

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 <u>reporting@aahrpp.org</u>.

The formatting requirements below apply to the following	materials:
 Step 1 Application 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) 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 Events that require reporting within 48 hours or 30 days 1. One PDF containing: • Reportable Events Form • Supporting documents, if applicable
 Step 2 Application One PDF file containing Sections A-D One Excel Spreadsheet containing Section E (IRB/EC Roster) One PDF containing Section F (Minutes, Correspondence with government oversight offices, and summary of internal audits) One Excel Spreadsheet containing Section G (Active protocols including name of researchers) One PDF containing Section H (Key Personnel and Research Team) 	Response to Council Requests For Status 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.

PDFs must be:	PDF), except where Microsoft Excel files are requested. Bookmarks	
 One, combined file Paginated Bookmarked Searchable (OCR-enabled) Multiple PDF files bound as an Adobe PDF Portfolio will	 Please add a bookmark for: 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) 	
not be accepted. In order to facilitate the most efficient review possible, it s encouraged, but not required, to hyperlink references to documents to jump to the corresponding supporting	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.	
documents within your PDF.	For examples of bookmarking for your PDF submission to AAHRPP, please refer to the appendix.	
For specific Adobe instructions, please visit the following	Pagination	
web pages: How to combine files into one PDF How to paginate your PDF	Please add page numbers to the PDF so that every page has a unique number in chronological order through the whole file.	
How to add bookmarks to your PDF How to create hyperlinks within your PDF	A document is paginated correctly when the page number of the current page matches the page number ir the left-hand box at the top of the screen.	
	For an example of pagination for your PDF submission to AAHRPP, please refer to the appendix.	

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 <u>Resource Library</u> on our website or contact AAHRPP staff for additional assistance.

C. Must be signed, where applicable.	
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.	Signing electronically: Please use the e-sign function in Adobe to add e-signatures or digital signatures. For specific instructions regarding signatures in PDFs, please visit the Adobe website:
AAHRPP forms must either contain an electronic signature or be signed by hand. PDF files containing	How to create e-signatures and digital signatures Acrobat Sign (adobe.com)
signatures that are typed will not be accepted.	Signing by hand: Please include a scanned copy of the forms containing the original signatures as a part of your PDF submission.

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 <u>reporting@aahrpp.org</u> or attach your files to an email.

Appendix

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.

	Bookmarks X	ß	Bookmarks X
 Section A - Application for Accreditation or Reaccreditation Section B - Overview of the Human Research Protection Program Organizational Chart Section C - Element by Element Index Section C - Element by Element Index Domain I: Organization Standard I-1 Element I.1.A Element I.1.B Element I.1.B Element I.1.D Element I.1.D Element I.1.F Element I.1.G 		 Section A - Application for Accreditation or Reaccreditation Section B - Overview of the Human Research Protection Program Section C - Element by Element Index Section D - Supporting Documents Section D - Supporting Documents POLICIES & PROCEDURES 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	
	Element I.1.H		6. 400-020 IRB or EC Review – Continuing Review
	Standard I-2 Standard I-3		7. 400-020 IRB or EC Review – Initial

