

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 for	The formatting requirements below apply to the following materials:					
	 Application One PDF file containing: Section A (Application; 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				
1.	Application One PDF file containing <u>Sections A-D</u> One Excel spreadsheet containing <u>Section E</u> (IRB/EC	Response to Council RequestsFor Status Reports and Improvement Plans1. One PDF containing:				
	Roster) One PDF containing <u>Section F</u> (Minutes, correspondence with government oversight offices, and summary of internal audits) One Excel spreadsheet containing <u>Section G</u> (Active protocols including name of researchers) One Word document containing <u>Section H</u> (Key Personnel and Research Team List)	 Response to Council Requests Form Supporting documents, if applicable 				
4. 5.	One PDF containing <u>Section F</u> (Minutes, correspondence with government oversight offices, and summary of internal audits) One Excel spreadsheet containing <u>Section G</u> (Active protocols including name of researchers) One Word document containing <u>Section H</u> (Key	<u>Response to Council Requests Form</u>				

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

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.

A. Must be submitted as a Portable Document Format (PD	F), except where otherwise specified.			
PDFs must be:	Bookmarks			
documents to jump to the corresponding supporting documents within your PDF.	 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) 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.			
	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: <u>How to combine files into one PDF</u> <u>How to paginate your PDF</u> <u>How to add bookmarks to your PDF</u> <u>How to create hyperlinks within your PDF</u>	Please add page numbers to the PDF so that every page has a unique number in chronological order through the whole file.			
	A document is paginated correctly when the page number of the current page matches the page number in Adobe page navigator.			
	For an example of pagination for your PDF submission to AAHRPP, please refer to the appendix.			
B. Must be completely filled out.	·			
Please answer each question or enter "N/A" to indicate that For descriptions of the content that belongs in each section for question, please refer to our <u>Resource Library</u> on our website	or submission, or if you need guidance on how to answer a			

C. Must be signed, where applicable.	
he forms require the signatures of the Application tact and Organization Official. Forms that are not signed not be accepted, except where explicitly noted erwise. IRPP forms must either contain an electronic signature be signed by hand. PDF files containing signatures that	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: <u>How to create e-signatures and digital signatures</u> <u>Acrobat Sign (adobe.com)</u>
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 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.

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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.

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0	 Section A - Application for Accreditation or Reaccreditation Section B - Overview of the 		0	 Section A - Application for Accreditation or Reaccreditation Section B - Overview of the Human Research Protection
	Human Research Protection Program		~	 Program Section C - Element by Element Index
	 Section C - Element by Element Index Domain I: Organization 			 Section D - Supporting Documents POLICIES & PROCEDURES
	✓ ☐ Standard I-1 ☐ Element I.1.A			 1. 200-010 Policy - Conflict of Interest Review 2. 200-010 Policy - Scientific
	Element I.1.B			Review 3. 300-050 IRB or EC
	Element I.1.D			Application Form – Expedited 4. 300-060 IRB or EC Application Form - Reliance
	Element I.1.F			 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			 7. 400-020 IRB or EC Review – Initial

iii.	Example of bookmarks for Section F: Minutes and Other Correspondence	
	Bookmarks Section F Minutes IRB/EC #1 - March Minutes IRB/EC #2 - March Minutes IRB/EC #2 - March Minutes Overnment Correspondence FDA Letters OHRP Letters Summary of Audits	
iv.	Examples of Correct Pagination (Adobe Acrobat)	
IV. ► (C) (C) (A) (A) (A) (A) (A) (A) (A) (A	Examples of Correct Pagination (Adobe Acrobat) scelerisque viverra maecenas est. Habitant interdum eleifend aliquet hendrerit curabitur. Portitior class taciti parturient auctor non pharetra. Penatibus eleifend portitior facilisis conubia maximus. Praesent dis ridiculus fames tortor; platea quis inceptos. Vestibulum imperdiet dis primis, proin molestie lacus tincidunt. Inceptos potenti venenatis cursus montes ipsum sociosqu malesuada. Enim sapien libero enim platea erat blandit. In purus curae pharetra enim varius facilisis. Ipsum tincidunt suspendisse urna integer aliquam accumsan. Rutrum neque suscipit quam bibendum diam commodo montes fringilla. Ultricies sollicitudin lorem adipiscing hendrerit litora himenaeos. Habitant sociosqu velit porta volutpat lorem donec sagittis ornare. Platea habitant maximus sagittis litora parturient pretium donec amet? Primis tincidunt adipiscing bibendum curabitur quisque. Conubia mattis elit ullamcorper vehicula lacus curabitur. Nulla nam luctus nulla praesent, ad justo pharetra dictum. Volutpat rutrum nec parturient tempus tellus ad. Penatibus mollis dolor a, placerat di class commodo. Pulvinar placerat dui conubia integer natoque montes eu placerat odio. Hendrerit dui ante finibus dis; rutrum dictum sollicitudin ad. Etiam vitae cursus aliquam vitae felis elementum. Malesuada libero nam dapibus natoque suscipit efficitur torquent. Primis etiam maximus luctus; nulla ligula condimentum. Amet	
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