30 August 2021

Human Subject Protocol Application

Campus:	Worldwide	**College:**	WCOA
Applicant:	Joe Student	**Degree Level:**	Master
ERAU ID:	12345678	**ERAU Affiliation:**	Student

Project Title: EXAMPLE with EXPLANATION of a Properly Completed IRB Application for Survey Research

Principal Investigator: Jill Researcher

Other Investigators: Joe Student, Jim Faculty, Jan Investigator

Submission Date: 08/30/2021

Beginning Date: 09/15/2021

Type of Project: Survey

Type of Funding Support: Student Internal Award

Questions

1. **Background and Purpose**: Briefly describe the background and purpose of the research. Include how the study contributes to existing knowledge; spell out acronyms the first time they are used; and use consistent terminology.*

There are different places to find information on Embry-Riddle's IRB process. Information can be found on Embry-Riddle's internal ERNIE site under the department of ***Research*** or located externally under ***Embry-Riddle Research***. The IRB website includes a ***"Frequently Asked Questions"*** section, a ***"How to Complete the IRB Application"*** document and sample ***"Informed Consent Forms."*** Through the compilation of comments collected throughout the year, new instructions are included in an effort to make the IRB application process clearer.

The purpose of this research is to see if providing a sample of a completed IRB application will provide better assistance in preparing an IRB application for review. [This top section describes the background and purpose of this IRB application.] Each question's response on this EXAMPLE Completed IRB Application will consist of two parts; 1) an EXPLANATION of what is needed in answering the question, and 2) an *EXAMPLE of a proper response.*

EXPLANATION: Describe how this study contributes to existing knowledge. Remember to spell out acronyms the first time they are used. The answer should not be lengthy and it should be explained so that an "educated non-expert" can understand. Be sure to use consistent terminology and be sure to check your grammar.

EXAMPLE: *The purpose of this study is to investigate the usability of mobile and website applications for products and services commonly used by college students including money transfer, ride sharing, and weather information. This study aims to examine features in these applications to determine the usability of each feature. This research will use a demographic and background gathering survey to collect relevant data regarding each product or service separately. This research will also look at the desirability of these applications and why participants have certain preferences for specific applications.*

2. **Time**: Include how much time will be asked of each participant. Include the amount of time it takes for each activity and the total time. The total amount of time must match what is written on the Informed Consent Form (ICF), but the ICF only need include the total amount of time. (Do NOT include the amount of time needed to read the ICF.)*

EXPLANATION: Enter the approximate amount of time it will take the participant to complete the study. If there is more than one part to the study, include the amount of time it takes to complete each part and then include the total approximate amount of time it will take to complete the entire study. The amount of time entered here should match what is written on any recruitment material and the Informed Consent Form.

EXAMPLE: *It is anticipated that it will take approximately five minutes to complete the NASA-TLX and another 10 minutes to complete the Website Applications survey for a total amount of approximately 15 minutes.*

3. **Design, Procedures and Methods**: Describe the details of the procedure(s) to be used; how the data will be collected and/or what will be done to collect the needed data and when the data will be destroyed. *Stating that the data will be destroyed when the Capstone project is completed is NOT acceptable. A specific time period must be indicated. Example: Data will be destroyed three years after completion of the research.

EXPLANATION: The IRB will need to know where the research is being conducted, how participants will be recruited and how you are going to conduct the study. Research conducted outside of Embry-Riddle employees or students requires permission from the outside entity. (Studies conducted using Military personnel and studies conducted outside of the Country [International studies] have additional requirements. Contact the IRB office before proceeding.)

EXAMPLE: *This study will be conducted using two surveys of ERAU associated pilots who are at least 18 years old. The surveys will be administered on paper. Because we are using a convenience sample, the surveys may be distributed to participants either in the public spaces on campus or in classrooms. Participants have the ability to move away from the researchers and other persons to complete the survey. Eligible participants will be presented with the Informed Consent Form. If consent is given, the participant will answer seven demographic questions and pilot qualifications. The second survey will follow the demographic survey. A sealed box with a place to insert the survey, will be used to collect the completed surveys to protect the anonymity of the participant.*

a. Will the activity be RECORDED?

No

b. LOCATION: Indicate where the activity will take place –

Embry-Riddle

Campus
Daytona Beach

Specify where the project will take place by including the building name and office/lab number:

Surveys will be available in the College of Aviation first floor Atrium and the sealed box for collection of surveys will be located in the same place.

4. **Measures and Data to be Collected**: What measures and data will be collected in the study? How will the measures and/or data be collected?

EXPLANATION: Indicate what data is being collected and what instrument you will use to collect the data. Also explain how the data collection method will be provided to the participant. Provide a brief description of the instrument you are using to collect the data. The IRB must verify that a reliable instrument is being used to obtain data. The IRB must review anything that is provided to the participant. You can upload it to the online system, but you do not need to explain that it is attached. All materials provided through the online IRB application system are combined into one PDF document for IRB review. (Do not include your Master's or Doctoral Thesis.)

EXAMPLE: *Age, gender, education, ethnicity, and experience with the applications will be collected as demographics. Participants will then rate their opinions of the features they have used in the applications in question. The System Usability Scale (SUS) is used to assess the perceived usability of something. The Eye Fatigue questionnaire is used to assess the perceived level of eye strain a person feels. The NASA Task Load Index (NASA-TLX) is used to assess the perceived workload of a task.*

5. **Participant Population and Recruitment Procedures**:

a. Who will be recruited to be participants? Check ALL that apply:

Embry-Riddle Students

b. Approximately how many participants do you hope to recruit?

100

c. Explain how and where recruitment will be conducted? (Emails, mailings, sign-up sheets, social media, flyers, etc.)

EXPLANATION: IRB review starts with recruitment. Include who and how many participants will be recruited and upload any recruitment materials. If you are recruiting participants at an airport, company, or branch of the military, you will need to obtain permission from the airport, company, or branch of the military to conduct the research and provide the IRB with

the approval document.

EXAMPLE: *Participants need to be 18 years of age or older and will be recruited using SONA, an online research pool. SONA allows students to participate in studies to acquire credit for courses. Students may be given a SONA account based on what class they are in or they can create one. Researchers list studies on SONA with information about the research, available time slots for sign up, and the credits that can be earned from participating. Participants can choose what study and time slot they want to sign up to, unless a study has certain requirements to participate in the research. Based on the duration of the study, participants can earn class credits.*

6. **Risks or Discomforts**: Describe any potential risks to the dignity, rights, health or welfare of the human subjects and how these will be mitigated. Risks may be physical, psychological, social, legal, economic, to reputation, or others. All other possible options should be examined to minimize any risks to the participants.

   EXPLANATION: There are risks to ALL research, even if the risks are no greater than what is experienced in daily life. All possible risks should be spelled out as well as how you will mitigate those risks. The risks on the IRB application must match what is written on the consent form, except that here they are written to the IRB reviewer.

   EXAMPLE: *The risks of participating in this study are no more than what is experienced in daily life.*

7. **Benefits**: Assess the potential benefits to be gained by the participants as well as to other in general as a result of this project. If there are no benefits to the participants, state that 'While there are no benefits to the participants…' The benefits here must match what is written on the consent form; here they are written to the IRB reviewer on the consent form they are written directly to the participant.

   EXPLANATION: Include the benefits to the participants if there are any. If there are no benefits to participants, simply state that. Include the benefits to others.

   EXAMPLE: *While there are no benefits to the participants in this study, results may help practitioners better understand participants' perceptions of websites and mobile applications commonly used by college students.*

8. **Informed Consent**: Describe the procedure you will use to obtain informed consent of the subjects. How and where will you obtain consent? The first page of an electronic survey must be the consent document. See *Obtaining Participant Consent* for more information on Informed Consent requirements.

   EXPLANATION: Explain how and where you will obtain consent from the participant. In survey research, it is not necessary to obtain a written signature from the participant. Use the 'Example Informed Consent Form' available on the IRB website. The Federal Regulations are specific as to the format of the Informed Consent Form.

   EXAMPLE: *The informed consent form will be presented to participants at the beginning of the online survey. Participants will indicate they have read the consent form and agree to participate by selecting 'yes' on the consent form page. Those who do not consent to the study will not continue to participate.*

9. **Confidentiality of Records/Data and Privacy**: Will participant information be:

   Anonymous

   a. Justify the classification and describe the safeguards you will employ to protect participant privacy in securing, sharing, and maintaining data during the study:

      EXPLANATION: If you do not ask for a participant's name or other identifying information, then the research is anonymous. Explain how you will keep participant information private. If you collect participant's names or any other identifying information, the study would be considered 'confidential' and you need to explain how you will keep participant private information confidential.

      EXAMPLE: *All data will remain anonymous, and no names will be associated with any data resulting from this study. Data in digital form will be keyed on an external hard drive in a locked room in the Usability Lab at ERAU and destroyed three months after it has been analyzed.*

   b. Indicate what will happen to data collected from participants that choose to "opt out" during the research process.

      EXPLANATION: Explain what you will do if a participant starts the study, but does not complete the study.

      EXAMPLE: *No data will be collected from participants who choose to 'opt out' during the research process; their data will be destroyed.*

   c. Where and how long will participant data be kept? Include the plan for storage or destruction of data upon study completion.

EXPLANATION: Include how long data will be kept and what happens to that data after the study is completed. It is best to store data on an Embry-Riddle computer as a way to increase data security.

EXAMPLE: *Individual information will be protected in all data resulting from this study. No personal information will be collected other than basic demographic descriptors. The online survey system will not save IP addresses or identifying information. Data will be kept on a password protected computer, locked in the Usability Lab in the COAS building and destroyed three years after completion of the research.*

10. **Economic Considerations/Incentives**: Are participants going to be paid for their participation or are you providing any other type of incentive; include extra credit?

Yes

What will be the compensation or incentive?

Extra Credit

EXPLANATION: If you are compensating participants, explain what the compensation will be.

EXAMPLE: *Participants can earn up to one SONA credit. Only participants who select "Agree" to participate will be able to receive SONA credit.*

Describe your policy for dealing with participants who start but fail to complete the research?

EXPLANATION: Explain whether or not those who begin the study but don't finish the study will be compensated (even if partially compensated).

EXAMPLE: *If a participant begins a survey, but fails to complete it, will still be given the credit.*

By submitting this application, you are signing that the Principal Investigator and any other investigators certify the following:

1. The information in this application is accurate and complete
2. All procedures performed during this project will be conducted by individuals legally and responsibly entitled to do so
3. I/we will comply with all federal, state, and institutional policies and procedures to protect human subjects in research
4. I/we will assure that the consent process and research procedures as described herein are followed with every participant in the research
5. That any significant systematic deviation from the submitted protocol (for example, a change in the principal investigator, sponsorship, research purposes, participant recruitment procedures, research methodology, risks and benefits, or consent procedures) will be submitted to the IRB for approval prior to its implementation
6. I/we will promptly report any adverse events to the IRB

Electronic Signature:

Joe Student