# Instructions for Formatting and Submitting Materials in Support of Accreditation
**Updated March 13, 2020**

Below are instructions for using the necessary tools needed to format submissions in support of accreditation so that they conform to the AAHRPP requirements. Organizations that submit documents that do not conform to these standards will be asked to resubmit. For explanations of the content of submissions, please consult the relevant instruction documents, the Evaluation Instrument for Accreditation, and Tip Sheets in the web document library on AAHRPP's website, www.aahrpp.org

An accurate and complete application is necessary to provide the AAHRPP staff, the site visitors, and the Council on Accreditation with sufficient information to make an objective judgment concerning accreditation and evaluating the Human Research Protection Program according to the Accreditation Standards.

Please contact AAHRPP staff with any questions about completing your submission.

The following requirements are universal for all submissions:
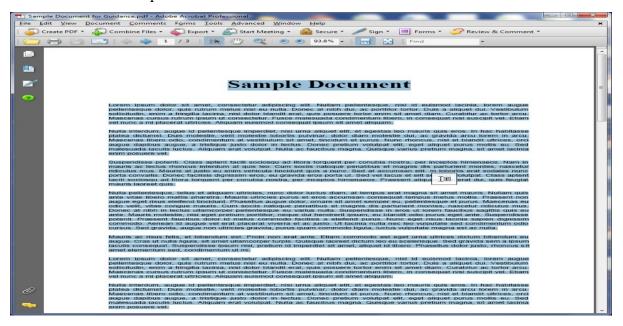
- All documents in support of accreditation must be submitted using the most current version of the application forms from the web document library on AAHRPP's website. The submission must also be on the correct type of form. There are four types of forms:
    - Step 1 Application Form
    - Step 2 Application Form
    - Annual Report Form
    - Submission Form
        - The Submission Form is used for Responses to the Draft Site Visit Report, Status Reports, Requests for Full Accreditation, and Improvement Plans.
- Application forms must be completely filled out.
- **Submissions that are not signed by the Application Contact and Organization Official will not be accepted and must be resubmitted with signatures. Electronic signatures are acceptable.**
- Application forms must either be signed by hand or contain an electronic signature. Portable Document Format (.PDF) files containing application forms must contain a scanned copy of the forms including the original signature.
    - .PDF files containing application containing signatures that are typed will not be accepted.
- **Electronic submissions must be submitted to AAHRPP via a cloud-based server (e.g., Drop Box).  If this presents a problem, please contact AAHRPP.**
- Electronic files must be submitted as Adobe .PDFs or Excel Spreadsheets.
- Except where indicated in the Step 2 Application Process or by AAHRPP staff, application forms should not be submitted as separate .PDF files; they should be included in the main file.
- **All .PDF files must be paginated, searchable, and bookmarked.**

Below are the various tools that should be used to ensure .PDF files adhere to the AAHRPP requirements.   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. These tools are unavailable in Adobe Reader.

A .PDF document is searchable when a ctrl + f search can find any word within the document. To check whether or not a submission is searchable, do the following:

- When viewing the .PDF file, press ctrl + a. This will highlight all of the searchable text in blue, leaving the empty space white. Perform this check on every page to be sure that the entire file is searchable.
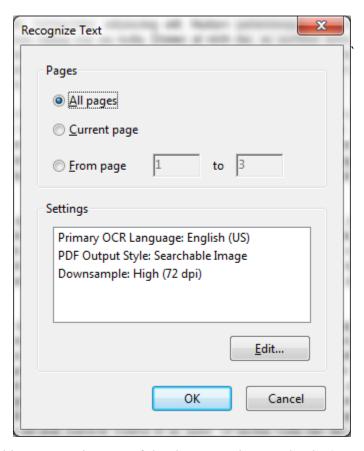
Below is an example of a file that is searchable:



To make a .PDF searchable, use a tool called Optical Character Reader (OCR). This is a built-in feature of Adobe Acrobat. To begin, click on the document button.



On the drop down menu, select OCR text recognition and then recognize text using OCR. A new window will open in Acrobat (see below):
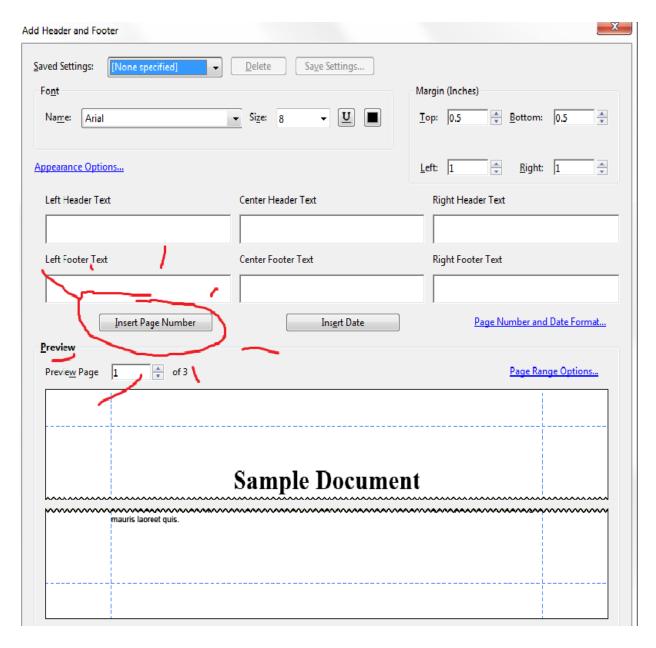
Please note the radial buttons at the top. If the document is completely (or mostly) unsearchable, select the "all pages" button and press "ok." After a few moments, the program will finish running (the time it takes is relative to the size of the file.) When it is complete, use the ctrl + a test again to ensure the file is searchable. If some of the pages are still unsearchable, there is an additional step. Open the box with the radial buttons again. This time select the "From Page" button. In the two boxes to the right, enter the page that is not searchable. Enter the same number in each box. Next, click "ok" and wait for the program to finish running. Use the ctrl + a method to see if the page is now searchable. Do this to capture pages that were not searchable after the first step.

Every page of a .PDF file should have a unique page number. To ensure that a .PDF file is paginated correctly, use the insert header and footer tool in Acrobat. To begin, select the document tab.



Hover over "Header and Footer" and then select "add." This will open a new box. In this box, click on the "Insert Page Number" button and click "ok."

## Add Header and Footer

Saved Settings: [None specified] ▾   Delete   Save Settings...

**Font**

Name: Arial ▾   Size: 8 ▾   U ▪

**Margin (Inches)**

Top: 0.5   Bottom: 0.5

Appearance Options...

Left: 1   Right: 1

Left Header Text

Center Header Text

Right Header Text

Left Footer Text

Center Footer Text

Right Footer Text

[Insert Page Number]   [Insert Date]   Page Number and Date Format...

**Preview**

Preview Page 1 of 3   Page Range Options...

### Sample Document

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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.

Sample Document for Guidance.pdf - Adobe Acrobat Professional

File  Edit  View  Document  Comments  Forms  Tools  Advanced  Window  Help

Create PDF ▼   Combine Files ▼   Export ▼   Start Meeting ▼   Secure ▼   Sign ▼   Forms ▼   Review & Comment ▼

2   3        93.8% ▼        Find

2

Nulla pellentesque, tellus et aliquam ultricies, nunc dolor luctus diam, at tempus erat magna sit amet mauris. Nullam quis ante vitae libero mattis pharetra. Mauris ultricies purus et eros accumsan consequat tempus metus mollis. Praesent non augue eget risus eleifend tincidunt. Phasellus augue dolor, ornare sit amet semper eu, pellentesque et purus. Maecenas eu odio velit, vitae congue mauris. Cum sociis natoque penatibus et magnis dis parturient montes, nascetur ridiculus mus. Donec at nibh in lectus ullamcorper pellentesque eu varius nulla. Suspendisse in eros ut lorem faucibus sagittis quis eu ante. Mauris molestie, nisi eget pretium porttitor, neque dui hendrerit ipsum, eu blandit odio purus eget ante. Suspendisse potenti. Praesent faucibus dolor id metus commodo facilisis a eleifend purus. Nunc eget risus lacinia sapien dignissim commodo. Aenean id augue vel erat placerat viverra et ac justo. Ut lacinia nulla nec leo vulputate sed condimentum odio
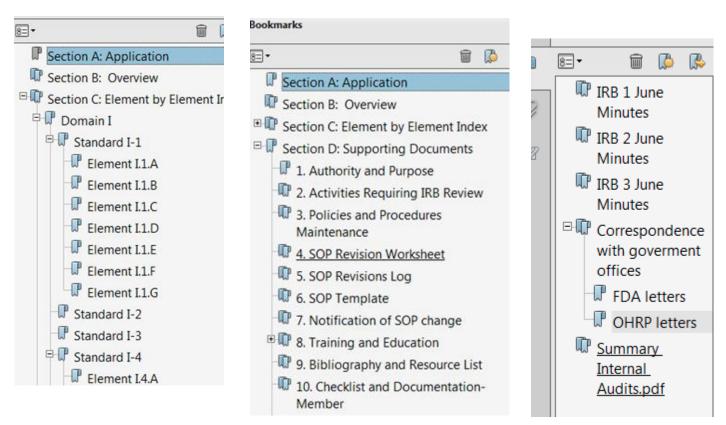
Adding page numbers to a file before printing ensures that the hard copy will be paginated correctly and that it will match the .PDF.

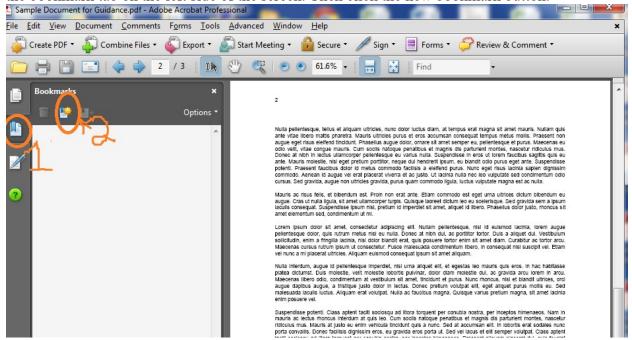All .PDF files should be bookmarked.  In the bookmark Section, please be sure to include:
- The first page of every Section (e.g. Section A, B, C, and D in a Step 2 Application or Sections A and B in a Response to the Draft Site Visit Report).
- Each element listed in the element by element index (e.g. Section C of a Step 1 or Step 2 Application).
- The first page of each supporting document (e.g. Section D of a Step 1 or Step 2 Application or Section B of a Response to the Draft Site Visit Report).

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. Below are sample bookmarks:

| **Section C** | **Section D** | **Section F** |
|---|---|---|



Section A: Application
Section B: Overview
Section C: Element by Element In
Domain I
Standard I-1
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
Standard I-2
Standard I-3
Standard I-4
Element I.4.A

**Bookmarks**

Section A: Application
Section B: Overview
Section C: Element by Element Index
Section D: Supporting Documents
1. Authority and Purpose
2. Activities Requiring IRB Review
3. Policies and Procedures Maintenance
4. SOP Revision Worksheet
5. SOP Revisions Log
6. SOP Template
7. Notification of SOP change
8. Training and Education
9. Bibliography and Resource List
10. Checklist and Documentation- Member

IRB 1 June Minutes
IRB 2 June Minutes
IRB 3 June Minutes
Correspondence with goverment offices
FDA letters
OHRP letters
Summary Internal Audits.pdf

When creating a bookmark, start on the page that the bookmark will redirect to. To begin, open the bookmark tab on the left side of the screen. Then click the new bookmark button.

Clicking the new bookmark button will create a bookmark called "Untitled" that can be renamed by double-clicking it. To create a sub-bookmark, create another bookmark, then click and drag it on top of an already existing bookmark.
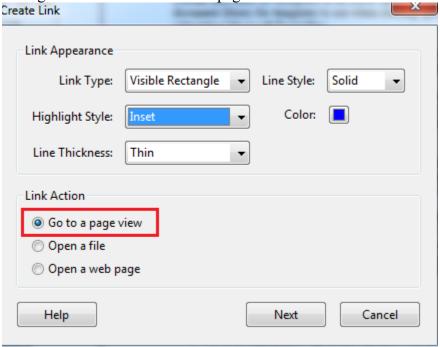
Certain files must be submitted as an Excel Spreadsheet rather than .PDF. Consult the web document library for templates to use when creating spreadsheets. Below are guidelines for submitting Microsoft Excel files:

- Organizations with multiple IRBs should either list each IRB in a separate worksheet within the spreadsheet, or add a column to the spreadsheet that lists the IRB(s) to which the member belongs.
- 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 spreadsheet or add a column to the spreadsheet that lists the location where the protocol is maintained.

Listed below are the documents and files required for each type of submission. Additional files should not be included unless otherwise specified. For descriptions of the content that belongs in each Section, please consult the guidance documents in the web document library.

***In order to provide the most efficient review possible, Organizations are strongly encouraged to hyperlink appropriate portions of Section C to the referenced supporting documents in Section D.***

Organizations may create hyperlinks by either highlighting the appropriate text, right clicking, and selecting "Create Link," to open the Create Link Dialogue Box. In the Create Link Dialogue Box select the "Go to a page view" radial dial and click "Next."



This will open a new dialogue box called "Create Go to View." It is important not to select the

"Set Link" option until you have scrolled to the page you wish to link to. For example, if an organization wished to link text on page 9 to a supporting document on page 105, they would not select the "Set Link" option until they scroll all the way to page 105.

***Note for organizations using Adobe Acrobat X: AAHRPP requires that submissions are enclosed as one, seamless .PDF file, allowing for each individual section of a submission to move directly to the next section without an interruption in pagination. Therefore a submission should begin on page 1 of Section A and scroll all the way through the last page of the final Section. Organizations submitting multiple .PDF files bound as an Adobe .PDF Portfolio, will be required to resubmit.***

Step 1 Application

- The Step 1 Application must contain:
  - One .PDF file containing:
    - Section A (Signed Submission Form)
    - Section B (an overview of the Human Research Protection Program)
    - Section C (An Element by Element Index to the Supporting Documents)
    - Section D (Supporting Documents)
  - One Excel Spreadsheet containing Section E (IRB Roster)

Step 2 Application

- The Step 2 Application must contain:
  - One .PDF file containing Sections A-D (same as Step 1. This file should not contain tracked changes.) Section A must include a signed copy of the Submission Form (electronic signatures are acceptable).
  - One Excel Spreadsheet containing Section E (IRB Roster)
  - One .PDF containing Section F (Minutes, Correspondence with government oversight offices, and summary of internal audits). Section F should be uniquely paginated and searchable.
  - One Excel Spreadsheet containing Section G (Active protocols including name of researchers)
  - One Excel Spreadsheet containing Section H (Key Personnel)

Submission Form Documents (Responses to the Draft Site Visit Report, Improvement Plans, Status Reports, and Requests for Full Accreditation)

- E-mail these submissions to reporting@aahrpp.org:
  - One .PDF file containing:
    - The signed Submission Form (electronic signatures are acceptable).
    - Section A
    - Section B

<u>Annual Reports</u>

- Email a .PDF of the Annual Report Form and supporting documents, if applicable, to [reporting@aahrpp.org](mailto:reporting@aahrpp.org)

**REVISIONS**

December 2018
- Updated AAHRPP's mailing address

March 2020
- Updated submission instructions