

**FULL INITIAL REVIEW (IR) SUBMISSION ELECTRONIC PROCESS
STEPS FOR SUBMITTING AN INITIAL FULL MEDICAL/NON-MEDICAL IRB APPLICATION
TO ORI VIA EMAIL:**

1. Fill out the IRB application forms (Form A, B . . .) and any other pertinent IRB application forms.
2. All applicable IRB forms and attachments (e.g., Investigator's Brochure, Sponsor Protocol, and Grant Application) must be submitted as one PDF document that is readable/searchable (Step D) and bookmarked (Step H). This requires Adobe Acrobat Software (Adobe Reader is not adequate). Instructions on obtaining the software and preparing the document are available below (or in an email attachment). Click the following links for detailed instructions:
 - A. [Downloading Adobe Acrobat from UK Software](#)
 - B. [Converting Word Documents to PDF](#)
 - C. [Checking to See if Text is Readable & Searchable](#)
 - D. [Making PDFs readable and searchable](#)
 - E. [Merging PDFs into Portfolio Process](#)
Follow Step E when merging files with an electronic signature into a Portfolio
 - F. [Combining Multiple PDF Files into 1 PDF](#)
Follow Step F when combining multiple PDF files from a file saved to desktop folder
 - G. [Inserting Additional Adobe PDFs into 1 PDF](#)
Follow Step G when inserting additional PDFs while working in Adobe
 - H. [Labeling Bookmarks to Guide the IRB Review](#)
 - I. [Naming Bookmarks Chart for Full Medical Applications](#)
 - J. [Naming Bookmarks Chart for Full Non-Medical Applications](#)
3. Use the *Naming Bookmark Chart* to label the applicable documents included in your submission.
4. Attach the application to an email then send to IRBSubmission@uky.edu.
5. Attachments should not be encrypted or password protected.
6. The email subject line must include PI's Last Name, type of submission:
IR PI's Last Name
7. Submit ONE paper copy to ORI in addition to your email submission within two business days. Mail to: ORI 315 Kinkead Hall, Lexington, KY 40506-0057
8. Upon receipt, the email application is distributed to appropriate ORI staff. An automated response will be sent to you with notification that the email and attachment has been received. The ORI administrative and professional associates managing the submission may contact with you regarding any questions that they might have.

A. DOWNLOADING ADOBE ACROBAT FROM UK SOFTWARE DOWNLOADS:

In order to work with PDF documents, (combine, make readable and searchable, bookmark) you will need Adobe Acrobat Software. Adobe Reader is not adequate as it only allows you to read PDF documents.

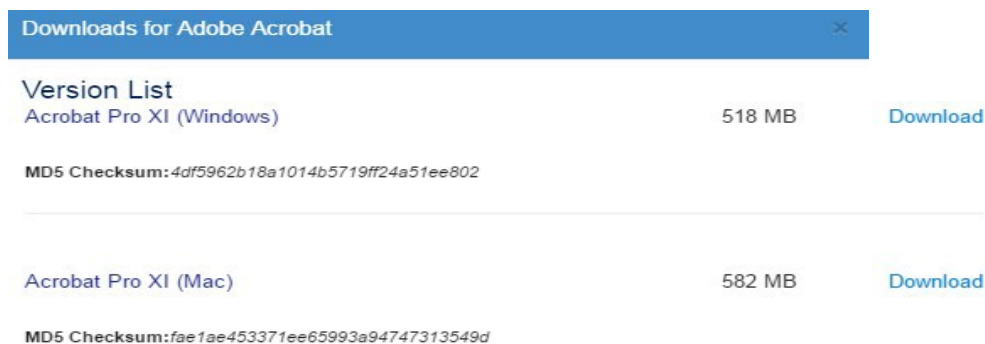
1. LOG INTO THE **UK SOFTWARE DOWNLOADS WEBSITE**
HTTPS://DOWNLOAD.UKY.EDU/ WITH YOUR LINK BLUE USERNAME AND PASSWORD.



2. SEARCH FOR **ADOBE ACROBAT**. CLICK **SEE DOWNLOADS**.



3. CHOOSE **ACROBAT PRO** AND CLICK **DOWNLOAD** FOR EITHER THE WINDOWS OR MAC VERSION.



[CLICK HERE TO RETURN TO STEPS](#)

B. CONVERTING WORD DOCUMENTS TO PDF:

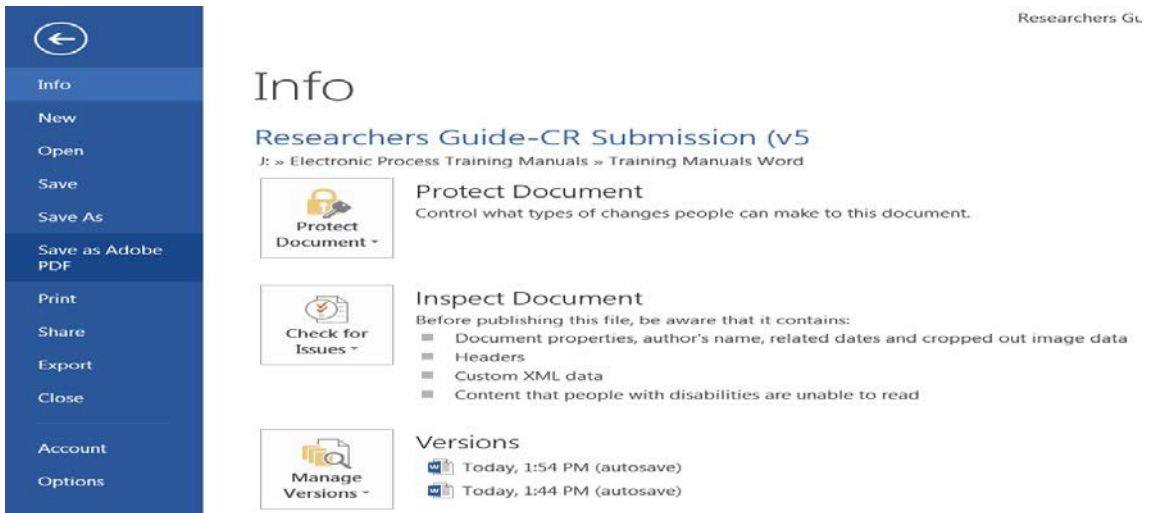
1. CREATE A WORD DOCUMENT.



2. CLICK FILE THEN SELECT SAVE AS ADOBE PDF.



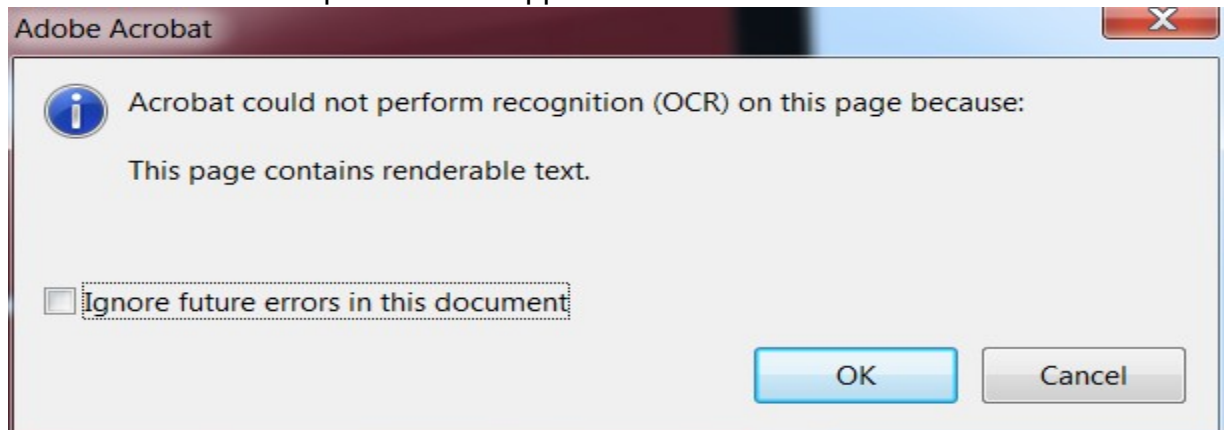
3. SAVE IR PDF FILES AS IR PI'S LAST NAME.



[CLICK HERE TO RETURN TO STEPS](#)


C. CHECKING TO SEE IF TEXT IS READABLE & SEARCHABLE:

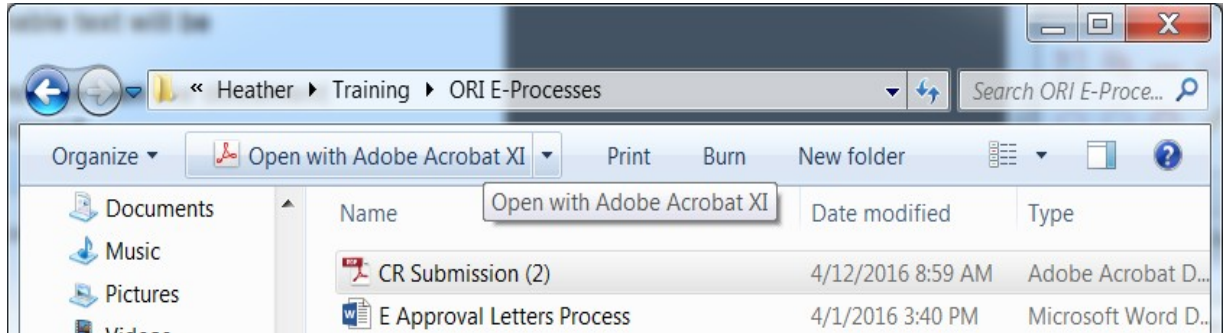
Documents that were originally created using Adobe Acrobat or documents that were saved as PDF are readable and searchable. To check whether the document is readable and searchable, select ctrl+a then all searchable text will be highlighted in blue. If the process has begun and you receive the below message then the document is readable & searchable so Step D can be skipped.



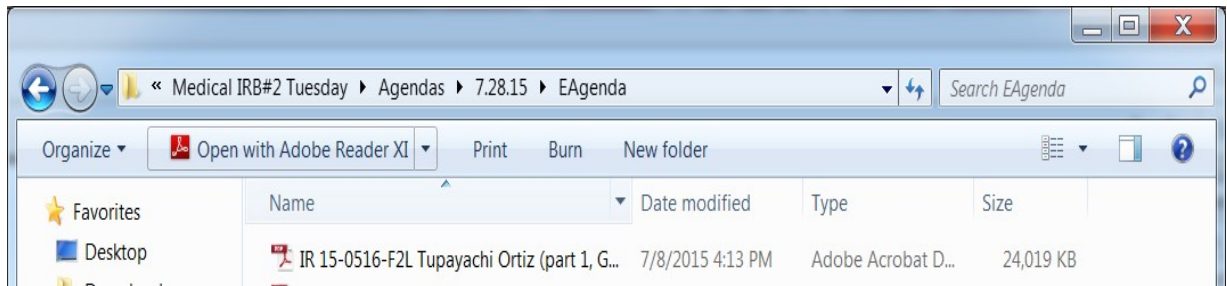
[CLICK HERE TO RETURN TO STEPS](#)

D. MAKING PDFS READABLE & SEARCHABLE:

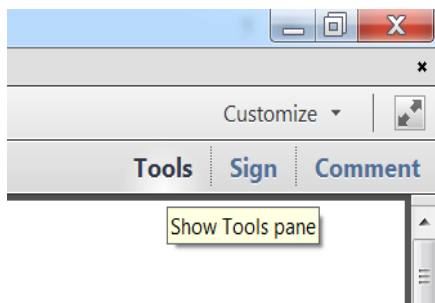
1. CLICK THE ADOBE  DROP DOWN BOX AND SELECT OPEN WITH ADOBE ACROBAT TO OPEN A DOCUMENT USING ADOBE ACROBAT.



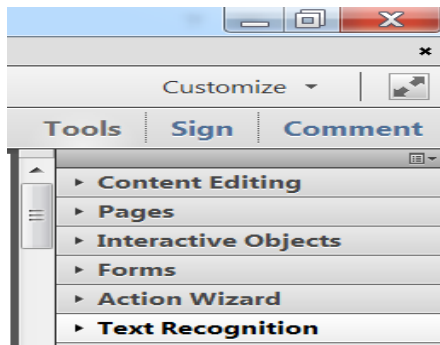
2. OPEN PDF FILE.



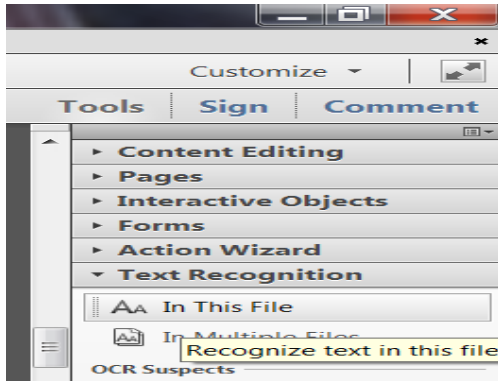
3. CLICK TOOLS.



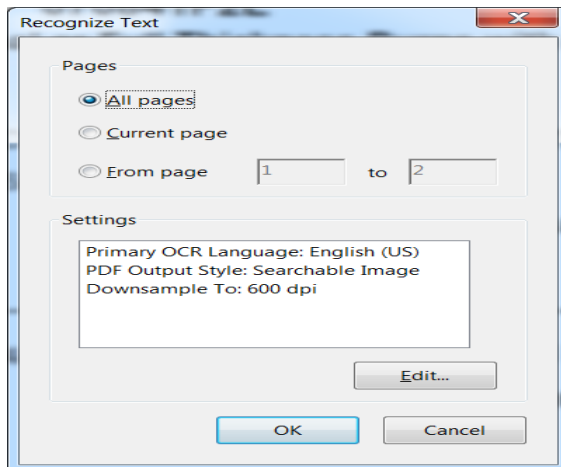
4. CLICK TEXT RECOGNITION.



5. CLICK IN THIS FILE.



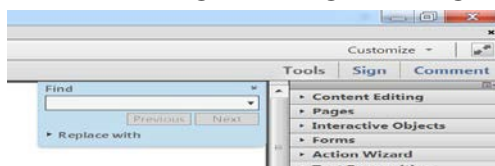
6. SELECT ALL PAGES.



7. TO CHECK IF TEXT IS READABLE, SELECT CTRL+A. READABLE TEXT WILL BE HIGHLIGHTED IN BLUE.



8. TO SEARCH FOR A WORD, SELECT CTRL+F TYPE THE WORD INTO THE POP-UP BOX.

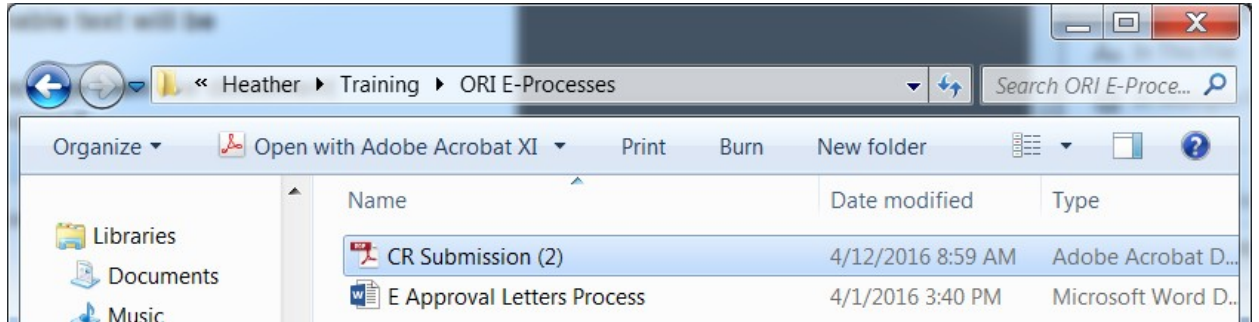


[CLICK HERE TO RETURN TO STEPS](#)

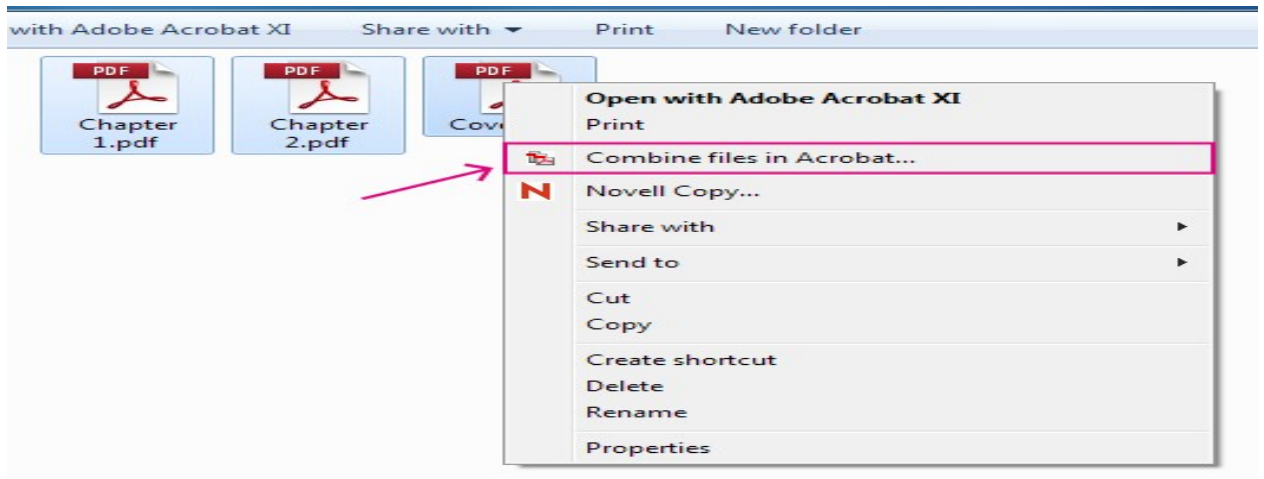
E. MERGING PDFS INTO PORTFOLIO:

Follow Step E when merging files with an electronic signature into a Portfolio.

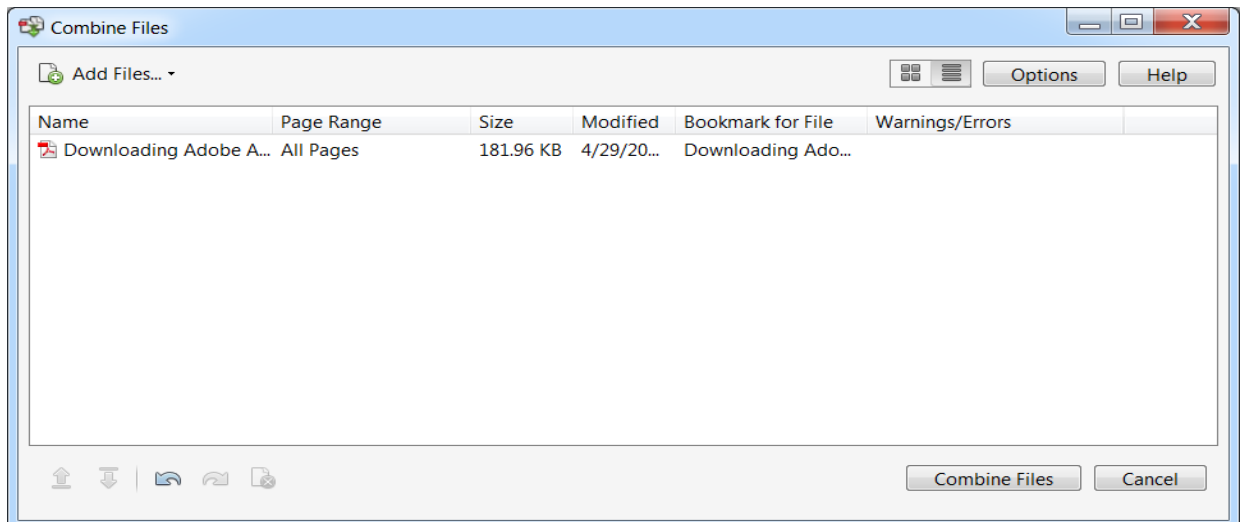
1. SELECT FILE.



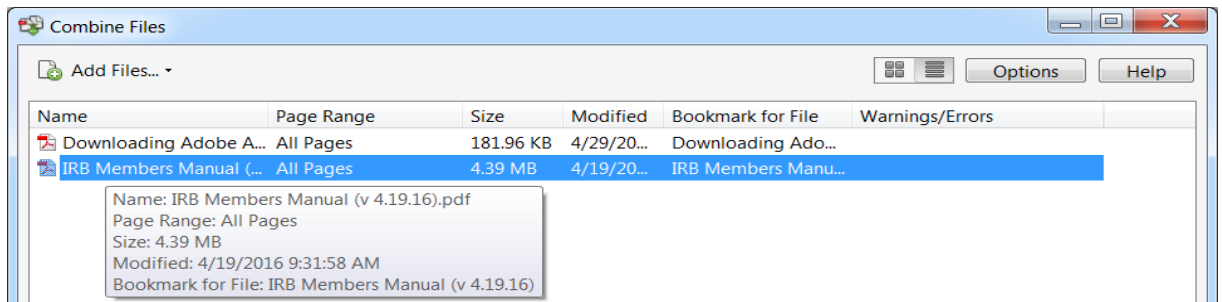
2. RIGHT CLICK COMBINE FILES.



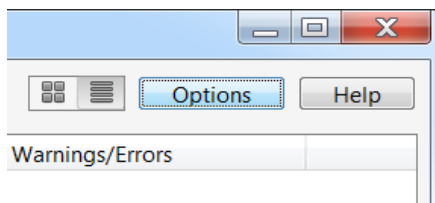
3. DRAG FILES INTO THE COMBINE FILES POP-UP BOX.



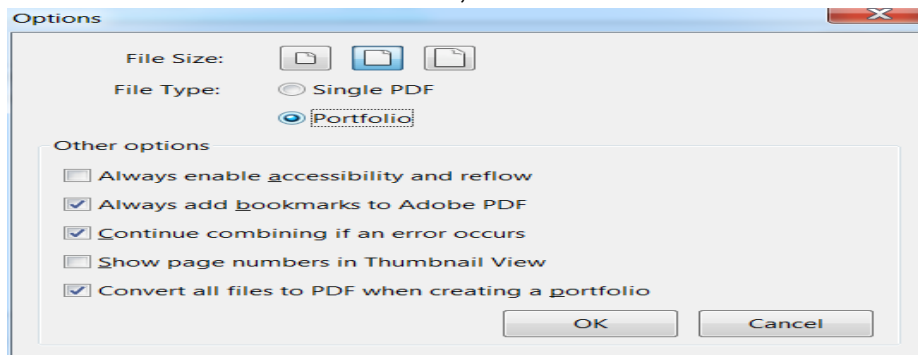
4. IF THE ORDER OF THE FILES NEEDS TO BE CHANGED, DRAG THE INDIVIDUAL FILE INTO THE APPROPRIATE LOCATION.



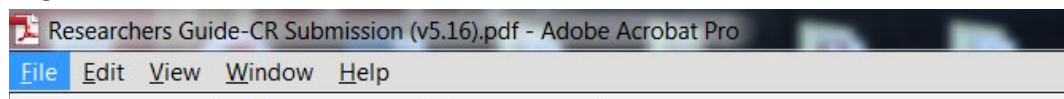
5. CLICK OPTIONS.



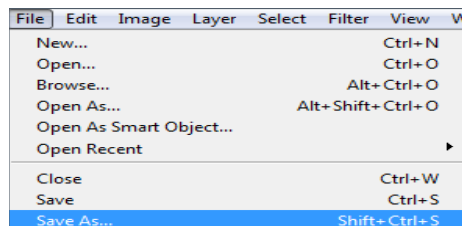
6. IN THE OPTIONS POP-UP BOX, CLICK PORTFOLIO THEN CLICK OK.



7. CLICK FILE.



8. CLICK SAVE AS.
SAVE AS IR PI'S LAST NAME.

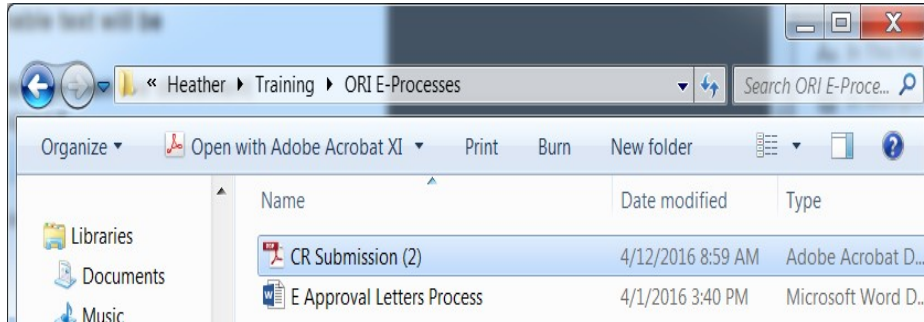


[CLICK HERE TO RETURN TO STEPS](#)

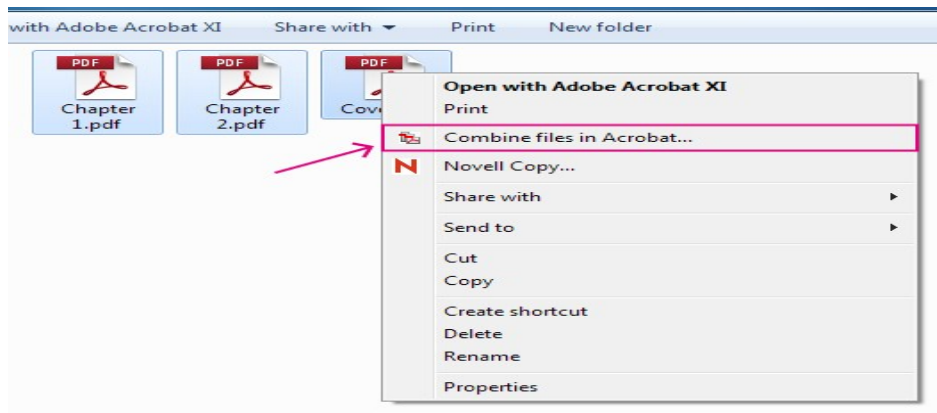
F. COMBINING MULTIPLE PDF FILES INTO 1 PDF:

Follow Step F when combining multiple PDF files from a file saved to a desktop folder.

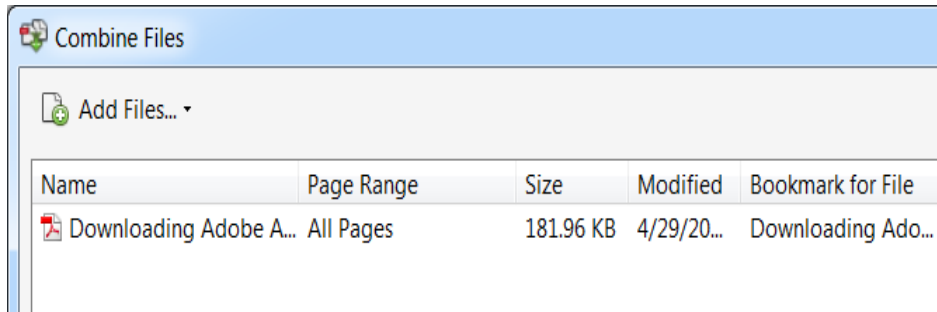
1. SELECT FILE.



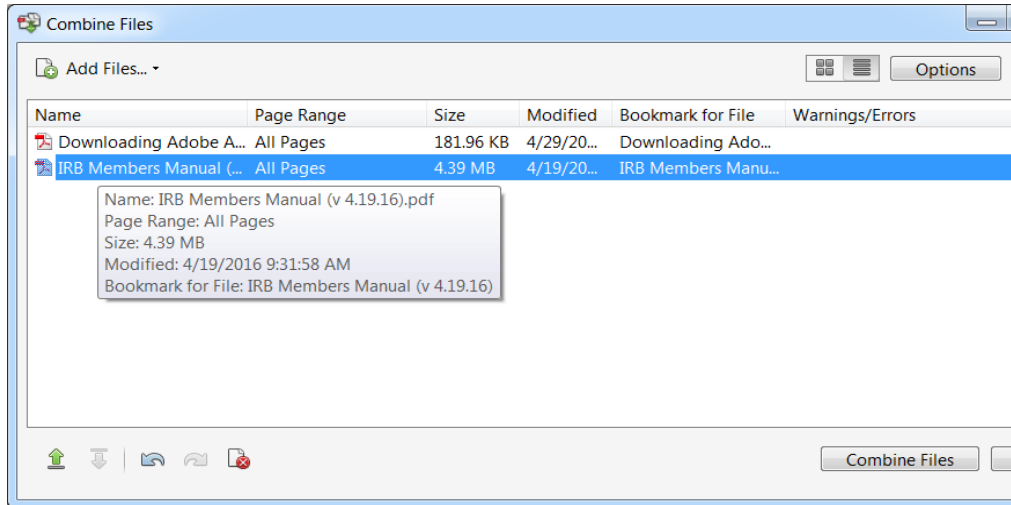
2. RIGHT CLICK COMBINE FILES.



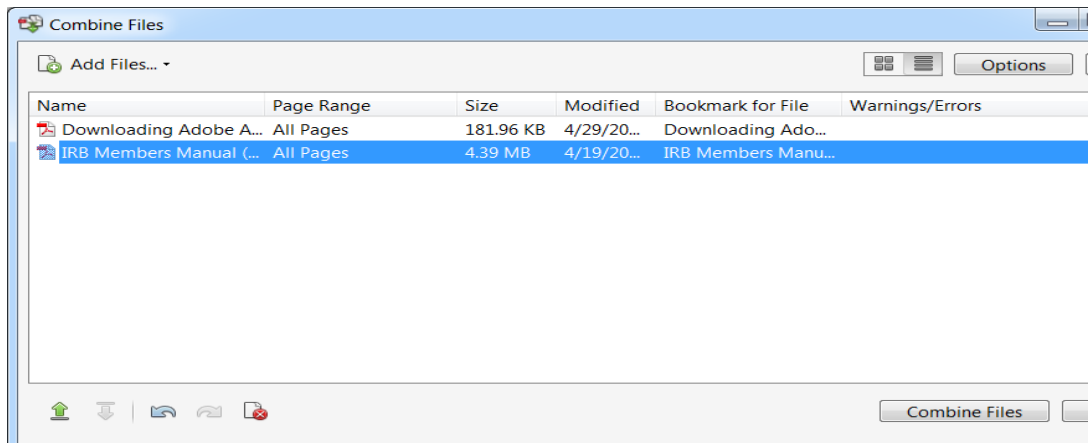
3. DRAG FILES INTO THE COMBINE FILES POP-UP BOX.



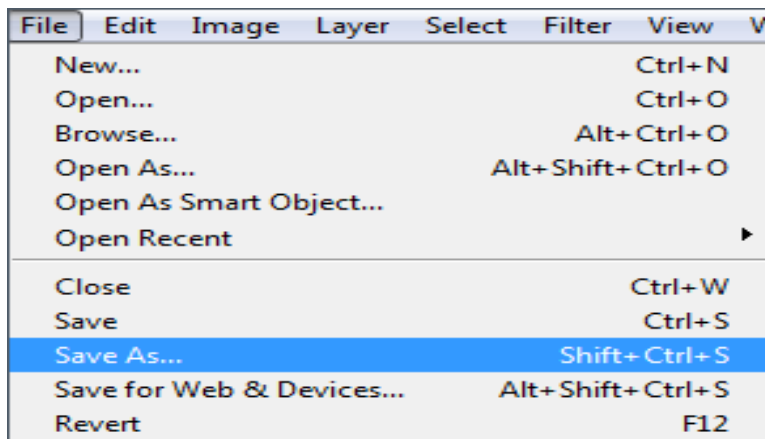
4. CHANGE ORDER OF FILE BY DRAGGING FILES TO THE CORRECT ORDER.



5. CLICK COMBINE FILES.



6. SAVE AS IR PI'S LAST NAME.

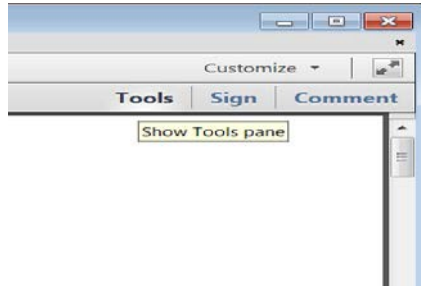


[CLICK HERE TO RETURN TO STEPS](#)

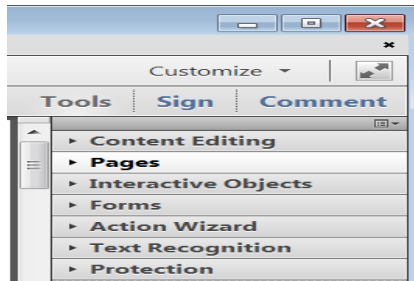
G. Inserting Additional PDFs into 1 PDF:

Follow Step G when inserting additional PDFs while working in Adobe.

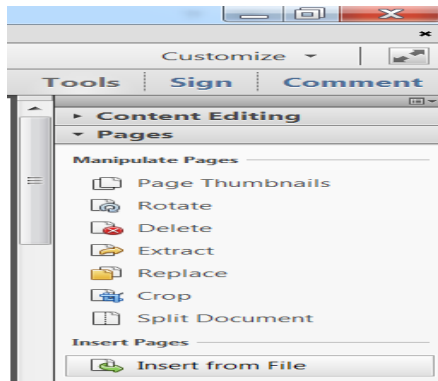
1. IN ADOBE ACROBAT PRO, CLICK TOOLS.



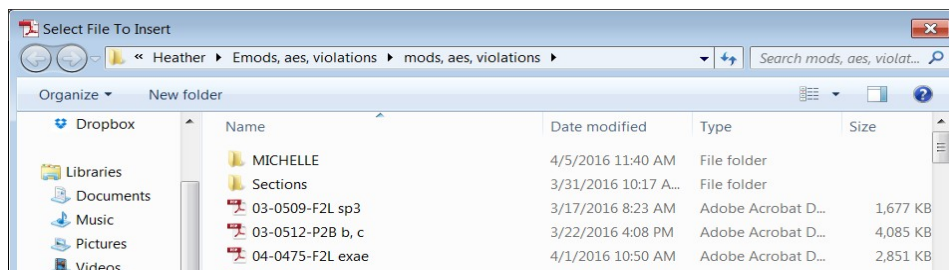
2. CLICK PAGES.



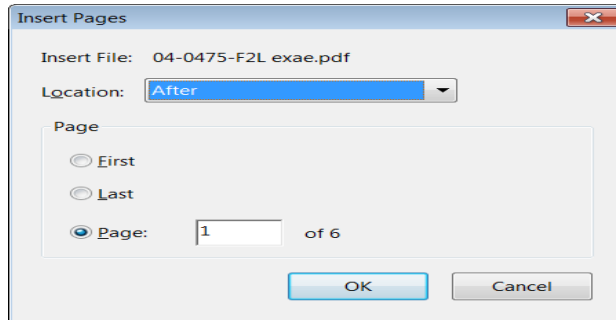
3. CLICK INSERT FROM FILE.



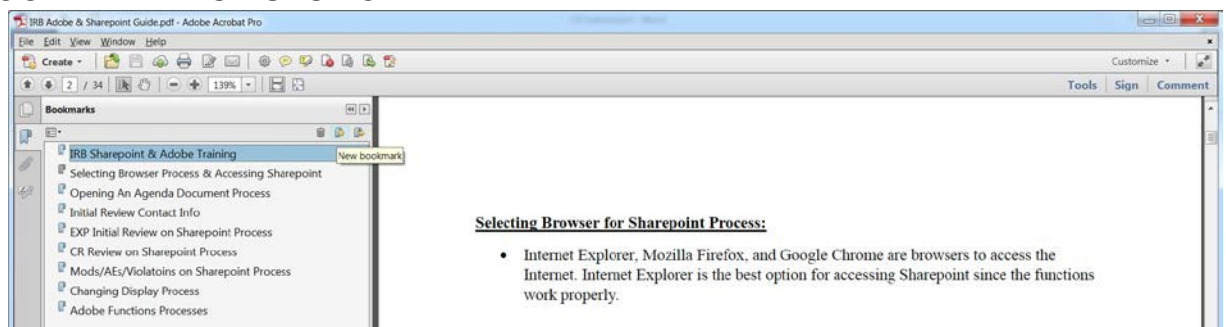
4. INSERT FILE.



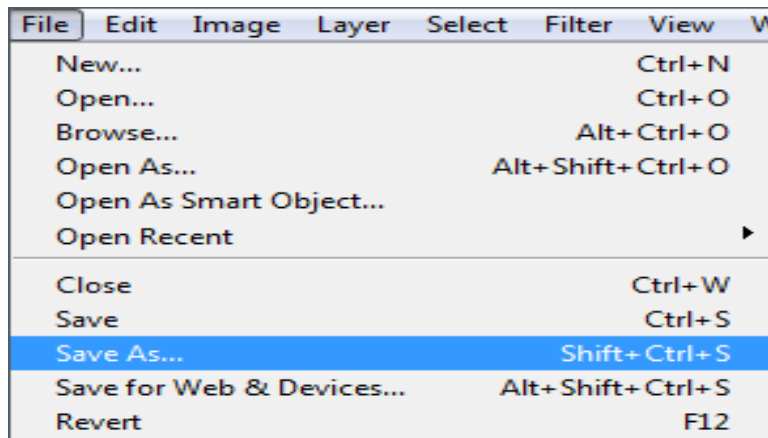
5. SELECT DESIRED LOCATION THEN CLICK OK.



6. BOOKMARK EACH SECTION.



7. CLICK FILE THEN CLICK SAVE AS.
SAVE AS IR PI'S LAST NAME.



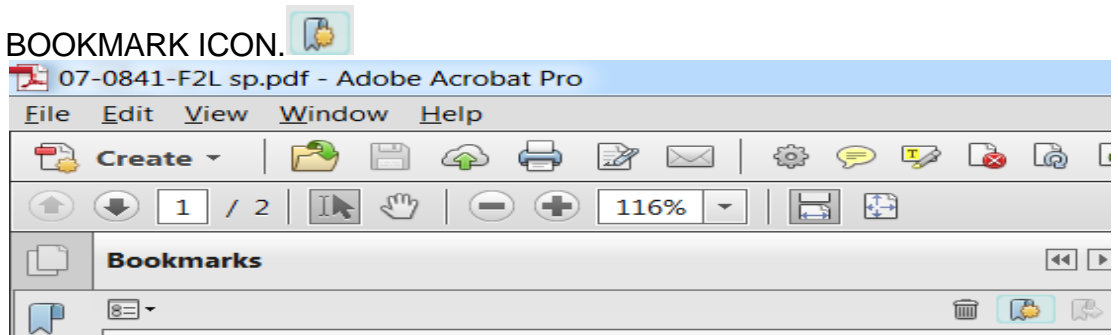
[CLICK HERE TO RETURN TO STEPS](#)

H. LABELING BOOKMARKS TO GUIDE IRB REVIEW:

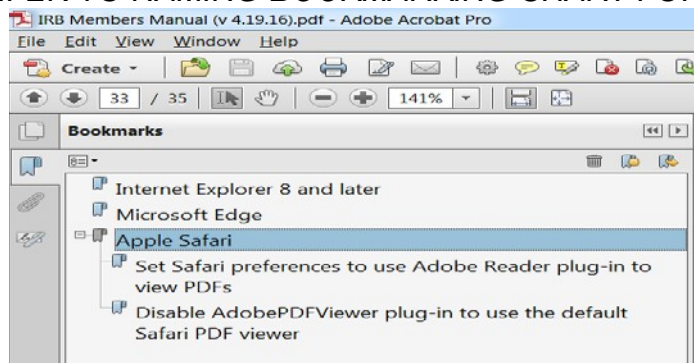
1. CLICK BOOKMARK ICON.



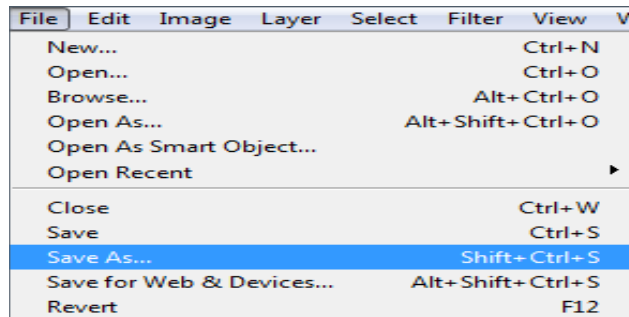
2. CLICK NEW BOOKMARK ICON.



3. ON THE FIRST PAGE OF EACH SECTION, LABEL EACH BOOKMARK WITH NAME OF FORM.
REFER TO *NAMING BOOKMARKING CHART* FOR NAMES OF FORMS.



4. CLICK FILE THEN CLICK SAVE AS.
SAVE AS IR PI'S LAST NAME.



[CLICK HERE TO RETURN TO STEPS](#)

I. NAMING BOOKMARKS CHART FOR MEDICAL FULL PROTOCOLS:

<i>Form</i>	<i>Bookmark Title</i>
Memo	IRB #/PI's Last Name*
GIS	A/GIS/PI's Last Name*
Research Description	B/RD
Appendix A(B, C, . . .)	B/Appendix A, B . . .
Consent Form	C/CF
Non-English Speaking Consent Form	C/(language)/CF
Assent Form	D/AF
Waiver of Informed Consent	E/WIC
Waiver of Documentation of Informed Consent	F/WDIC
Cover Letters/Scripts	F/CL/Script
DHHS-approved Sample Informed Consent Form	G/DHHS
Non-English Speaking Subjects	H/Non-English
HIPAA De-Identification Certification Form	I/De-ID HIPAA
HIPAA Authorization Form	J/HIPAA
Waiver of Authorization Form	K/WofHIPAA
Flyers/advertisements	L/flyers or ads
Data Collection Instruments	M/instruments
Use of any Drug Being Tested in Research	O/Drug
Use of any Device Being Tested	P/Device
Use of Radioactive Materials	Q/RSF
Package insert or FDA approved label	S/FDA or Insert
Research Involving Adults with Impaired Consent Capacity	T/Impaired Consent
Research Involving Pregnant Women, Fetuses, Neonates	U/Neonatal
Research Involving Prisoners	V/Prisoners
Research Involving Children	W/Children
Signature Assurance Sheet	Z/Sig. Assur.
Grant/Contract Application	AA/App
Drug Protocol/DHHS Protocol/NIH Trial	BB/Protocol
Investigator Brochure/Drug Label/Monograph	CC/IB/DL/M
Device Protocol/Label/Manufacturer Operating Manual/HUD Info	DD/DP/L/MOM/HUD
Institutional Biosafety Committee	EE/IBC
Radioactive Drug Research Committee	FF/RDRC
Medical Center/College of Medicine	II/COM

**PI's last name needs to be included in the title of the first bookmark; if the submissions' first page is a memo from the PI, bookmark the memo as IRB#/PI's Last Name.*

[**CLICK HERE TO RETURN TO STEPS**](#)

J. NAMING BOOKMARK CHART FOR NON-MEDICAL FULL PROTOCOLS:

<u>Form</u>	<u>Bookmark Title</u>
Memo	IRB#/PI's Last Name *
GIS	A/GIS/PI's Last Name*
Research Description	B/RD
Consent Form	C/CF
Non-English Speaking Consent Form	C/Language/CF ex: C/Spanish/CF
Assent Form	D/AF
Waiver of Informed Consent	E/WIC
Waiver of Documentation of Informed Consent	F/WDIC
HIPAA De-Identification Certification Form	I/De-ID HIPAA
HIPAA Authorization Form	J/HIPAA
Waiver of Authorization Form	K/WofHIPAA
Flyers/advertisements	L/flyers or ads
Non-English Speaking Flyers/Ads	L/Language/Flyer or Ad
Data Collection Instruments	M/instruments
Non-English Speaking Instruments	M/Language/Instruments ex: C/Spanish/CF
Research Involving Adults with Impaired Consent Capacity	T/Impaired Consent
Research Involving Pregnant Women, Fetuses, Neonates	U/Neonatal
Research Involving Prisoners	V/Prisoners
Research Involving Children	W/Children
Signature Assurance Sheet	Z/Sig.Assur.
Grant/Contract Application	AA/App

**PI's last name needs to be included in the title of the first bookmark; if the submissions' first page is a memo from the PI, bookmark the memo as IRB#/PI's Last Name.*

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