



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



March 14, 2023



# What is “Ask AAHRPP”?

- Bimonthly (six times per year) forum with:
  - Practical approach to achieving and maintaining accreditation
  - Brief presentations on topics relevant to organizations applying for initial accreditation or reaccreditation
  - An emphasis on Q&A on topics presented as well as questions submitted when participants register
  - Organized around the steps in the accreditation process
- Open and free to everyone
- Recordings available



## 2023 Schedule

- January 10, 2023: Conduct a Self-Assessment
- **March 14, 2023: Build and Develop an Application**
- June 13, 2023: Evaluation of Written Materials
- August 8, 2023: Evaluation of Practice
- October 10, 2023: Council on Accreditation Review
- December 12, 2023: Respond to Council Review and maintain accreditation



## FYIs

- Please provide feedback by completing the survey
- A link to the talk will be sent to those who registered for the talk when it is posted
- If you have any questions during the sessions, please use the chat function or Q&A function to submit them



## AAHRPP's Online Accreditation Management System

As you know, AAHRPP has been committed to developing and implementing an Online Accreditation Management System (OAMS) for several years now. Indeed, as we have also reported, starting in late 2021 and throughout much of 2022 we were fully engaged with a vendor we had selected -- after a rigorous RFP and vetting process -- to build the system with and for us. Sadly, although we were about 2/3 of the way through development, in late 2022 we hit a major glitch with our developer. In plain language: they went out of business.

As anyone who as ever worked in this space can attest, and as we have now learned the hard way, these undertakings can sometimes be a bit choppy.

To be clear: AAHRPP is still fully committed to delivering to our accreditation community a user-friendly, efficient, and smoothly functioning OAMS in the near future. We are working actively now to identify our best solution going forward. And, in the spirit of the AAHRPP transparency that we hope you've come to know and expect, we will continue to keep you posted regarding progress on the OAMS development.



# Assembling the AAHRPP application is easy not too difficult, if you adopt these best practices

By the end of this session, you will be able to:

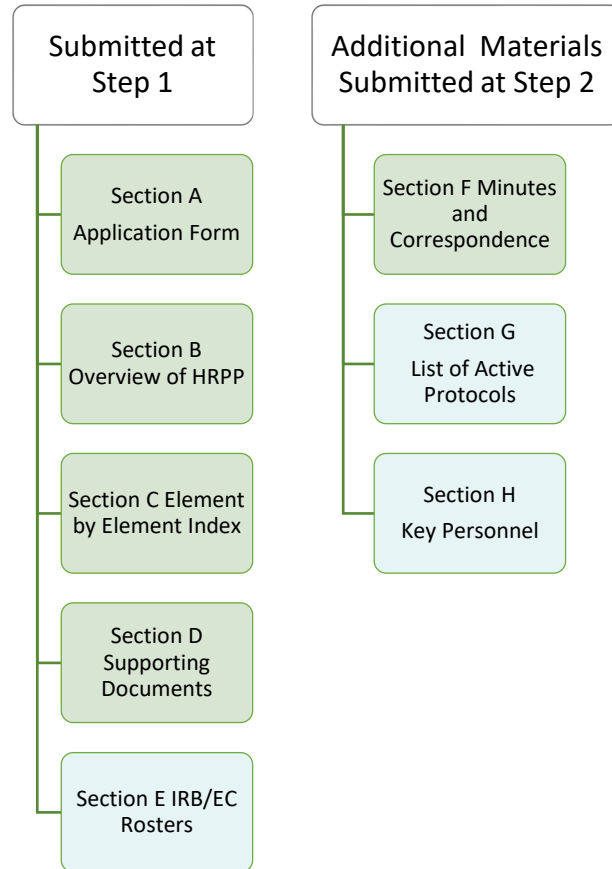
- Describe the parts of the AAHRPP application and locate application forms, templates, and instructions
- Follow best practices to:
  - Combine all the files in support of your application
  - Develop the Index to Supporting Documents (Section C)
  - Use Adobe Acrobat Pro to assemble the AAHRPP application
  - Be able to automatically create bookmarks based on document names
- Develop procedures to manage document updates (“policy on policies”) so you always have a current AAHRPP application
- Identify common reasons applications are returned



## **Parts of the AAHRPP application: Finding forms, templates, and instructions**



# What are the parts of the application? What information do you need to provide?







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# Forms, templates, and instructions? [www.aahrpp.org](http://www.aahrpp.org)



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- ABOUT
- ACCREDITATION
- RESOURCES
- EDUCATION, NEWS & EVENTS
- FIND AN ACCREDITED ORGANIZATION
- CONTACT US

**An independent, non-profit accrediting body, AAHRPP uses a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for quality and protection.**



**GET ACCREDITED**



**MAINTAIN ACCREDITATION**



## ACCREDITATION

### Why Accreditation Matters

- [Overview](#)
- [Eligibility](#)

### Get Accredited

- [Overview](#)
- [Getting Started](#)
- [Application and Annual Fees](#)
- [Part 1: Conduct a Self-Assessment](#)
- [Part 2: Build and Develop an Application](#)
- [Part 3: Evaluation of Written Materials](#)
- [Part 4: Evaluation of Practice](#)
- [Part 5: Council on Accreditation Review](#)
- [Part 6: Response to Council Review](#)

### Maintain Accreditation

- [Applying for Reaccreditation](#)
- [Required Reports](#)



## ACCREDITATION: Get Accredited - Part 2: Build and Develop an Application



Once you have completed your Self-Assessment, it is time to start putting together a formal Application for Accreditation.

The application submission process for initial and renewing applicants involves two steps:

**Step 1.** Submit the application form, the program overview (no more than seven pages), copies of your policies and procedures (supporting documents), and an index for these documents. AAHRPP will review the application materials and request revision or additional documentation, if needed. AAHRPP typically provides feedback on application materials within approximately 60 calendar days.

**Step 2.** Once the written documents are complete, AAHRPP staff will schedule your site visit. Normally, site visits are scheduled within three months after the Step 2 application for accreditation or reaccreditation is submitted and determined to be complete.

To get started see the [Instructions to Apply for Initial Accreditation and Reaccreditation](#).

### APPLICATION SUBMISSION PROCESS

#### STEP 1 & 2 SUBMISSION

 SECTION A: Application form

 SECTION B: Overview of your Human Research Protection Program

 SECTION C: Element-by-Element Index of Supporting Documents

 SECTION D: Supporting Documents

 SECTION E: IRB/EC Roster(s)

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Instructio  
Support c  
Reaccredi



## RESOURCES: For Accreditation - Additional Resources



### APPLICATION FOR ACCREDITATION OR REACCREDITATION: SECTION A

Latest Update: January 24, 2023

The Application for Accreditation Section A 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.

[Application for Accreditation or Reaccreditation: Section A](#)

[Guidance on Completing Section A](#)

[Changes to Section A for 2023](#)



# Acrobat Pro: Create a pdf of Section C



## Create a folder structure and train staff

- Create a folder for current policies, applications, forms, reviewer worksheets, and other materials
- Create a folder for policies being revised
- Create a folder of prior policies and a summary of changes
- Create one folder each for initial accreditation and reaccreditation cycles

erials >

Name	Date modified	Type	Size
Applications - initial	3/14/2023 2:09 PM	File folder	
Applications - reaccred 2023	3/14/2023 2:09 PM	File folder	
Applications - reaccred 2019	3/14/2023 2:09 PM	File folder	
Current materials	3/14/2023 2:04 PM	File folder	
Prior versions for records of changes	3/14/2023 2:05 PM	File folder	
Working versions currently being revised	3/14/2023 2:05 PM	File folder	



## Create an index of all documents in Section C

- List all documents in support of each Element or Standard
- Check to be sure that:
  - All documents in Section C are included in the application (in Section D)
  - All documents referenced in the application (Section D) are listed in Section C
- Use Acrobat Pro to generate Section C with hyperlinks
  - Use styles to create bookmarks
  - Select styles for Domain, Standard, Element



## Example: Section C

**Standard II-4: The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research.**

**Element II.4.A. The IRB or EC has and follows written policies and procedures for determining the risks to prospective participants who are vulnerable to coercion or undue influence and ensuring that additional protections are provided as required by applicable laws, regulations, codes, and guidance.**

Supporting Documents

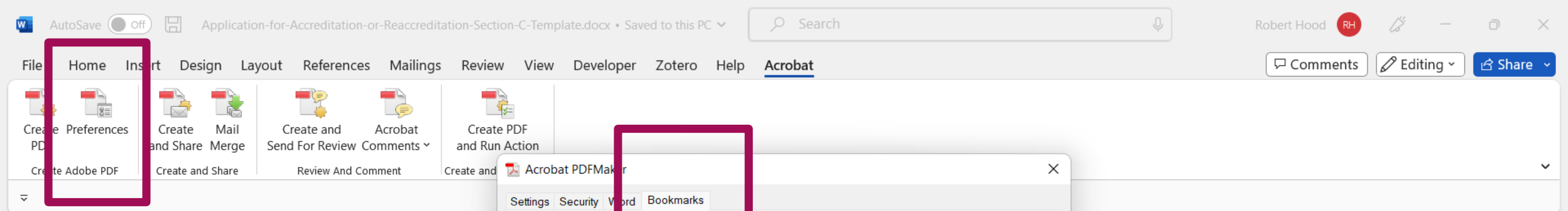
- Research Involving Pregnant Women (300-25)
- Research Involving Prisoners (300-26)
- Research Involving Children (300-27)
- Research Involving Adults Unable to Consent (300-28)
- IRB application: Vulnerable population questions (500-03, 500-04, 500-05, 500-06, and 500-07)
- Research Involving Pregnant Women Fetuses Neonates (700-15)
- Research Involving Prisoners (700-16)
- Research Involving Children (700-17)
- Research Involving Cognitively Impaired Persons (700-18)

Lists documents in support of each Element or Standard

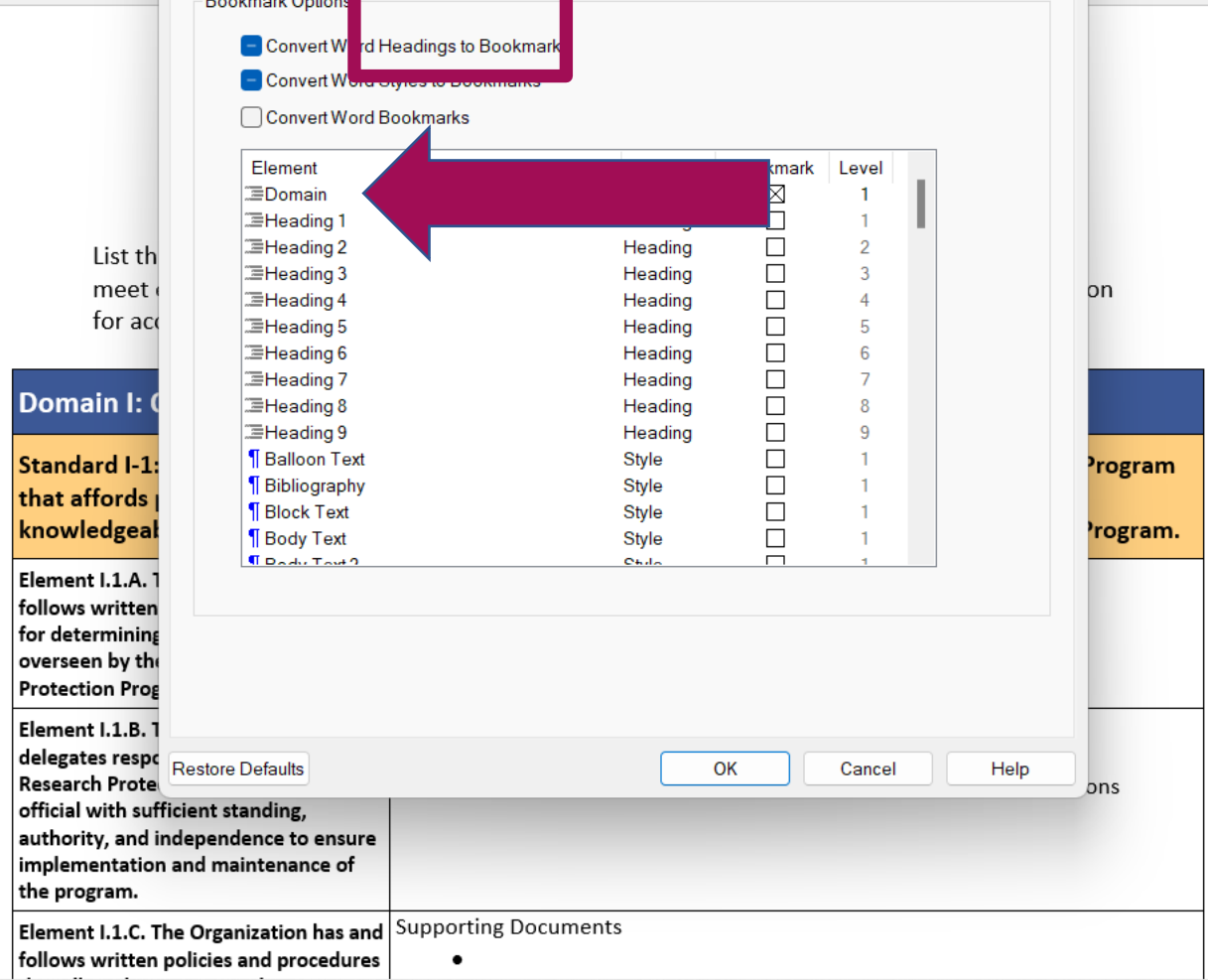
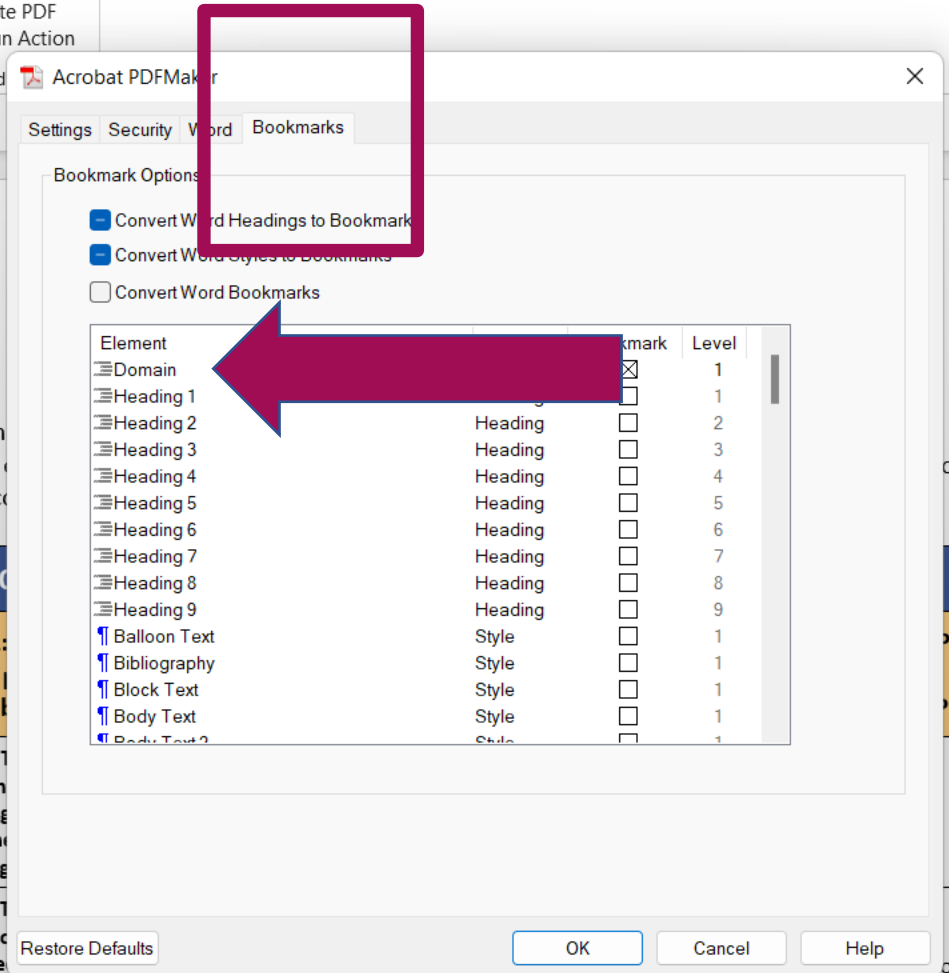
Includes a document number – used to assemble Section D







Go to preferences > bookmarks > then select the following styles:  
Domain  
Standard  
Element  
Then create the pdf



# Acrobat creates bookmarks: Section C

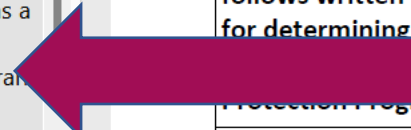
Application-for-Accreditation-or-Reaccreditation-Section-C-Template2.pdf - Adobe Acrobat Pro (32-bit)

File Edit View E-Sign Window Help

Home Tools Application-for-Acc... x



Bookmarks	
Domain I: Organization	
Standard I-1: The Organization has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants. Individuals	
Element I.1.A. The Organization has and follows written policies and procedures for determining when activities are overseen by the Human Research Protection	
Element I.1.B. The Organization delegates responsibility for the Human Research Protection Program to an official with sufficient standing, authority, and	
Element I.1.C. The Organization has and follows written policies and procedures that allow the Institutional Review Board or Ethics	



**Standard I-1: The Organization has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants. Individuals within the organization must be knowledgeable about and follow the policies and procedures of the Human Research Protection Program.**

**Element I.1.A. The Organization has and follows written policies and procedures for determining when activities are overseen by the Human Research Protection Program.**

Supporting Documents

- 100-010 Determining when an activity is research
- 100-020 Application for non-research activities
- 100-020 Chair worksheet on non-research activities

**Element I.1.B. The Organization delegates responsibility for the Human Research Protection Program to an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program.**

Supporting Documents

- 100-030 Responsibilities of personnel
- 100-040 Web page – contact the IRB

**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.**

Supporting Documents

- 



# Acrobat Pro: Combining multiple documents to create Section D



## Create a folder structure and train staff

- Create a folder for current policies, applications, forms, reviewer worksheets, and other materials
- Create a folder for policies being revised
- Create a folder of prior policies and a summary of changes
- Create one folder each for initial accreditation and reaccreditation cycles

erials >

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Working versions currently being revised	3/14/2023 2:05 PM	File folder	



## Create bookmarks for Section D

### Save documents in one folder, group similar materials

- Group similar materials by number:
  - 100-010 HRPP organization chart
    - Use “100s” for org charts, roles and responsibilities of people in the HRPP
  - 200-010 Policy: Scientific review
  - 200-020 Policy: Conflict of interest review
    - Use 200s for Domain I materials
  - 300-010 IRB/EC application form – initial review
  - 300-020 IRB/EC application form – modifications
    - Use 300s for IRB applications
  - 400-010 IRB/EC review – initial
  - 400-020 IRB/EC review – continuing review
    - Use 400s for IRB review policies
  - 500-010 IRB review worksheet/checklist – expedited
    - Use 500s for IRB reviewer worksheets
  - 600-010 Minutes templates
    - Use 600s for minutes templates, letters, policies on documentation

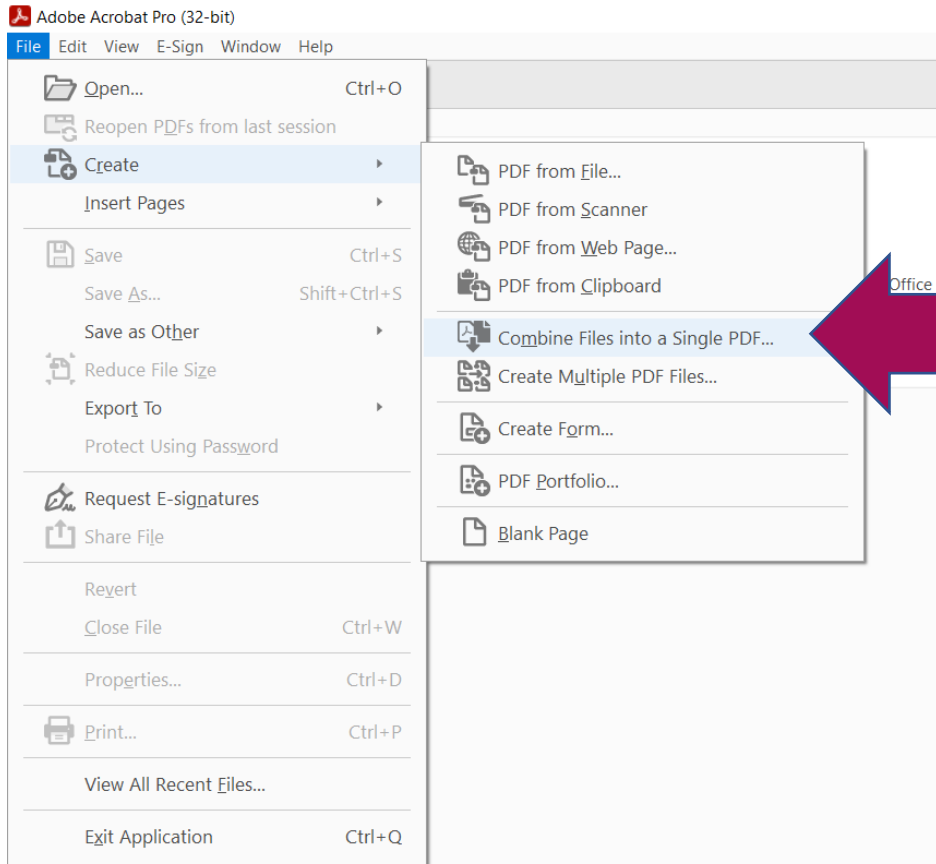


## Add a number at the beginning of the filename

- Don't rename policies, just add a number
  - 300-010 IRB/EC application form – initial review
  - 300-020 IRB/EC application form – modifications
  - 300-030 IRB/EC application form – continuing review
  - 300-040 IRB/EC application form – exemption
  - 300-050 IRB/EC application form – expedited
  - 300-060 IRB/EC application form - reliance
  - 400-010 IRB/EC review – IRB member conflicts of interest
  - 400-020 IRB/EC review – initial
  - 400-030 IRB/EC review – modifications
  - 400-040 IRB/EC review – continuing review
- Use numbers that make sense for your program



# Acrobat: Combine multiple files to a single pdf



## Add files



Add files by clicking the button below or drag and drop them here.  
You can also add the current open files from below.

Add Files





















Add Open Files

Help



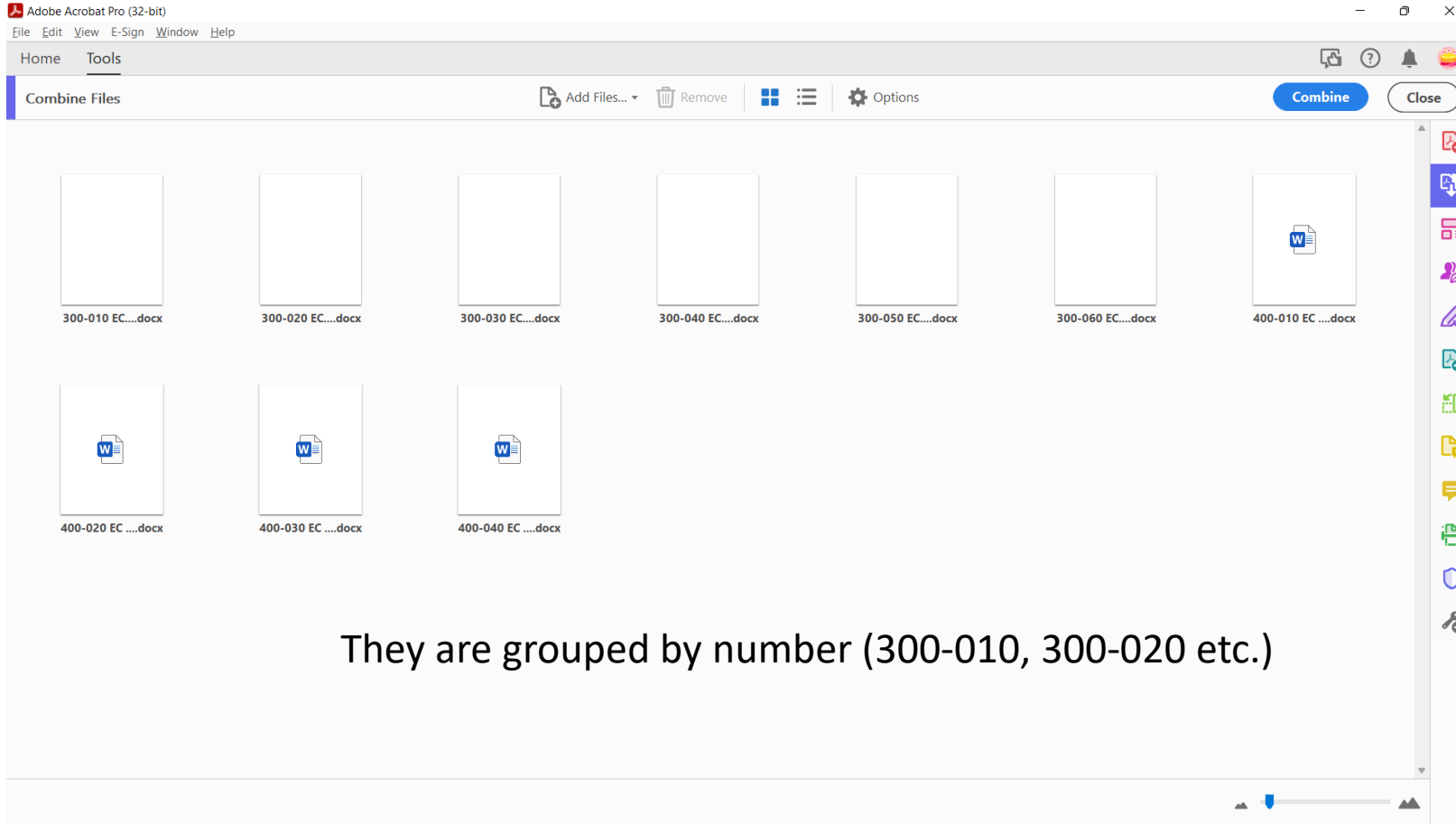


# Select files

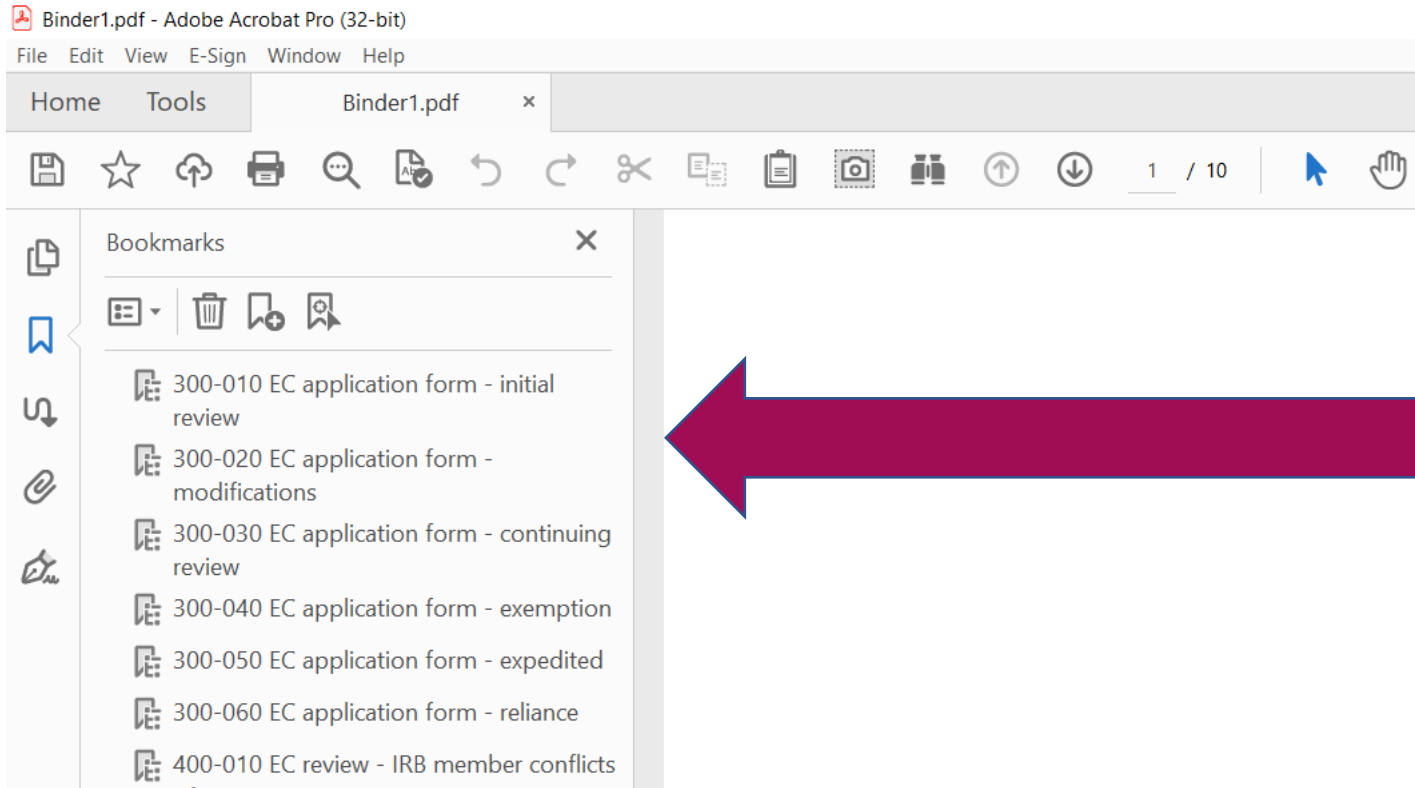
Name	Status	Date modified
 300-010 EC application form - initial review.docx		3/10/2023
 300-020 EC application form - modifications.docx		3/10/2023
 300-030 EC application form - continuing review.docx		3/10/2023
 300-040 EC application form - exemption.docx		3/10/2023
 300-050 EC application form - expedited.docx		3/10/2023
 300-060 EC application form - reliance.docx		3/10/2023
 400-010 EC review - IRB member conflicts of interest.docx		3/10/2023
 400-020 EC review - initial.docx		3/10/2023
 400-030 EC review - modifications.docx		3/10/2023
 400-040 EC review - continuing review.docx		3/10/2023



# Acrobat combines files, ordered by number



# Acrobat Pro: automatically creates bookmarks for Section D



## Procedure to maintain a current AAHRPP application

- Define who is responsible
- Define how often policies/forms/applications are reviewed to ensure they are current and that changes are updated.
  - Quarterly, yearly
- Describe process to update the “AAHRPP folder” when a policy is updated
  - Move the prior version of the policy to a separate “prior policies” folder (not in the same directory)
  - Save the new pdf of updated policy in the special (“AAHRPP folder 2023”)
  - Update the spreadsheet with the revised version and date



# Keep application up to date between cycles

Policy	Revised version	Prior version	Owner/person responsible	Change	Education
100-01-HRPP-01	8/01/2023	5-Aug-21	HRPP Administrator	Clarified who serves as backup when organizational official when VP for Research is not available	planned
300-01-Form-DoD	9/15/2022	4/2/2021	IRB Administrator	Added IRB required determinations when following DoD requirements	complete
500-06-COI-Disclosures	9/15/2022	1/1/2020	COI administrator	Added COI disclosures due to changes in state law	complete

## Written materials

- Create a list (spreadsheet) of all policies and versions
- When policies are updated, replace the version in the “AAHRPP application folder”



# Common reasons applications are returned



## Be sure to:

- Sign Section A
- Create a single pdf for Sections A-D
- Paginate the entire application
- Use the OCR function of Acrobat Pro to ensure applications are searchable
- Be sure that the regulations checked in Section A are consistent with what is listed in Section B



# Thank You!

- A link to the talk will be sent to those who registered for the talk when it is posted
- Look for future dates on the AAHRPP website:
  - June 13, 2023: Evaluation of Written Materials
  - August 8, 2023: Evaluation of Practice
  - October 10, 2023: Council on Accreditation Review
  - December 12, 2023: Response to Council Review





## Contact AAHRPP

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# 2023 AAHRPP Annual Conference



*Challenge and Change in Charm City*

May 16-18, 2023 | Hyatt Regency Baltimore