Human Subject Protocol Application

Campus: Daytona Beach
College: WCOA

Other Institution Name & Address:

Applicant: Jill Researcher
Degree Level: Master

ERAU ID: 
ERAU Affiliation: Student

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

Principal Investigator: Teri Gabriel

Other Investigators: Joe Student, Jim Faculty, Jan Investigator

Submission Date: 06/11/2019
Beginning Date: 07/01/2019
Type of Project: Survey

Type of Funding Support (if any): No

Questions:
1. **Background and Purpose:** Briefly describe the background and purpose of the research.

Over the years I have attempted to include information on the IRB process through the website located externally under Embry-Riddle Research. This includes a "Frequently Asked Questions" section, a "How to Complete the IRB Application" document and sample "Informed Consent Forms." I also compile a list of those comments that are returned to applicants throughout the year in an effort to use them to incorporate new instructions for making the IRB application process clearer.

Recently, a faculty member explained that she used one of her completed, approved IRB applications to provide to her students so they can use it as a guide to completing the IRB application. This gave me the idea to provide an 'EXAMPLE' completed IRB application for use as a guide on the website. Therefore, 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 IRB 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 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:** Approximately how much time will be required of each participant?

**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, Materials and Methods:** Describe the details of the procedure(s) to be used and the type of data that will be collected.

**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.
4. Measures and Observations: What measures or observations will be taken in the study?

**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.

**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.

4b. If any questionnaires, tests, or other instruments are used, provide a brief description.

**EXPLANATION**
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 collect data. This section must be completed. 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**
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: Who will be recruited to be participants and how will they be recruited. Any recruitment email, flyer or document(s) must be reviewed by the IRB. Note that except for anonymous surveys, participants must be at least 18 years of age to participate.

**EXPLANATION**
IRB review starts with recruitment. Include who and how 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**
Up to 100 participants will be recruited for this study. 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 and Discomforts: Describe any potential risks to the dignity, rights, health or welfare of the human subjects. 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 they are written to the IRB reviewer.

**EXAMPLE**
There is little risk associated with participation in this study; however, if participants feel uncomfortable with a question they may skip it. Likewise, if they experience fatigue, they are encouraged to take a short break.
7. **Benefits**: Assess the potential benefits to be gained by the subjects as well as to society in general as a result of this project.

**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 society. The benefits on the IRB application must match what is written on the consent form, except that they are written to the IRB reviewer.

**EXAMPLE**
While there are no benefits to the participants in this study, results may help practitioners better understand students' 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? See [Informed Consent Guidelines](#) 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**: Will participant information be anonymous (not even the researcher can match data with names), confidential (Names or any other identifying demographics can be matched, but only members of the research team will have access to that information. Publication of the data will not include any identifying information.), or public (Names and data will be matched and individuals outside of the research team will have either direct or indirect access. Publication of the data will allow either directly or indirectly, identification of the participants.)?

Anonymous

9b. Justify the classification and describe how privacy will be ensured/protected.

**EXPLANATION**
If you do not ask for a participant's name, then the research is anonymous. Explain how you will keep participant information private. If you collect participant's names or any other identifying information, you need to explain how you will keep it 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.

10. **Privacy**: Describe the safeguards (including confidentiality safeguards) you will use to minimize the risks. Indicate what will happen to data collected from participants that choose to "opt out" during the research process. If video/audio recordings are part of the research, please describe how that data will be stored or destroyed.

**EXPLANATION**
Explain what you will do with data collected from a participant that decides not to complete the study. If you are video or audio recording data explain how that data will be stored to protect the participant's privacy and when it will be destroyed.

**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 address or other identifying information. Data will be kept on a password protected computer, locked in a university office and destroyed three years after completion of the research. No data will be collected from participants who choose to 'opt out' during the research process; their data will be immediately destroyed.
11. Economic Considerations: Are participants going to be paid for their participation?

Yes

11b. If yes, what will the compensation be? Describe your policy for dealing with participants who 1) Show up for research, but refuse informed consent; 2) Start but fail to complete research.

**EXPLANATION**
If you are compensating participants, you need to explain whether or not those who show up, but don't sign the informed consent will be paid and/OR those who show up, but don't finish will be compensated (even if partially compensated).

**EXAMPLE**
Participants will be paid $10 for their participation. Those who show up for the survey, but do not sign the informed consent form will not be compensated. Those who start the survey, but do not complete the survey will still be compensated.

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:

Theresa Gabriel