bookmarks</p> <p>Please add a bookmark for:</p> <ul style="list-style-type: none"> ▪ The first page of every Section ▪ The first page of each supporting document ▪ Each Standard, Domain, and Element listed in Section C: Element by Element Index (in Step 1 and Step 2 Applications) <p>The titles of bookmarks should be intuitive and easy to understand. An organization will not be asked to resubmit because there are too many bookmarks; however, inadequate bookmarking will result in a resubmission request.</p> <p><i>For examples of bookmarking for your PDF submission to AAHRPP, please refer to the appendix.</i></p> <p>Pagination</p> <p>Please add page numbers to the PDF so that every page has a unique number in chronological order through the whole file.</p> <p>A document is paginated correctly when the page number of the current page matches the page number in the left-hand box at the top of the screen.</p> <p><i>For an example of pagination for your PDF submission to AAHRPP, please refer to the appendix.</i></p>
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B. Must be completely filled out.

Please answer each question or enter “N/A” to indicate that the question is not applicable. For descriptions of the content that belongs in each section for submission, or if you need guidance on how to answer a question, please refer to our [Resource Library](#) on our website or contact AAHRPP staff for additional assistance.

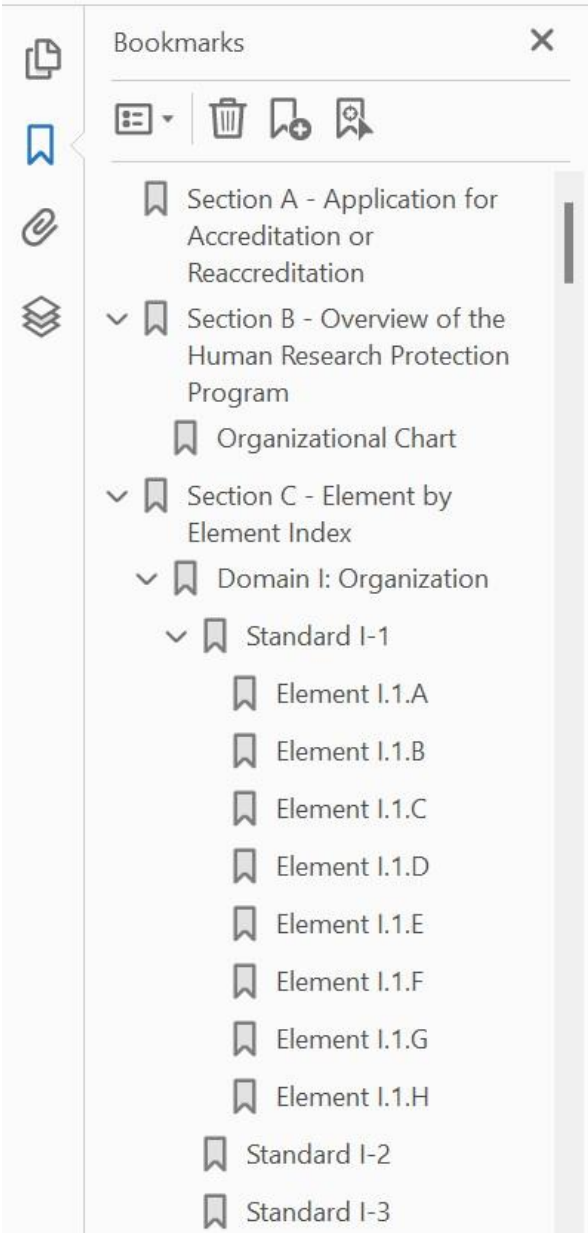
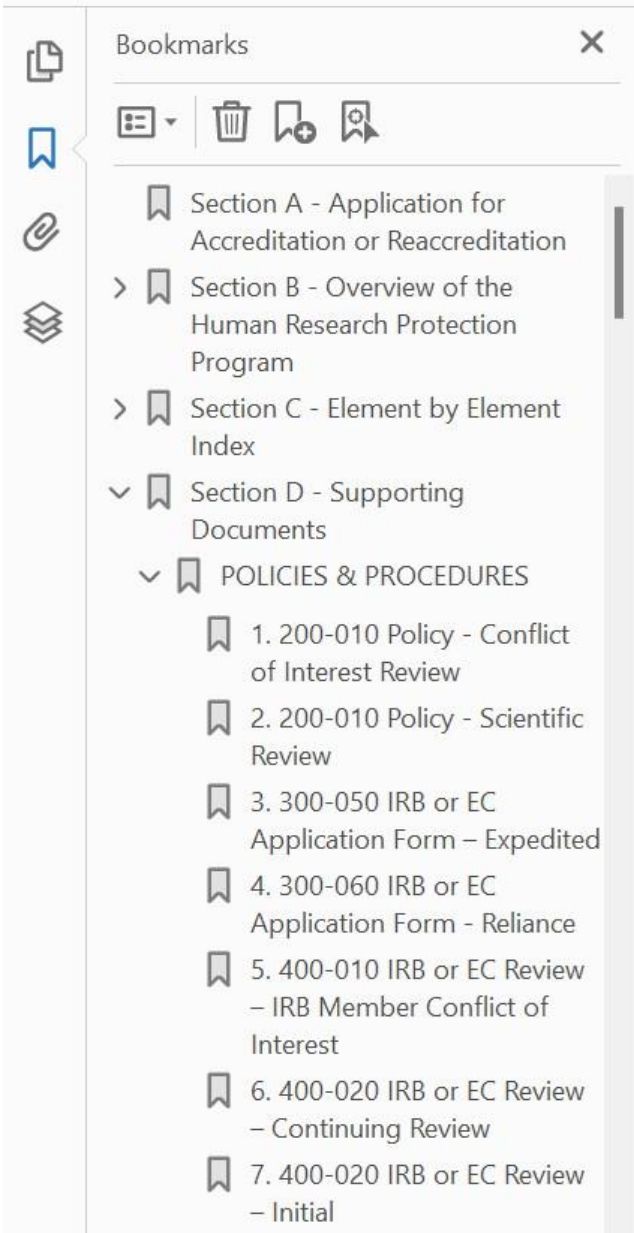
C. Must be signed, where applicable.

<p>Some forms require the signatures of the Application Contact and Organization Official. Forms that are not signed will not be accepted, except where explicitly noted otherwise.</p> <p>AAHRPP forms must either contain an electronic signature or be signed by hand. PDF files containing signatures that are typed will not be accepted.</p>	<p>Signing electronically: Please use the e-sign function in Adobe to add e-signatures or digital signatures.</p> <p>For specific instructions regarding signatures in PDFs, please visit the Adobe website: How to create e-signatures and digital signatures Acrobat Sign (adobe.com)</p> <p>Signing by hand: Please include a scanned copy of the forms containing the original signatures as a part of your PDF submission.</p>
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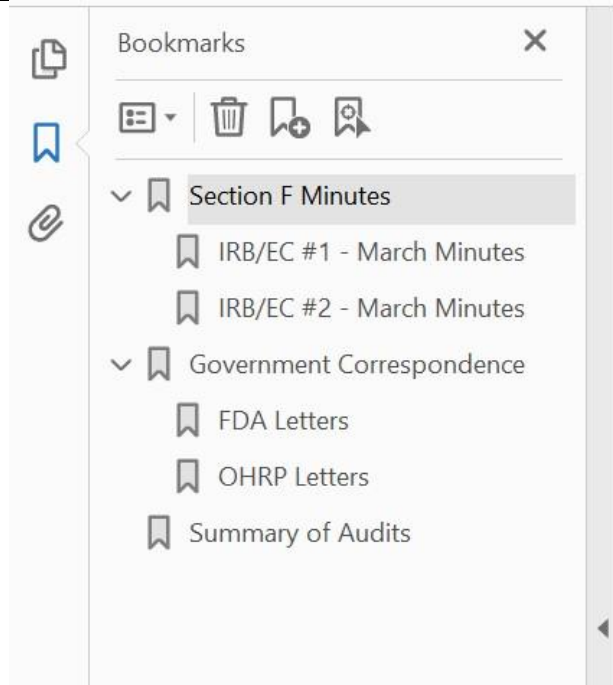
Submitting materials electronically:

AAHRPP now accepts electronic submissions and does not require submissions to be mailed on a flash drive and/or CD-ROM. Please submit documents through a file sharing system permitted by your organization (e.g., Box, Dropbox, etc.). To that end, please provide access to reporting@aahrpp.org or attach your files to an email.

The examples below are from Adobe Acrobat 8 Professional. Other versions of Adobe Acrobat may look different from the one below, but the concepts will remain the same.

i. Example of bookmarks for Section C: Element by Element Index in Step 1 and Step 2 Applications	ii. Example of bookmarks for Section D: Supporting Documents in Step 1 and Step 2 Applications
 <p>Bookmarks</p> <ul style="list-style-type: none"> Section A - Application for Accreditation or Reccreditation Section B - Overview of the Human Research Protection Program <ul style="list-style-type: none"> Organizational Chart Section C - Element by Element Index <ul style="list-style-type: none"> Domain I: Organization <ul style="list-style-type: none"> Standard I-1 <ul style="list-style-type: none"> Element I.1.A Element I.1.B Element I.1.C Element I.1.D Element I.1.E Element I.1.F Element I.1.G Element I.1.H Standard I-2 Standard I-3 	 <p>Bookmarks</p> <ul style="list-style-type: none"> Section A - Application for Accreditation or Reccreditation Section B - Overview of the Human Research Protection Program Section C - Element by Element Index Section D - Supporting Documents <ul style="list-style-type: none"> POLICIES & PROCEDURES <ul style="list-style-type: none"> 1. 200-010 Policy - Conflict of Interest Review 2. 200-010 Policy - Scientific Review 3. 300-050 IRB or EC Application Form – Expedited 4. 300-060 IRB or EC Application Form - Reliance 5. 400-010 IRB or EC Review – IRB Member Conflict of Interest 6. 400-020 IRB or EC Review – Continuing Review 7. 400-020 IRB or EC Review – Initial

iii. Example of bookmarks for Section F: Minutes and Other Correspondence



iv. Example of Correct Pagination

