

**MODIFICATION (M), UNANTICIPATED PROBLEMS (UP), AND VIOLATIONS (V) ELECTRONIC PROCESS
STEPS FOR SUBMITTING MODIFICATIONS (M), UPS, OR VIOLATIONS (V) TO ORI VIA EMAIL:**

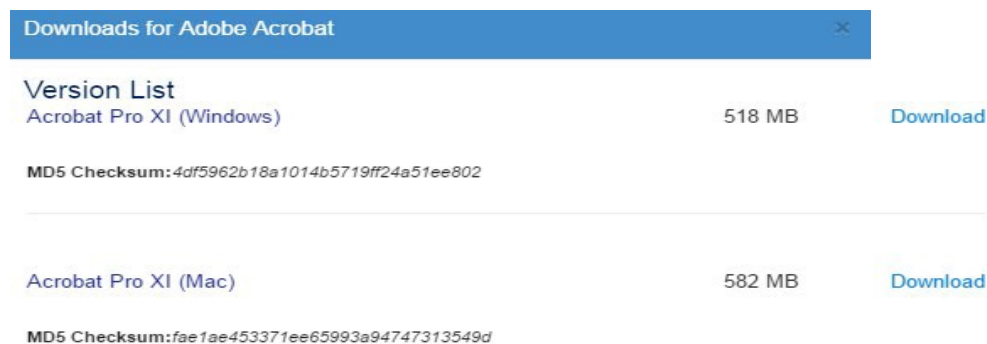
1. Fill out the applicable IRB form (e.g., Modification, Internal Unanticipated Problem, etc.).
2. All applicable IRB forms and attachments (e.g., Revised Sponsor Protocol, safety reports, etc.) must be submitted as one PDF document that is readable/searchable (Step D) and bookmarked (Step H). This requires Adobe Acrobat Software (Adobe Reader is not adequate). Instructions on obtaining the software and preparing the document are available below. 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 MODIFICATIONS](#)
 - J. [NAMING BOOKMARKS CHART FOR UNANTICIPATED PROBLEMS & SAFETY REPORTING](#)
 - K. [NAMING BOOKMARK CHART FOR VIOLATIONS](#)
3. Use the *Naming Bookmark Charts* to label the applicable documents included in your submission.
4. Attach the submission 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:
M IRB# PI's Last Name/ UP IRB# PI's Last Name/V IRB# PI's Last Name.
7. ORI will print out a copy of the submission to go into the file. Please do not submit a paper copy.
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 you regarding any questions that they may 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/](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.**

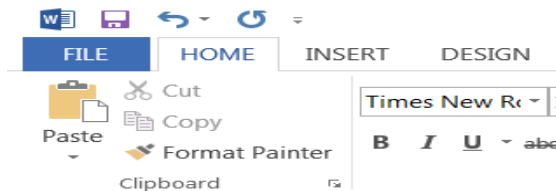
[CLICK HERE TO RETURN TO STEPS](#)

B. CONVERTING WORD DOCUMENTS TO PDF:

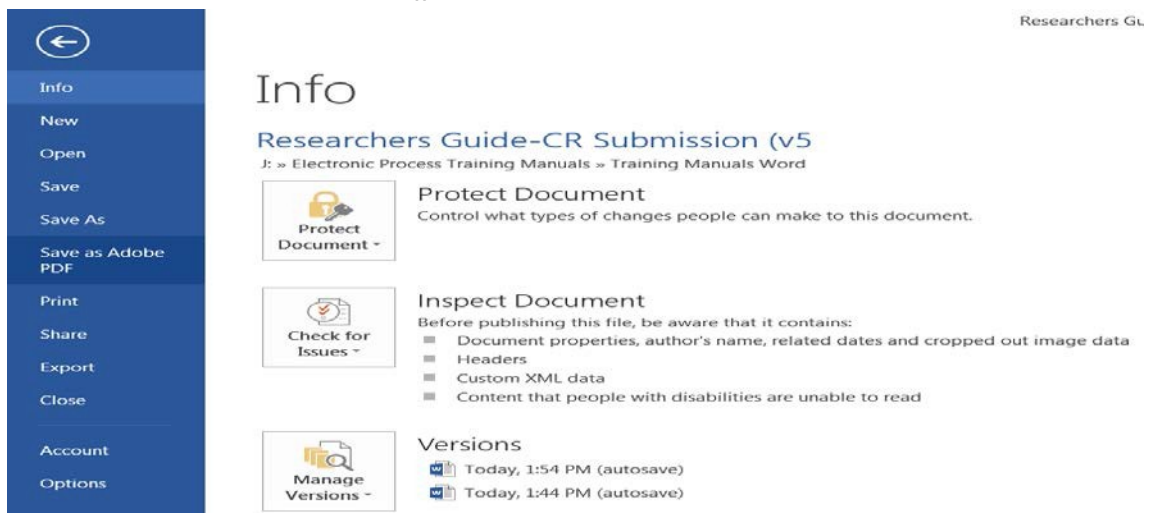
1. CREATE A WORD DOCUMENT.



2. CLICK FILE THEN SELECT SAVE AS ADOBE PDF.



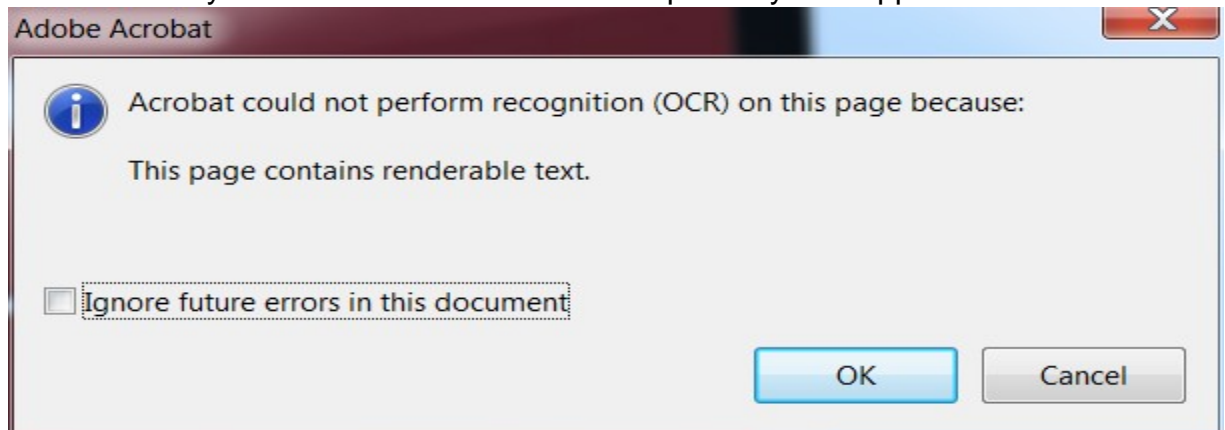
3. SAVE MODIFICATIONS AS *M IRB# PI'S LAST NAME*.
 SAVE UNANTICIPATED PROBLEMS AS *UP IRB# PI'S LAST NAME*.
 SAVE NON-PROMPT UPS AS *NP IRB# PI'S LAST NAME*.
 SAVE VIOLATIONS AS *V IRB# PI'S LAST NAME*.



[CLICK HERE TO RETURN TO STEPS](#)


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

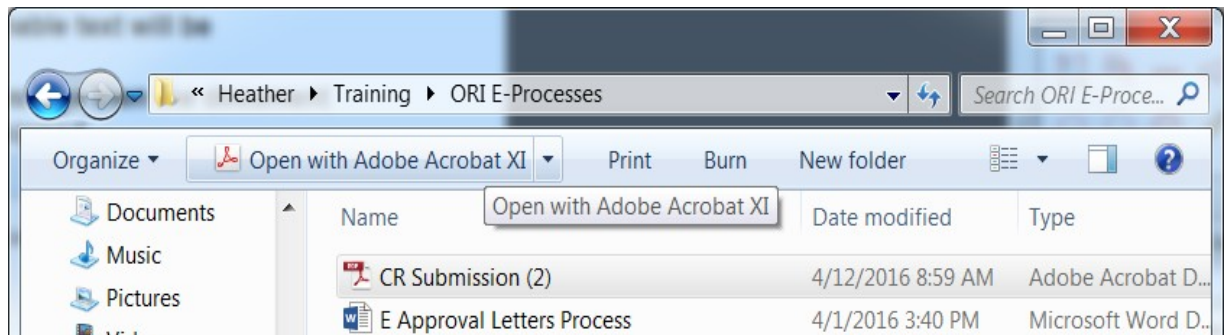
Documents that were originally created using Adobe Acrobat or documents that were saved as PDF are readable and searchable. To check whether the document is readable and searchable, select ctrl+a then all searchable text will be highlighted in blue. If the process has begun and you receive the below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



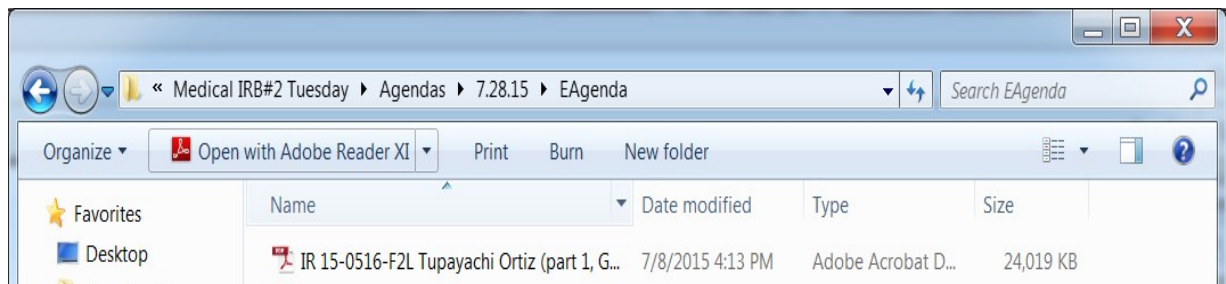
[CLICK HERE TO RETURN TO STEPS](#)

D. MAKING PDFS READABLE & SEARCHABLE:

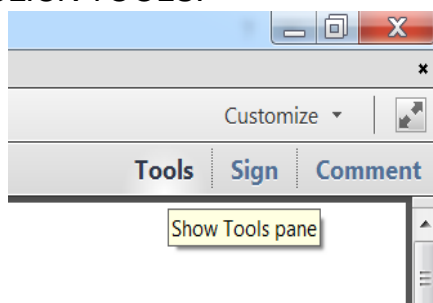
1. CLICK THE ADOBE  DROP DOWN BOX AND SELECT OPEN WITH ADOBE ACROBAT TO OPEN A DOCUMENT USING ADOBE ACROBAT.



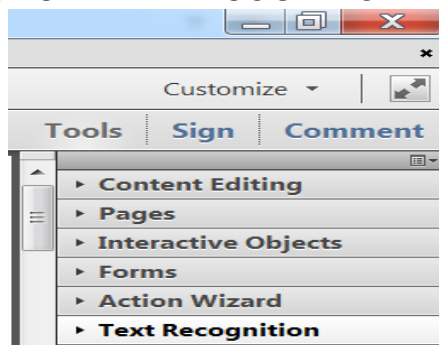
2. OPEN PDF FILE.



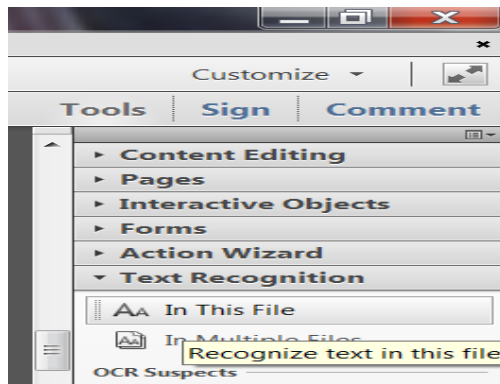
3. CLICK TOOLS.



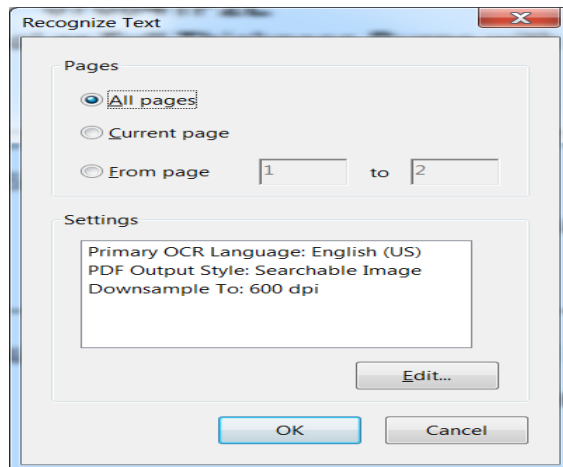
4. CLICK TEXT RECOGNITION.



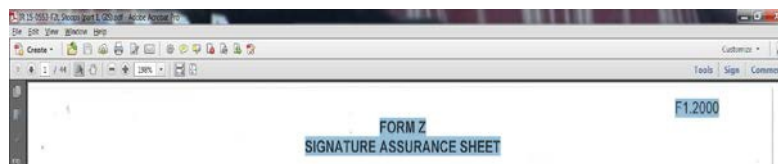
5. CLICK IN THIS FILE.



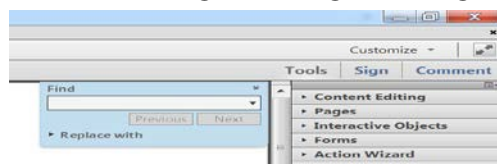
6. SELECT ☒ ALL PAGES.



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



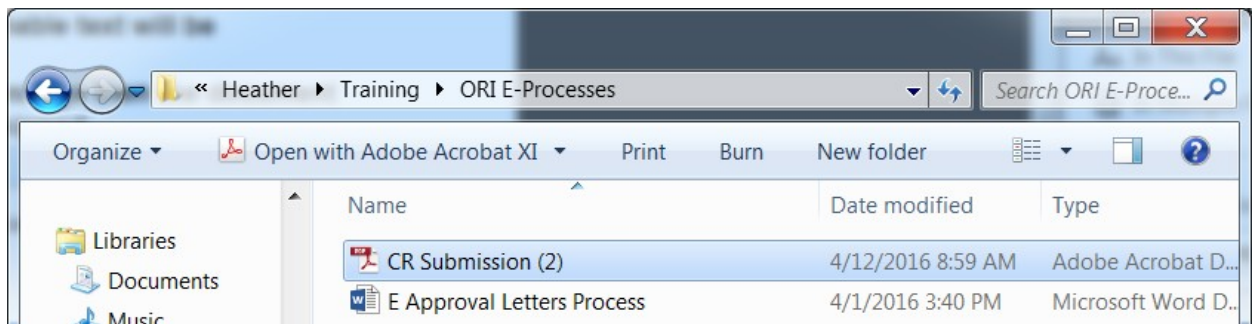
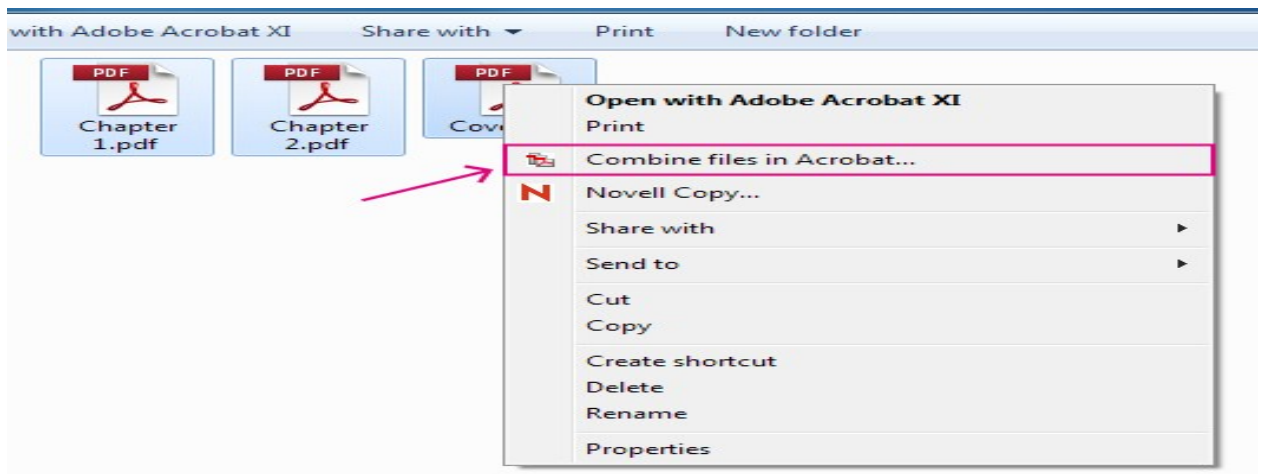
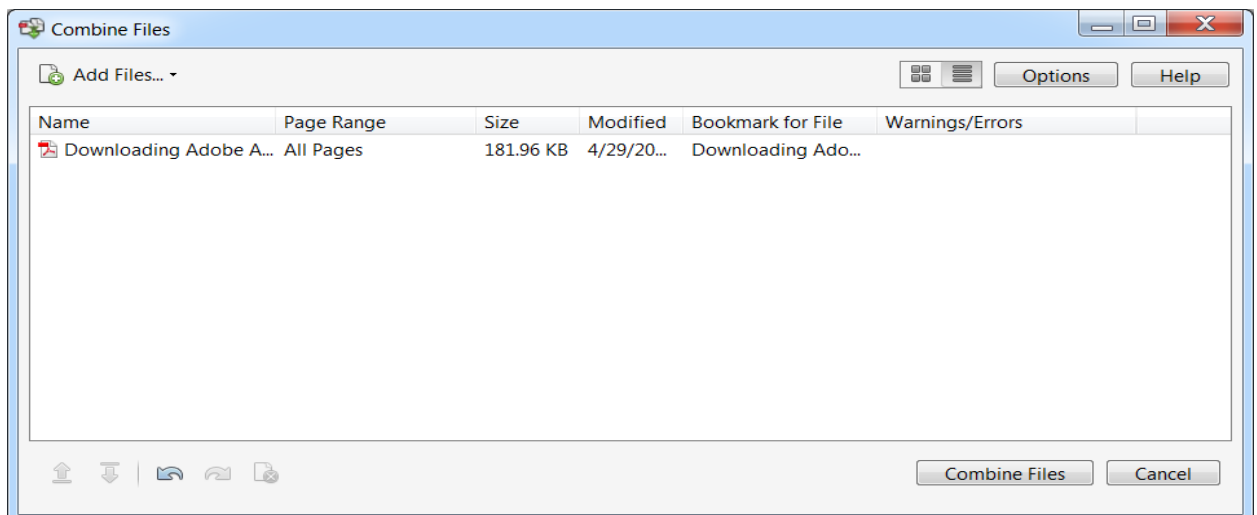
8. TO SEARCH FOR A WORD, SELECT CTRL+F. TYPE THE WORD INTO THE POP-UP BOX.



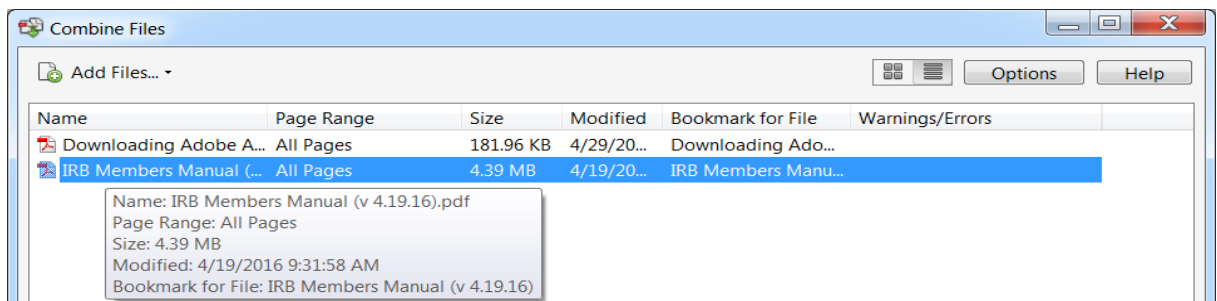
[CLICK HERE TO RETURN TO STEPS](#)

E. MERGING PDFS INTO PORTFOLIO:

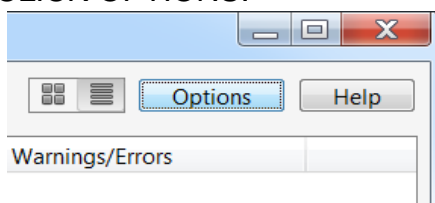
Follow Step E when merging files with an electronic signature into a Portfolio.

1. SELECT FILE.**2. RIGHT CLICK COMBINE FILES.****3. DRAG FILES INTO THE COMBINE FILES POP-UP BOX.**

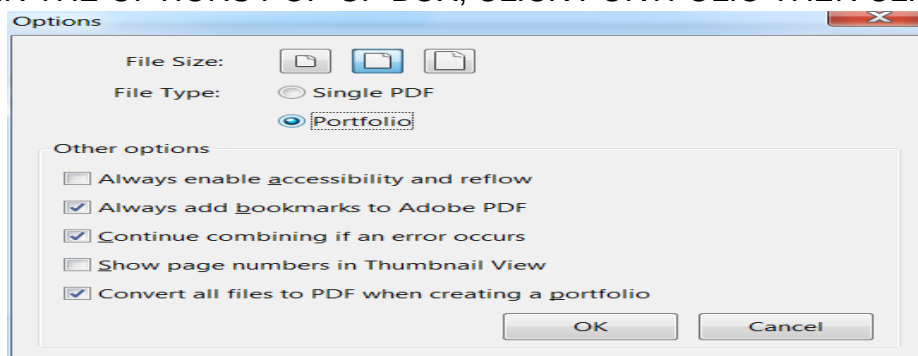
4. IF THE ORDER OF THE FILES NEEDS TO BE CHANGED, DRAG THE INDIVIDUAL FILE INTO THE APPROPRIATE LOCATION.



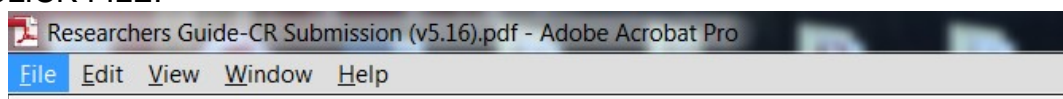
5. CLICK OPTIONS.



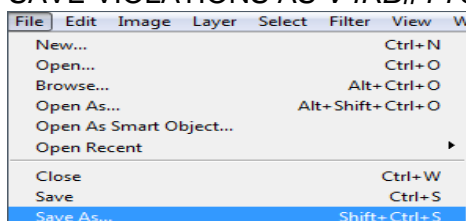
6. IN THE OPTIONS POP-UP BOX, CLICK PORTFOLIO THEN CLICK OK.



7. CLICK FILE.



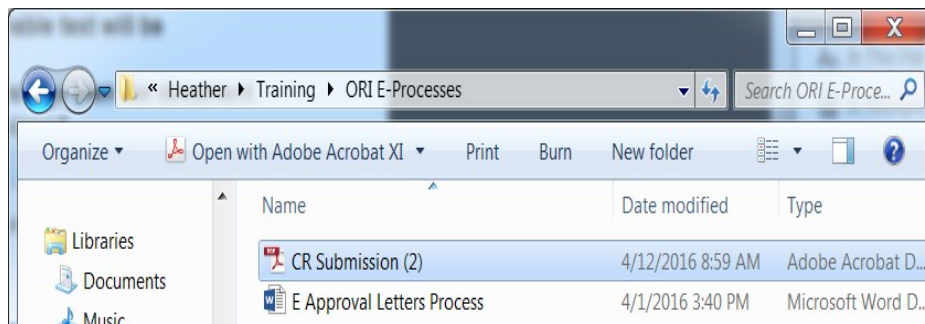
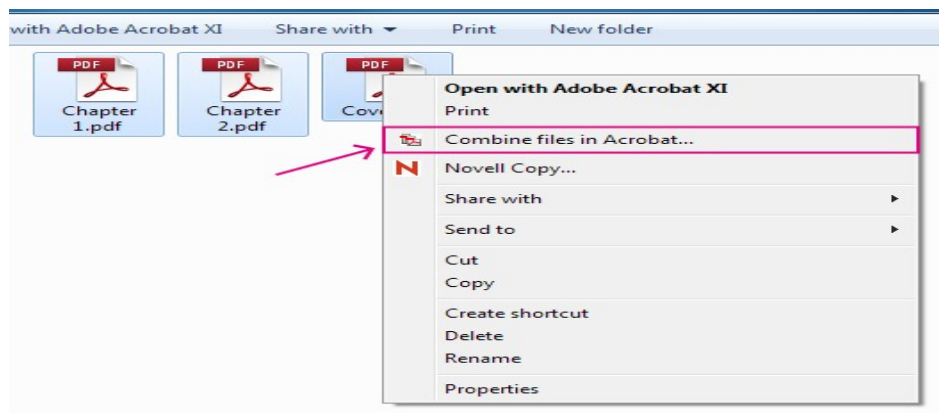
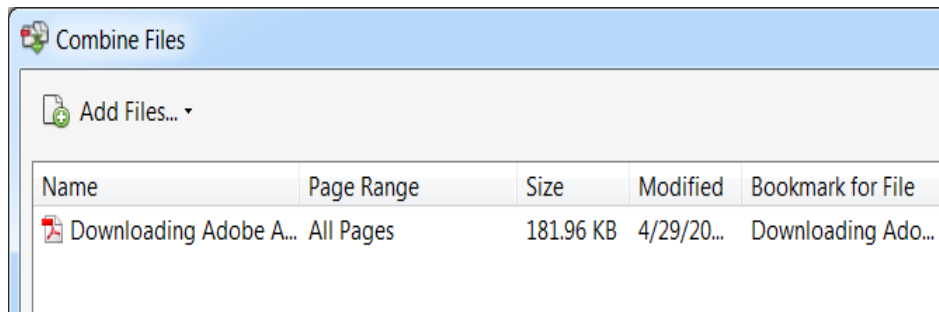
8. CLICK SAVE AS:
 SAVE MODIFICATIONS AS *M IRB# PI'S LAST NAME*.
 SAVE UNANTICIPATED PROBLEMS AS *UP IRB# PI'S LAST NAME*.
 SAVE NON-PROMPT UPS AS *NP IRB# PI'S LAST NAME*.
 SAVE VIOLATIONS AS *V IRB# PI'S LAST NAME*.



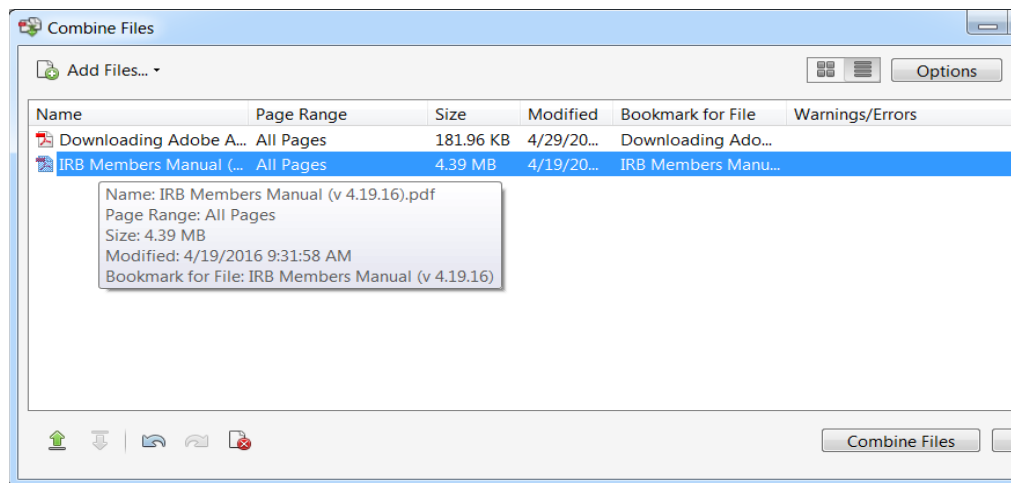
[CLICK HERE TO RETURN TO STEPS](#)

F. COMBINING MULTIPLE PDF FILES INTO 1 PDF FILE:

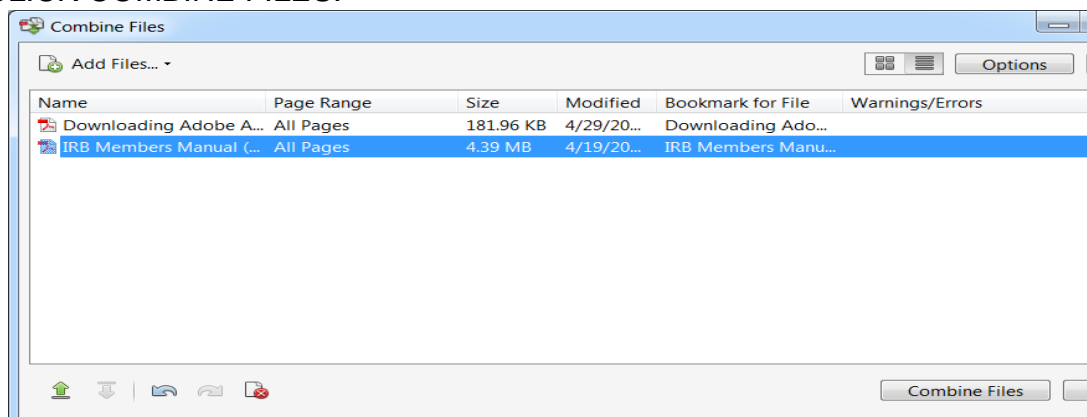
Follow Step F when combining multiple PDF files from a file saved to a desktop folder.

1. SELECT FILE.**2. RIGHT CLICK COMBINE FILES.****3. DRAG FILES INTO THE COMBINE FILES POP-UP BOX.**

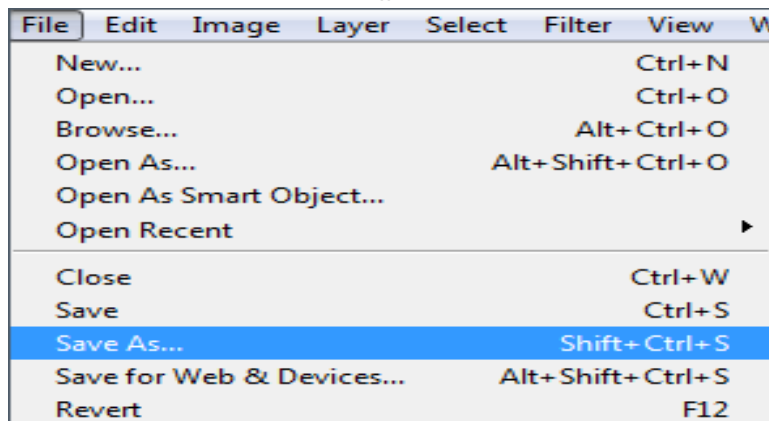
4. CHANGE ORDER OF FILES BY DRAGGING FILES TO THE CORRECT ORDER.



5. CLICK COMBINE FILES.



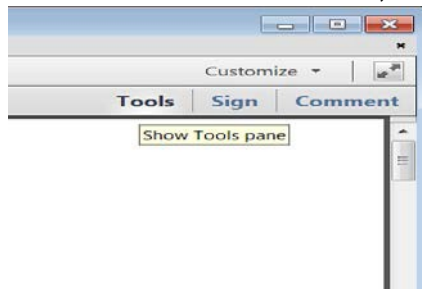
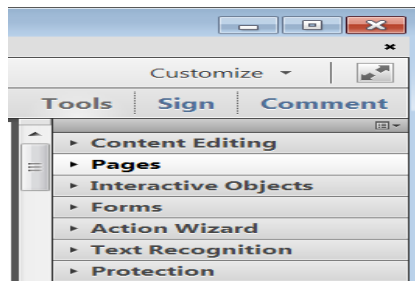
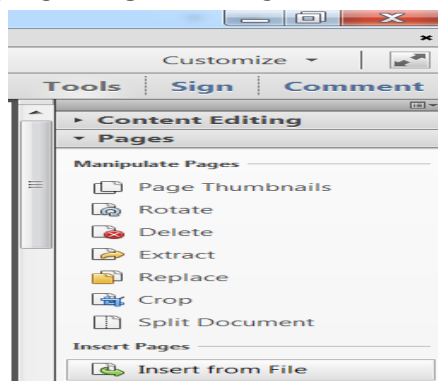
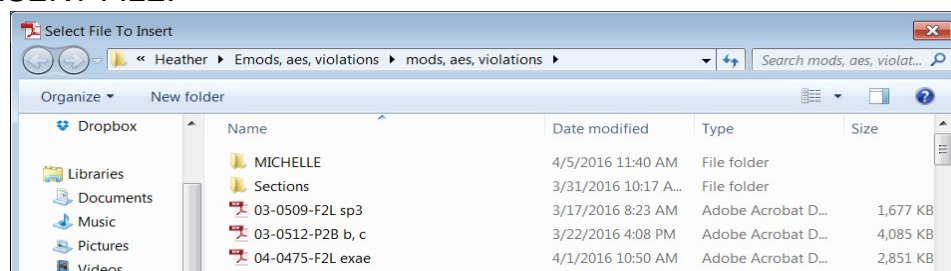
6. CLICK FILE THEN SELECT SAVE AS:
 SAVE MODIFICATIONS AS *M IRB# PI'S LAST NAME*.
 SAVE UNANTICIPATED PROBLEMS AS *UP IRB# PI'S LAST NAME*.
 SAVE NON-PROMPT UPS AS *NP IRB# PI'S LAST NAME*.
 SAVE VIOLATIONS AS *V IRB# PI'S LAST NAME*.



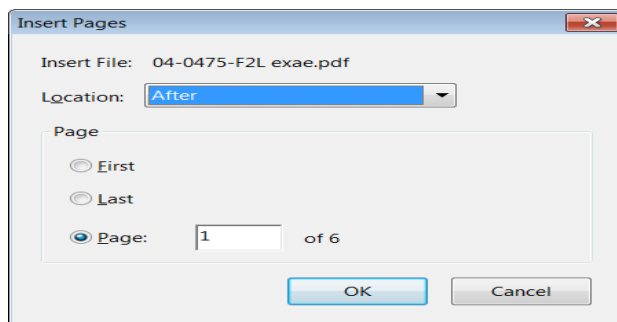
[CLICK HERE TO RETURN TO STEPS](#)

G. INSERTING ADDITIONAL PDFS INTO 1 PDF FILE:

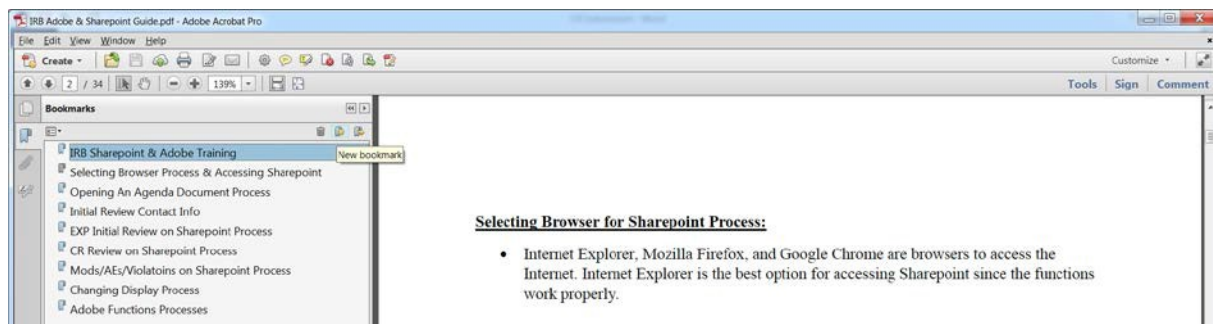
Follow Step G when inserting additional PDFs while working in Adobe.

1. IN ADOBE ACROBAT PRO, CLICK TOOLS.**2. CLICK PAGES.****3. CLICK INSERT FROM FILE.****4. INSERT FILE.**

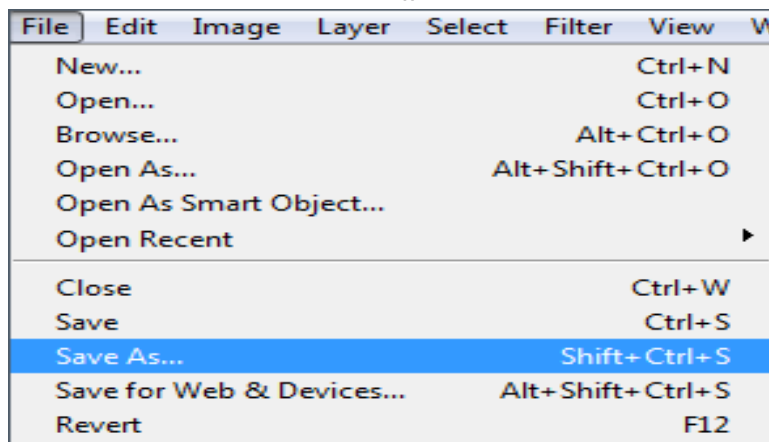
5. SELECT DESIRED LOCATION THEN CLICK OK.



6. BOOKMARK EACH SECTION.



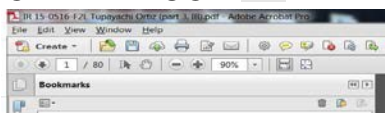
7. CLICK FILE THEN SELECT SAVE AS:
 SAVE MODIFICATIONS AS *M IRB# PI'S LAST NAME*.
 SAVE UNANTICIPATED PROBLEMS AS *UP IRB# PI'S LAST NAME*.
 SAVE NON-PROMPT UPS AS *NP IRB# PI'S LAST NAME*.
 SAVE VIOLATIONS AS *V IRB# PI'S LAST NAME*.



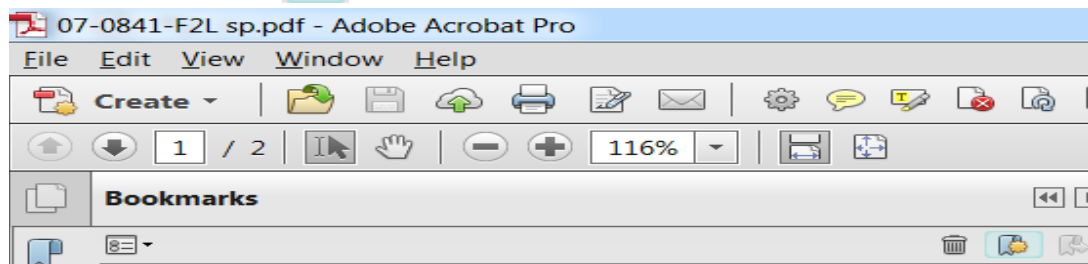
[CLICK HERE TO RETURN TO STEPS](#)

H. LABELING BOOKMARKS TO GUIDE THE IRB REVIEW:

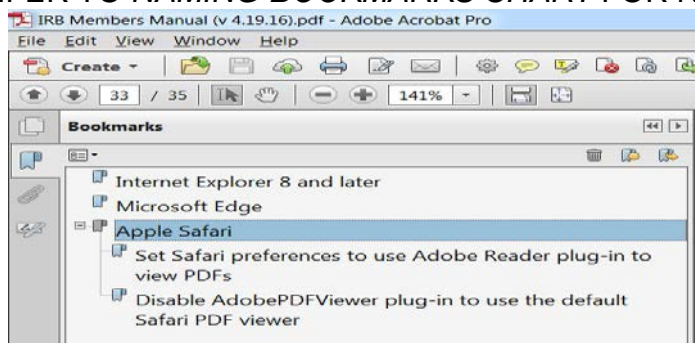
1. CLICK BOOKMARK ICON. 



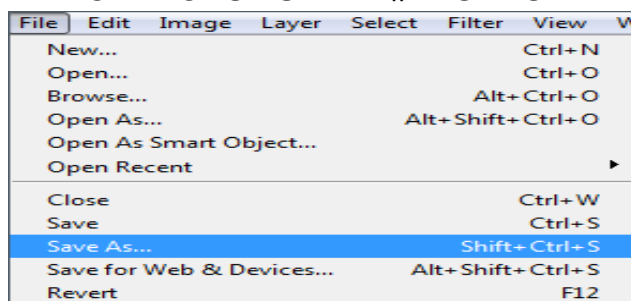
2. CLICK NEW BOOKMARK ICON. 



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



4. CLICK FILE THEN SELECT SAVE AS:
SAVE MODIFICATIONS AS *M IRB# PI'S LAST NAME*.
SAVE UNANTICIPATED PROBLEMS AS *UP IRB# PI'S LAST NAME*.
SAVE NON-PROMPT UPS AS *NP IRB# PI'S LAST NAME*.
SAVE VIOLATIONS AS *V IRB# PI'S LAST NAME*.



[CLICK HERE TO RETURN TO STEPS](#)

I. NAMING BOOKMARKS CHART FOR MODIFICATIONS:

<i>Form</i>	<i>Bookmark Title</i>
Memo	IRB#/PI's Last Name *
GIS	A/GIS/PI's Last Name*
Study Personnel	SP
Research Description	B/Research Description
Appendix A (B . . .C . . .etc.)	B/Appendix A, Appendix B . . .
Consent Form	C/Consent Form
Non-English Speaking Consent Form	C/Language/Consent Form ex: C/Spanish/Consent
Assent Form	D/Assent Form
Waiver of Informed Consent	E/WIC
Waiver of Documentation of Informed Consent	F/WDIC
Cover Letters/Scripts	F/Cover Letter or Script
DHHS-approved Sample Informed Consent Form	G/DHHS
Non-English Speaking Subjects	H/Non-English Speaking
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
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

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

J. NAMING BOOKMARKS CHART FOR UNANTICIPATED PROBLEMS & SAFETY REPORTING:

<u>Form</u>	<u>Bookmark Title</u>
Internal Prompt UP Reporting Form (with PI's signature)	IUP/IRB#/ PI's Last Name
External Prompt UP Reporting Form (with PI's signature)	EUP/IRB#/PI's Last Name
Non-Prompt Cover Form (with PI's signature)	NP/IRB#/ PI's Last Name
Memo	Memo/PI's Last Name

PI's last name needs to be included in the title of the first bookmark

K. NAMING BOOKMARKS CHART FOR VIOLATIONS:

<u>Form</u>	<u>Bookmark Title</u>
Protocol Violation Reporting Form (with PI's signature)	V/IRB#/ PI's Last Name
Memo	Name Memo

PI's last name needs to be included in the title of the first bookmark

[CLICK HERE TO RETURN TO STEPS](#)