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of Human Research Protection Programs, Inc.®

Ask... AAHRPP®

January 9, 2024

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Conducting the Self-Evaluation

- Heather Bridge
  - Director HRPP Policy & Accreditation
  - Office of Human Subjects Research Protections
  - Office of Intramural Research
  - National Institutes of Health
- Robert Hood
  - Director of Accreditation and Global Outreach
  - AAHRPP

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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

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2024 Schedule

- January 9, 2024 – Self-Evaluation
- April 9, 2024 - Evaluation of Written Materials
- June 11, 2024 - Evaluation of Practice - What to Expect during the Site Visit
- August 13, 2024 – Responding to Draft Site Visit Report
- October 8, 2024 - Council on Accreditation Review
- December 10, 2024 - Responding to Council Review and Maintaining Accreditation

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Useful Information

- Submit questions during the sessions using the Chat or Q&A function
- A link to the talk will be sent to those who registered for the talk when it is posted
- Please provide feedback by completing the survey

Online Accreditation Management System (OAMS)

- Creating an OAMS to streamline all accreditation processes and operations
- Working closely with constituents to provide input in development of OAMS
- Development process allowing AAHRPP an opportunity to revisit its procedures
- Projected launch of the Minimum Viable Product – late May 2024

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Focus of Accreditation

Domain I: Organization **+ Domain II:** IRB/EC **+**
Domain III: Researchers and Research Staff
= Human Research Protection Program (HRPP)

- All domains are equally important
- AAHRPP is looking for a well integrated, systematic and comprehensive Human Research Protection Program (HRPP) by evaluating its systems, processes and people

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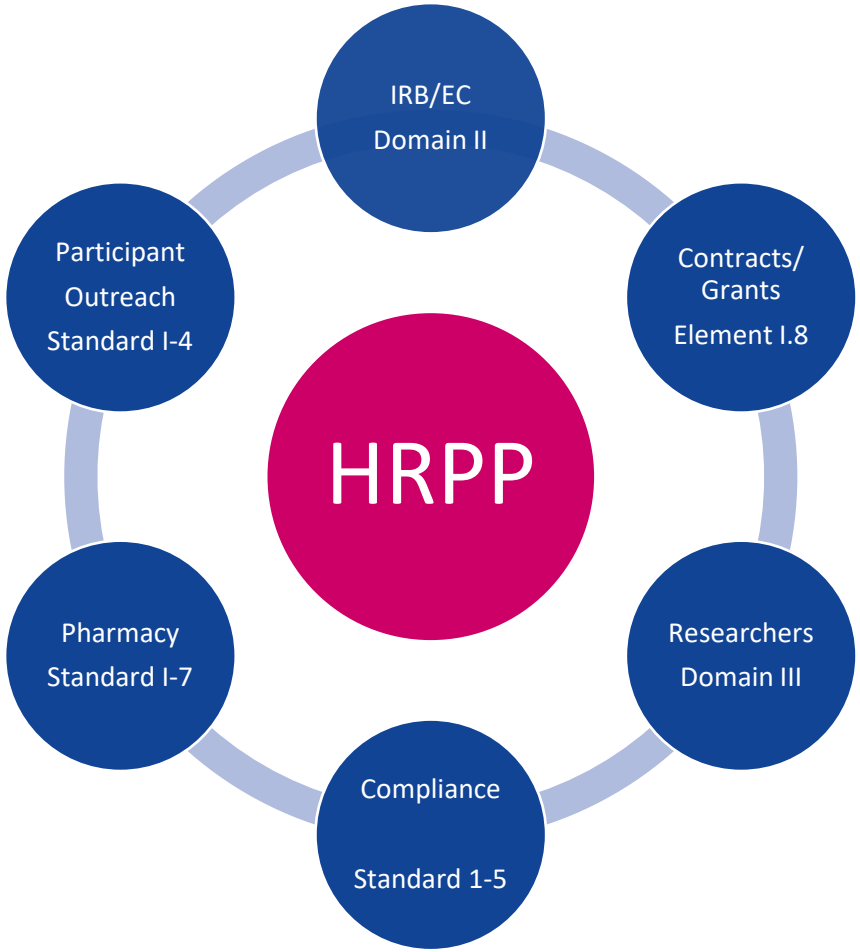
The Human Research Protection Program



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Step 1 – Conduct Self-Assessment

Self- Assessment (*in the context of accreditation*) – *A systematic evaluation of your HRPP, its policies and practices against the AAHRPP Accreditation Standards*

- Get to know the AAHRPP Standards and Elements using the Evaluation Instrument and Tip Sheets
- Establish a working group/team to conduct self-assessment
- Working Group will perform gap analysis of policies, materials, systems and tools

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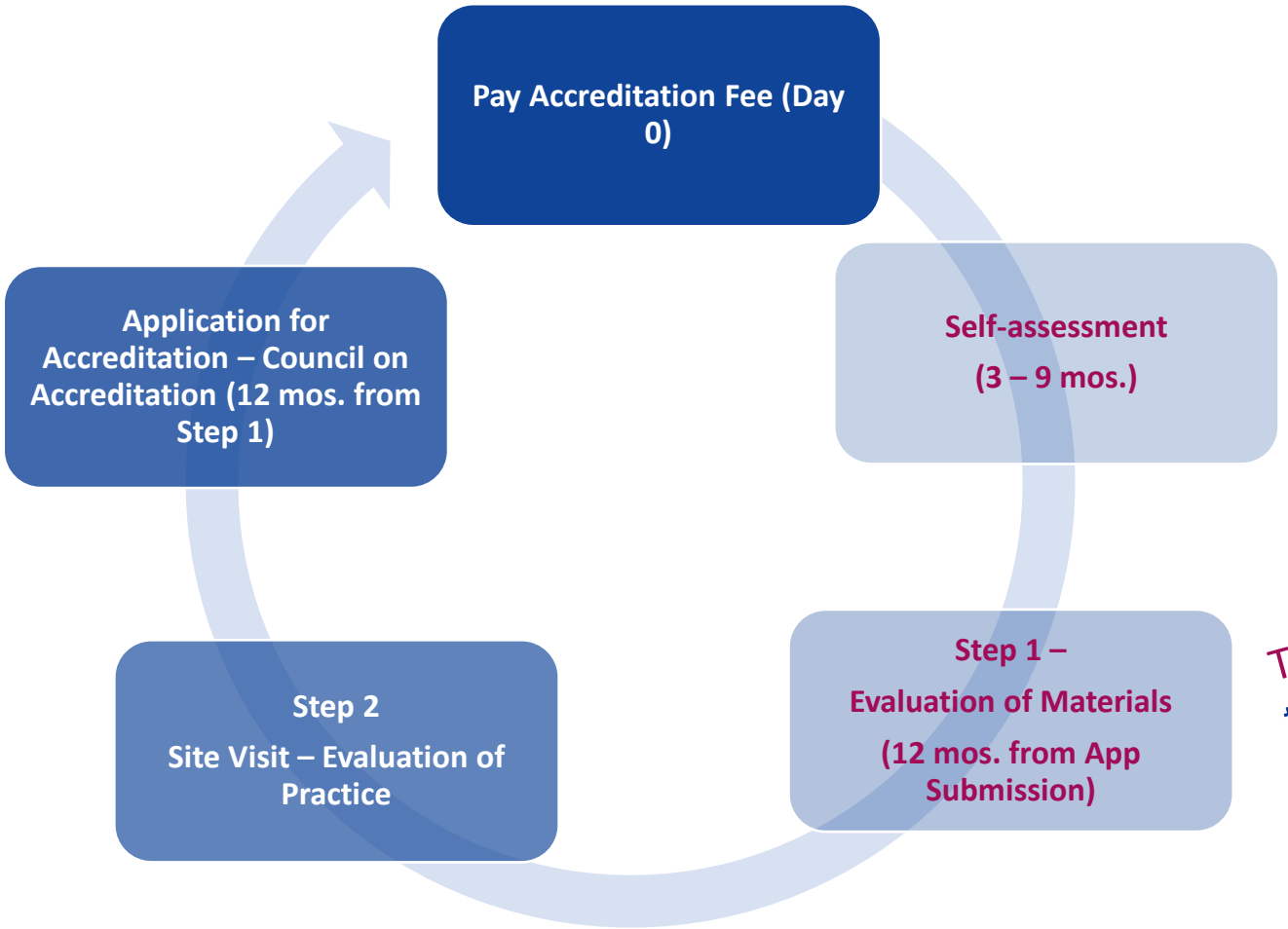
Timeline for Accreditation



TIP: Factors that affect the timeline: Type of organization, complexity of HRPP, budget and Research portfolio

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The Evaluation Instrument

RESOURCES: For Accreditation - Evaluation Instrument

EVALUATION INSTRUMENT FOR ACCREDITATION

DOWNLOAD AS PDF

Latest Update: May 15, 2022

GET ACCREDITED

TABLE OF CONTENTS

INTRODUCTION

USE OF THE EVALUATION INSTRUMENT FOR ACCREDITATION

The Evaluation Instrument for Accreditation is intended for use by organizations seeking accreditation and by site visitors who evaluate organizations. To achieve accreditation, an organization must meet all the accreditation Standards and Elements. If an organization meets the Elements for a particular Standard, it meets the Standard. This Evaluation Instrument provides the information necessary to meet each Element.

AAHRPP has defined Domains of responsibility: *Organization*, *Institutional Review Board (IRB) or Ethics Committee (EC)*, and *Researchers and Research Staff*. Within each Domain are Standards, and for each Standard there are Elements that provide more specificity for the Standard. Each Element contains four parts: Commentary, Regulatory and Guidance References, Required Written Materials, and Outcomes.

For some Elements, Common Types of Materials That May Be Used to Meet the Element are included. Listed under this heading are examples of written materials that organizations have used to meet the Element. They are not required, and organizations may use other types of written materials to meet the Element. If an Element refers to written policies and procedures it generally means that a written procedure (e.g., standard operating procedure) is required to meet the Element. In some cases, an application form or reviewer checklist can serve the same purpose as a written procedure. AAHRPP has attempted to identify those Elements.

By designating certain types of written materials that may be used to meet an Element, AAHRPP does not desire to reduce the flexibility of the accreditation or limit creativity. The listing of Common Types of Materials That May Be Used to Meet an Element is intended to be helpful by providing guidance on the types of materials that can meet an Element.

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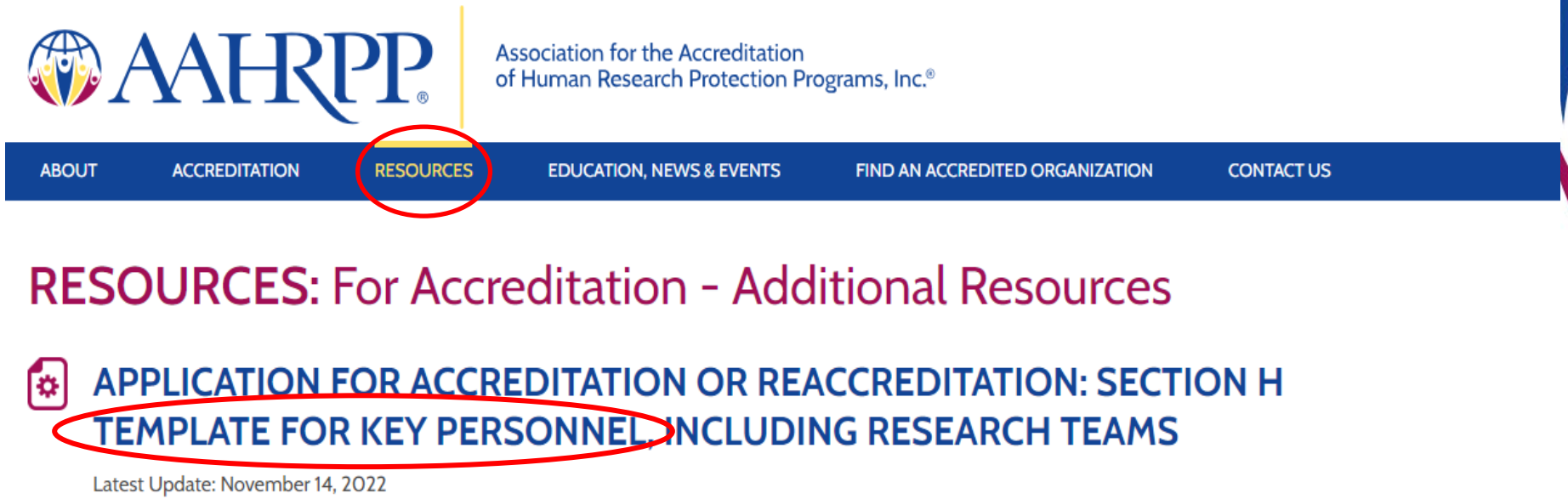
Build Your Working Group/Taskforce

Resource: Section H - [AAHRPP Key Personnel List]



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Self-Assessment Steps

Part 1 - Build your Working Group

- Describe your HRPP
- Complete Key Personnel List
- Select members
- Set goals and timeline
- Establish Working Group/Accreditation Team

Part 2 – Gather your Materials

- HRPP Policies
- HRPP/IRB Procedures
- Systems
- Checklist and Tools
- Organize by Domains, Standards and Elements

Part 3 – Self-Assessment

- Divide and conquer
- Identify Gaps
- Fill Gaps (e.g., policies, systems, checklists, tools)
- Educate
- Put into practice
- Compile the Element Index (Section C)

Track Progress

Gather and evaluate - policies, applications, IRB or EC worksheets and checklists, minutes and letter templates, websites and manuals

- Decide what needs to be developed, if anything, or revised
- Establish a tracking system and set goals

*If you anticipate major changes, e.g., new electronic system - contact AAHRPP ASAP

Standard/ Element	Reg/Office	SOP/Tool/ System	Gap?	Due Date	Who?	Complete?	Notes
I.1.A.	HHS Common Rule	100.1. - HRPP	Institutional Official designee	3/20/024	HRPP Director		
1.7.A.	Central Pharmacy	200.2 - IRB Membership	No presence on IRB	6/20/24	Pharmacy Director		

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Step 2 - Assembling the AAHRPP Application

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

- Describe the parts of the AAHRPP application
- Locate important resources - application forms, templates, and instructions, including
- Some videos on how to compile your application
- Develop procedures to manage document updates so you always have a current AAHRPP application
- Identify common reasons applications are returned

TIP: Do you have a Policy on Policies?

Parts of the AAHRPP Application

Step 1 – Written Materials

SECTION A: Application form

SECTION B: Overview of your HRPP

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

SECTION D: Supporting Documents

SECTION E: IRB/EC Roster

Step 2 – Additional Materials

SECTION F: Minutes and correspondence

SECTION G: List of Active Studies

SECTION H: Key Personnel and Research Teams

*Everything you need is on the AAHRPP website -

www.aahrpp.org

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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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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

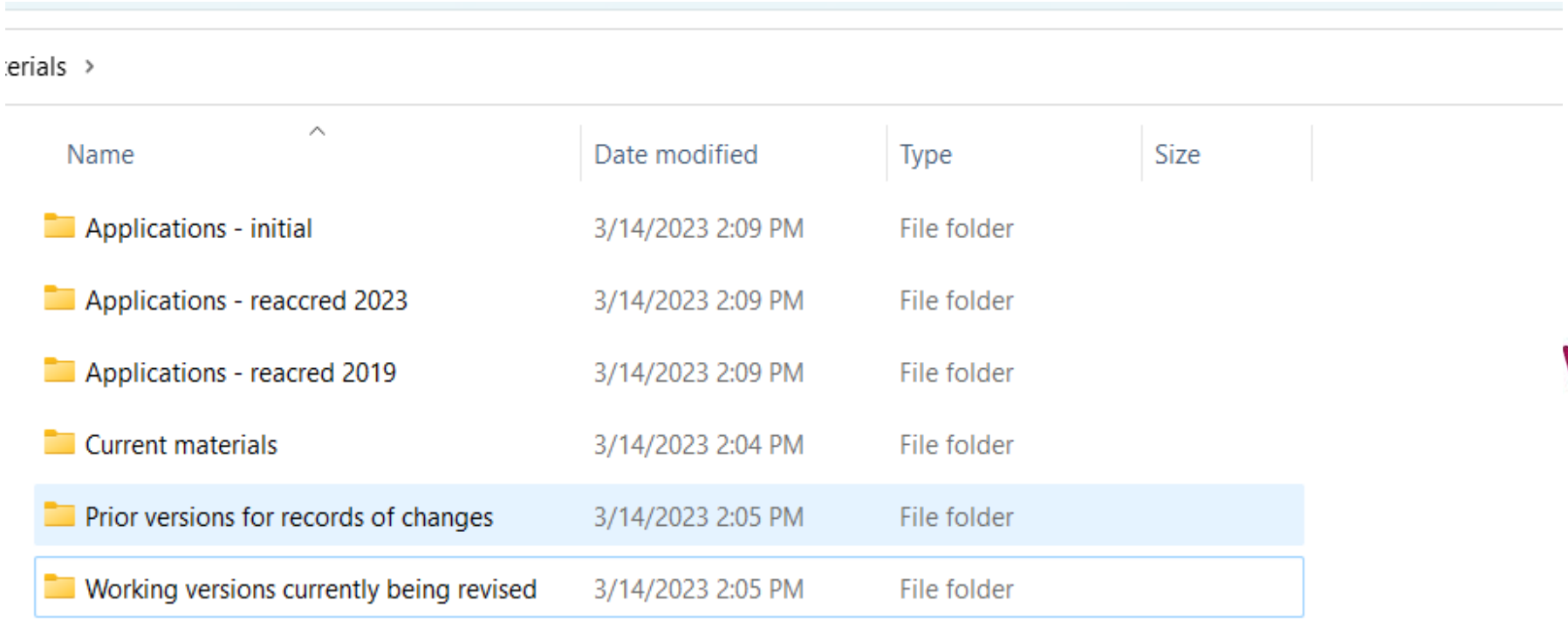
Guidance on Completing Section A

Changes to Section A for 2023

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

Sample Folder Structure



Save Documents in One Folder

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

Organize Filenames by Number

- Don’t rename policies, just add a number
- Use numbers that make sense for your program
  - 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

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

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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

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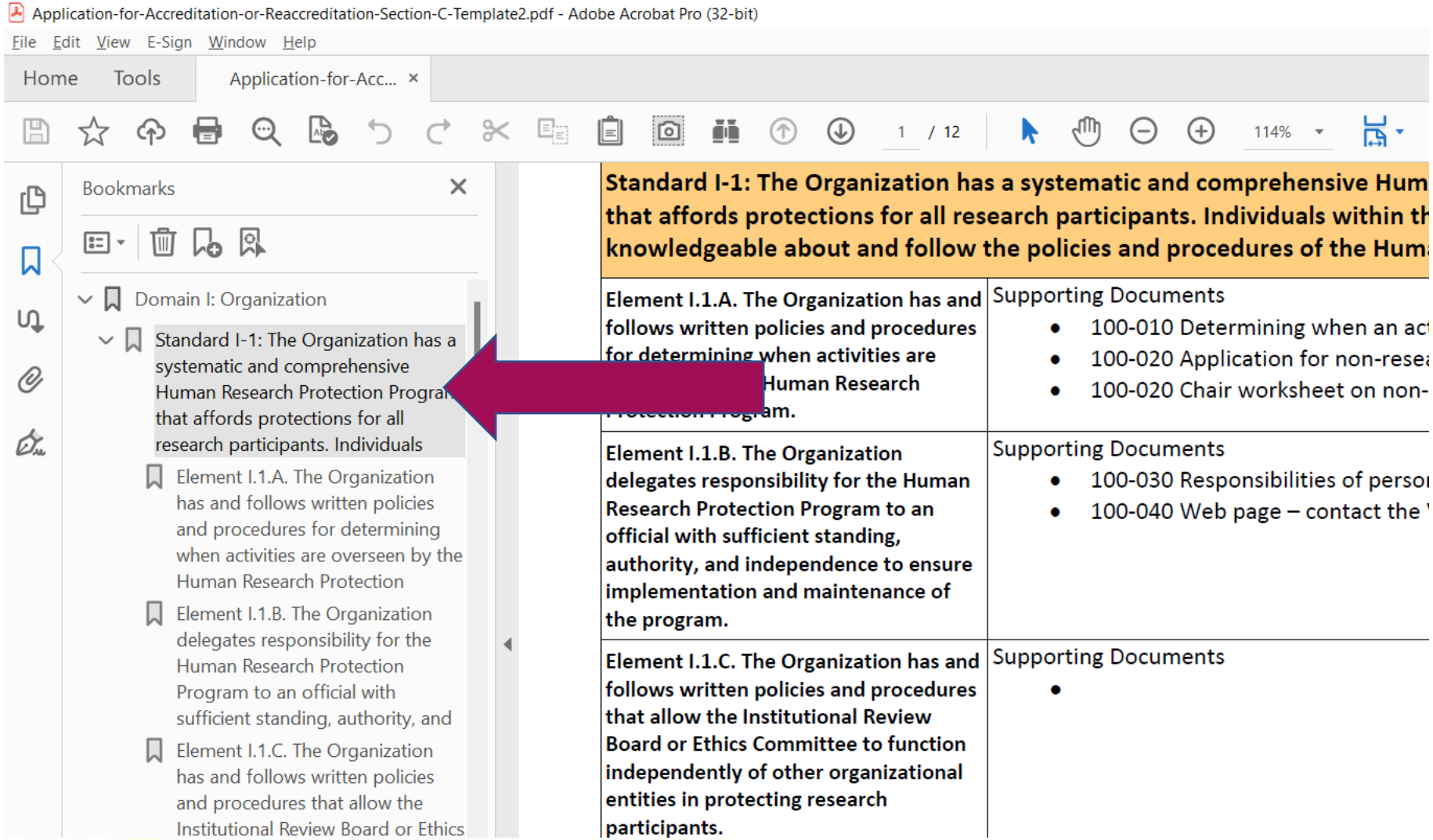
Section C - Create Bookmarks



Standard I-1: The Organization has a systematic and comprehensive Hum that affords protections for all research participants. Individuals within th knowledgeable about and follow the policies and procedures of the Hum	
Element I.1.A. The Organization has and follows written policies and procedures for determining when activities are Human Research Program.	Supporting Documents • 100-010 Determining when an act • 100-020 Application for non-resea • 100-020 Chair worksheet on non-
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 perso • 100-040 Web page – contact the
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 •

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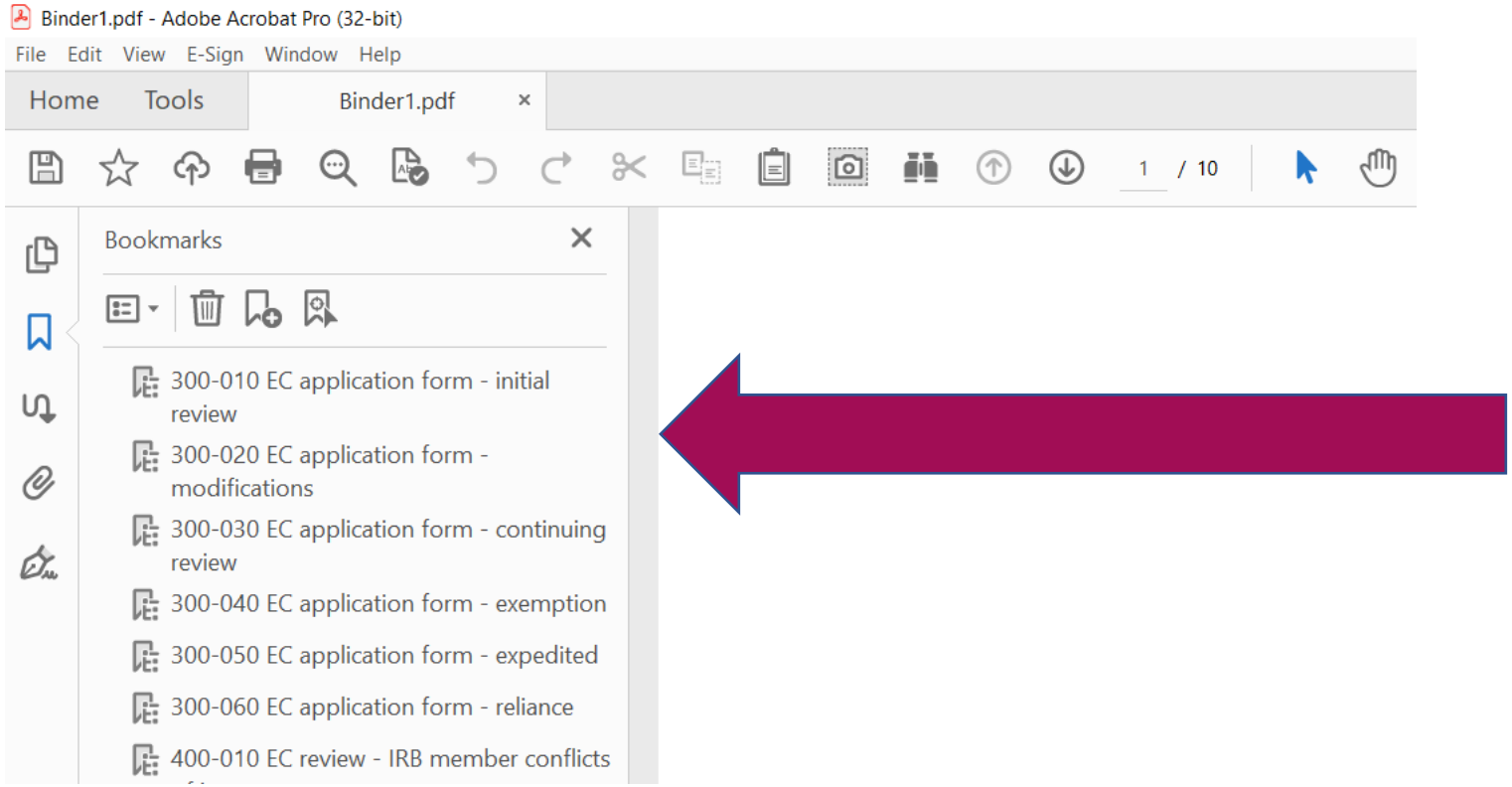
Acrobat Pro: Automatically Creates Bookmarks for Section D



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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

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Procedures to Maintain a Current AAHRPP Application – Policy on Policies

- Define who is responsible
- Define how often materials are reviewed to ensure they are current and that changes are updated. (Quarterly, yearly, triennially)
- Describe process to update the "AAHRPP folder" when a policy is updated
  - Move the prior version of the policy to a separate archive folder (not in the same directory)
  - Save the new pdf of updated policy in the current accreditation folder (AAHRPP 2024)
  - Update the tracking sheet with the revised version and date

Keep Application Up To Date Between Cycles

- Maintain these living documents as needed
- Track revisions, educate your community, monitor your practices
- Makes applying for re-accreditation more efficient

Standard/ Element	SOP/Tool/ System	Revision	Version - old	Version - new	Education	monitoring
I.1.A.	100.1. - HRPP	Updated IO designee	3/20/20	4/1/23	Complete	NA
1.7.A.	200.2 - IRB Membership	Consultant COI	6/22/29	5/1/23	In-progress	Monitoring training and COI Forms

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Thank You!

- Please complete the survey
- Plan to attend upcoming “Ask AAHRPP” webinars:
  - April 9, 2024 - Evaluation of Written Materials
  - June 11, 2024 - Evaluation of Practice, What to Expect During the Site Visit
  - August 13, 2024 – Responding to Draft Site Visit Report
  - October 8, 2024 - Council on Accreditation Review
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Contact AAHRPP

Robert Hood, Ph.D.
Director of Accreditation and Global Outreach
rhood@aahrpp.org

Jemelle Williams, BS, PMP
Assistant Director of Operations
jwilliams@aahrpp.org