Expedited IRB Application Cheat Sheet

BEFORE YOU BEGIN:

Decide which application you need:

- Exempt – no interaction with human subjects
- Expedited – interaction with human subjects
- Full – interaction with human subjects in protected categories – minors, offenders etc.

Read the **Application Form Checklist** and make sure you check each document that you are submitting and then make sure they are included in your submission. Note which ones need signatures. Make sure you are NOT using your personal email on any documentation.

On the Cover sheet make sure that you fill in every section. That includes not only the degree –DBA. but also, the discipline – Business. Place an X next to the type of work you are submitting – CRP/Dissertation.

Section 1 – Purpose of the Study

Make sure you have completed the following:

- Identified the purpose in a clear statement with supporting information
- Identify the connection between the study and the degree program
- .

Section 2 – Summary of the Study

- Identify clear research questions
- Provide specific clear step by step procedures in chronological order.

If facilitating a quantitative survey, identify step by step and in chronological order how it will be given to participants. Include how participants will be recruited, where they will take the survey, how it will be distributed, how it will be collected and how you will maintain the anonymity of those taking the survey. Refer to the location of the instrumentation in the appendix (see appendix___).

If using an online survey discuss all of the above and how participants will be notified of the location of the survey site. Include the web link to the survey site. The online survey must be created before the IRB application is submitted and a screen shot of the entire survey must be included in the appendix. If facilitating a quantitative survey, identify the statistical test(s) that will be used to analyze the data. **Note: An Internet based survey must also contain the Informed Consent with a button allowing participants to confirm their permission for you to use their data before they begin the survey**.

If facilitating qualitative protocols (interviews or focus groups), identify step by step and in chronological order how the interviews or focus groups will take place. Include how participants will be recruited, where you will meet, how will participants know where to meet, how the meeting place is private, how it will be recorded, how you will keep others from knowing the meeting is taking place, or how the data will be recorded, transcribed, coded and analyzed.

Section 3 – Subject/Participant Demographics

- 3a. The anticipated sample size is the number of people you plan to survey and/or Interview. Describe who they are, ex. 25 4th grade teachers or 30 people who have been diagnosed with Bipolar Disorder.
- 3b. Special Ethnic Groups should only be stated if you are targeting a specific group in your research otherwise state:
    - There are no special ethnic groups.
- 3c. Institutionalized/Protected Group should only be stated if you are targeting children and minors, pregnant women, patients, physically or mentally challenged individuals, prisoners and those under court supervision otherwise state:
    - No institutionalized individuals or protected groups are participating in this study.
- 3d. Age group: Be specific. State:
    - Study will target adults ages 21 – 65 or Study will target adults 18 – 35. If you are targeting anyone under 18 you must fill out a full application. If the actual ages are unknown approximate as long as they are adults.
    - General State of Health: If the study is targeting participants with physical or mental health challenges a full application must be submitted otherwise state:
    - Participants are expected to be healthy.
- 3f. Other details to describe sample group: This section will only be filled out if you need to provide details that have not been noted above. Otherwise state:
    - There are no other details to describe the sample group.

Section 4 – Will Deception be used in the Study?

Will deception be used in the study? Check the yes or no box. If yes give a detailed step by step explanation of how deception will be used. Include how participants will be protected and how harm will be minimized. If no deception will be used state:

- No deception will be used in this study.

Section 5 – Will Audio or Video Tapes be Used in the Study?

Will audio or video tapes be used in the study? Check the yes or no box. If yes give a detailed step by step explanation of how they will be used. Include how participant's identity will be protected and how harm will be minimized. Tell who will transcribe these tapes and what will happen to the transcribed documents. If they will be transcribed by someone other than the researcher, you must submit a notarized statement from the transcriber that they will keep the information confidential. If no audio or video tapes will be used, then state:

- No audio or video tapes will be used in this study.

Section 6 – Confidentiality

Confidentiality protection issues (pertains to audio and video as well as written documents):

a. What precautions will be taken to insure the privacy and anonymity of the participants? (i.e. closed door, private rooms, handling of materials where subject's identity could be discovered, etc.)

Based on your research design state what you will do to ensure that no one knows who your participants are.

If a survey instrument is being facilitated discuss how you will keep others from knowing who took the survey and the individual responses of each participant. Also discuss where the survey will take place and what has been done to keep the room private. Also discuss how the researcher will collect the materials so that no one else will see them or have access to them.

If an interview is being facilitated discuss how you will keep others from knowing who is being interviewed and what the responses of the interviewee are. Also discuss where the interview will take place and how the room will be kept private from others. Also discuss how the recordings will be handled so that they will be private and others will not have access to them.

b. What specific precautions will be taken to safeguard and protect subject's confidentiality while handling data (audio/video/paper) both in principal investigator's possession and in reporting the findings? (i.e., coding, removal of identifying data).

Identify what steps you will take to make sure that no one will know any individuals responses. If the study is quantitative discuss disaggregated data. If the study is qualitative discuss how you will code individual's responses.

c. Describe procedures where confidentiality may be broken by law (e.g., child abuse, suicidal intent).

Confidentiality must be broken by law if a participant reveals the following:

Child abuse (to participant or that they have abused)

Suicidal intent

Intent to harm another.

Describe the step by step procedures you will follow if a participant reveals one or more of the above to the researcher. Do not state that confidentiality will not be broken. By law you must break confidentiality if one of these things is revealed. If you are working with children or people that work with children you must address what you would do if child abuse were revealed. In all cases state the name, address and phone number of the agency that the incident will be reported to.

Section 7 – Review by Institutions Outside Westcliff University

Review by institutions outside Westcliff University

- Yes or No. Check yes or no.

If the research is being conducted with participants from a site you must gain permission from that site before you submit the IRB application. Sites include but are not limited to schools, school districts, businesses, churches, hospitals, clinics, colleges and universities. If you are recruiting individuals from the workplace you must have permission from their workplace. If you are recruiting

individuals from schools, school districts, hospitals, clinics, colleges or universities you may have to complete an IRB process for that institution also. If using social media such as Facebook, Twitter or Instagram you must have permission from the organization you are recruiting through. If you are using a survey or interview protocol that is copyrighted, you must provide permission to use or change the instrument. This must be done before you submit your Westcliff IRB application. Please note in the appendix where your approval documents are located. (i.e. See appendix____)

Section 8 – Informed Consent

Informed Consent and Assent (Attach copies of all relevant forms). If consent is not necessary (e.g. anonymous interview), describe how you will inform all participants of the elements of the consent (see instructions).

Read pages 33 – 44 in the Westcliff IRB guide.

Describe how you will make the participants aware of what is in the consent and what it means for them to give consent. If the study is quantitative describe how they will provide consent before the survey is given. If you are using an online survey describe how participants will have to click a button to give their consent before they can take the survey. If the study is qualitative describe how you will all the participant time to read and sign before the interview begins. In all cases include how the participant will be able to address any questions they have about the consent.

Section 9 – Oral Informed Consent

If written or oral informed consent is required, describe the manner in which consent and/or assent was obtained for each level of participants:

a) Adult
b) Child
c) Institutionalized

What will you do to actually get the participants permission on the consent form? If you are using Survey Monkey how will you get participants permission? (see note in section 2) How did you get permission from the site to access the participants? If you are working with minors, how did you get their permission and their parent's permission? How did you get assent from the minors?

Section 10 – Risk

Describe any possible physical, psychological, social, legal, economic or other risks to participants.

a. Describe the precautions taken to minimize risk to participants.

Tell how your study is designed to minimize risks for participants. What did you do to make sure that they remain anonymous? What did you do to ensure their confidentiality? This should be specific regarding your research design. All of the above risks may not be possible in your study but please take into account that although you do not intend it, people may react in ways you may not have considered. Always consider that someone may be harmed by what you ask or what they read. You don't know what might trigger a past event that may cause psychological harm. If your study involves someone at their workplace there is always a possibility that they may be subject to social or economic harm. What will you do to ensure this doesn't happen?

b. Describe procedures implemented for correcting harm caused by participating in the study (e.g., follow up calls, referral to appropriate agencies).

So now that you have identified the harm in the previous section, what will you do if someone is harmed? Where will you refer them? Be specific. Include the name, address and phone number of the agency. Include that you will notify your Dissertation Chair and include his/her name, Westcliff email address and phone number. Include that you will notify the Westcliff IRB committee Chair, Dr. Diane Watkins, 16715 Von Karman Ave., Ste, 100, Irvine, CA 92606. Her email is dianewatkins@Westcliff.edu. Make sure that you have also included the risk and procedure for correcting on the informed consent.

Section 11 – Benefits of the Study

a. Assess the potential benefit(s) of the study for the participants.

If there is no direct benefit for the participants, then say so but why would they participate if there is no benefit? They may be benefited because this study will provide information that will improve something for them, their workplace or their community.

b. Assess the potential benefit(s) to the professional community.

How will the educational, psychological or business community benefit from your study? Remember where the gap was that caused you to want to do this study. This is probably a good place to start.

Attach any other required forms, including the principal investigator and faculty research supervisors' CITI completion forms, the principal investigators' Conflict of Interest form, tests, institutional permission slips, etc., related to this study. Failure to do so will result in delayed processing of the application.

The following forms must be included:

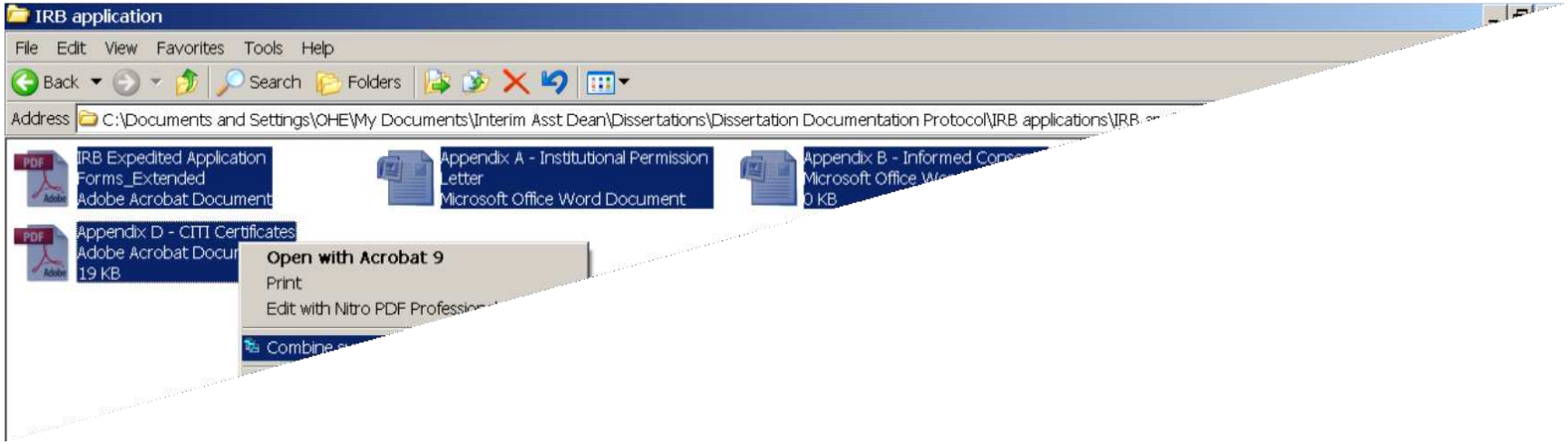
1. Permission Letters – on letterhead of the business or institution providing permission.
2. Institutional Review – from another institution if necessary.
3. Data gathering instrument(s)
4. CITI of the researcher/Dissertation Chair and Dissertation Committee Member(s) – all must be current.
5. Consent Forms – for each instrument and 1 for each language.
6. Translation/Notarization documents if applicable
7. Any survey(s) you are giving with the Informed Consent for the Survey(s)
    a. If you are using Survey Monkey you must include a screenshot of each page of the instrument in Survey Monkey with the Informed Consent at the beginning and a button at this bottom of that page stating that the participant is giving consent for their information to be used in your study. If you are using the survey with non-English speakers you must have a translated copy of the survey and informed consent along with a notarized statement from the translator.
8. Any interview protocol – with a copy of the Informed Consent for the Interview. If you are using the interview protocol with non-English speakers you must have a translated copy of the interview protocol and informed consent along with a notarized statement from the translator.
9. If you are working with minors you must also include a parent permission form and the assent form.

Application should be free of typos and grammatical errors.

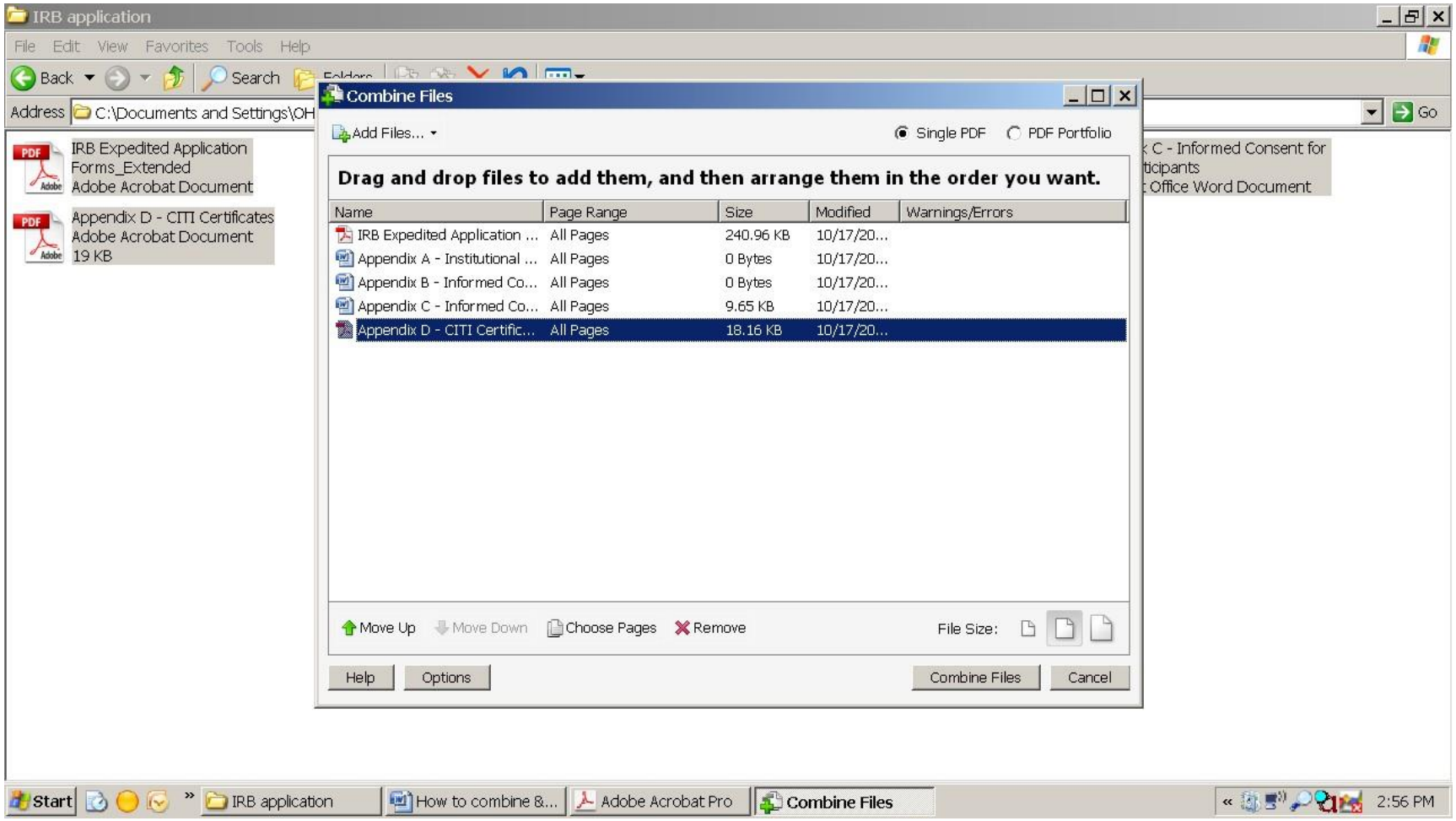
Submission should be in the form of a pdf.

This can be achieved by:

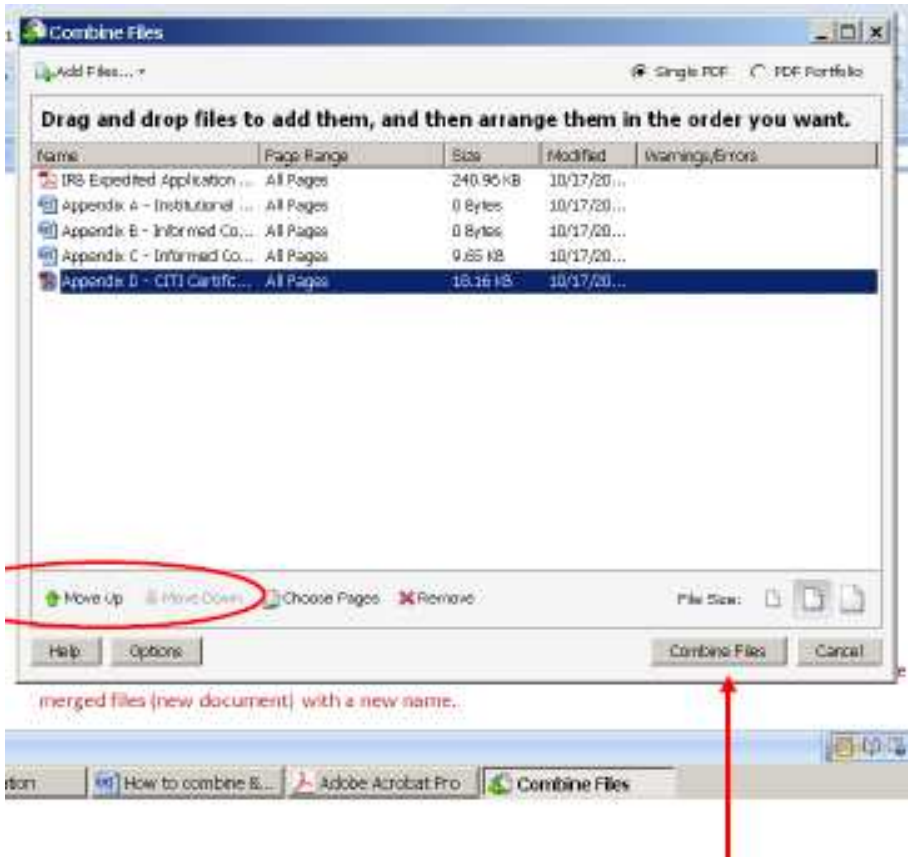
Clicking (to highlight) all documents that you would like to combine into one. Then **Right** clicking and selecting "Combine supported files in Acrobat"



Look for the “combine files” tab at the bottom of your screen and click on it to open up a screen displaying your documents (if the “combine files” screen doesn’t automatically open up):

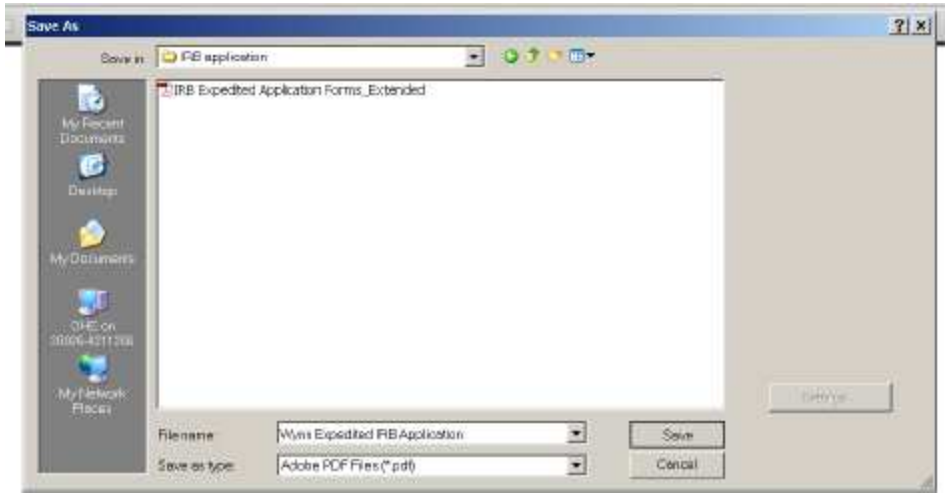


Rearrange your files into the right order by clicking on a document and moving it up or down.



When you have the documents in the right order, click combine files.

You will see the progress it makes when "Merging Files." Once complete, it will ask you to save the merged files (new document) with a new name.



Now you have one document with all attachments/files saved.

NOTE:

- Resubmissions are reviewed within 5 business days.
- To speed up the revision process:
  - make sure that the Letter to Correct IRB Application Deficiencies is completed in detail and accompanies the resubmission.
  - Ensure that all documents, including those submitted in the original application are all resubmitted in one pdf file.
  - **DO NOT SCAN** submissions.
- Embolden or underline all changes within the Application.
- Make sure that the resubmission portion of the Review Form is signed by the Dissertation Chair. No resubmission will be accepted without the signature.
- IRB review results will be sent to the Dissertation Chair.