Fresno Pacific University
Institutional Review Board
Application for the Conduct of Research Involving Human Participants

Title of Study

Date Submitted (today's date)

Researcher Information

Researcher's Name

Program/Major

School (select from list, or specify if other than FPU)

Street Address

E-mail Address

Affiliation

◯ Student ◯ Faculty

City/State/ZIP

Phone Number

If Student, Project Advisor's Name

Co-Researcher Information - Include name, address, and contact information if applicable, or enter "None."

Regulatory Items - Please check "Yes," "No," or "N/A", and fill in descriptions as required.

Review the Belmont Report (www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm).
Do you agree to comply with the principles discussed in this report? ◯ Yes ◯ No ◯ Not Applicable

Have you submitted/are you also submitting to an IRB other than FPU? ◯ Yes ◯ No ◯ Not Applicable

If yes, please enter institution name

Is this study being conducted in a country **other** than the United States? ◯ Yes ◯ No ◯ Not Applicable

If yes, please list all countries where the research activities will take place

If you will conduct research in a country other than the US, read the Declaration of Helsinki (http://www.wma.net/e/policy/b3.htm). Will you comply with the principles discussed in this document? ◯ Yes ◯ No ◯ Not Applicable

Description of Proposed Research

1. Provide a **brief** description of the **background and purpose** of your research. Avoid using technical terms and jargon. This should be no more than 350 words, and may only be a paragraph.

2. Provide a **brief** description of the **basic research question/issue**. Avoid using technical terms and jargon. This should be no more than one page, and may only be a paragraph.

3. Provide a description of the **design and procedure** of your research. Avoid using technical terms and jargon. Be sure to describe **all activities** that participants will engage in and the total time required. Also, at each step in the procedure that you describe, list **all the means you will use to collect data** during that step in the procedure (e.g. instruments, measures, tests, questionnaires, surveys, interview schedules, focus group questions, observations). If a research assistant will support your research, describe his/her responsibilities here.

3a. Provide a listing that has the name followed by a short description of the tests, instruments, or measures and **attach copies of instruments and questionnaires for review**. For some well-known instruments, it may not be necessary to send a copy - please check with the IRB for final determination.

3b. In addition to describing the design and procedure of your research, please indicate the methods that your research will include by checking all that apply. This list is neither preferred nor comprehensive. Please let us know if you are using another method or methods:

☐ Action Research ☐ Descriptive ☐ Ethnographic ☐ Experimental ☐ Field Work ☐ Formative

☐ Grounded Action ☐ Grounded Theory ☐ Longitudinal ☐ Narrative ☐ Phenomenological ☐ Oral History

☐ Qualitative ☐ Quantitative ☐ Other:

4. Indicate whether recruitment of participants and/or data collection will involve the use of any of the following:

Audiotapes, videotapes, digital recordings or photographs ◯ Yes ◯ No

Electronic communications (e.g. E-mail, Internet) ◯ Yes ◯ No

Archival data that is publicly available ◯ Yes ◯ No

Archival data that is not publicly available ◯ Yes ◯ No

If your response is "Yes" to any item in #4, state what specifically will be used, describe how the media will be used (e.g. coded and then destroyed, kept for possible publication or broadcast, etc.), how the media will be stored and for how long. If you are using archival data, discuss what permissions are required (if any) and include a copy of the permission to use the archival data in your appendices.

5. Does the proposed research require that you **deceive** participants in any way? ◯ Yes ◯ No ◯ Not Applicable

If your response is "Yes," describe the type of deception you will use, indicate why it is necessary for this study, and provide a copy of the debriefing script.

6. Name any source(s) of **funding** for the proposed research (e.g. NIH, NSF, Foundation, FPU funds, other).

7. Benefits: Is there any potential for financial or professional benefit from the outcome of this study (for participants, the researcher(s), others) (e.g. stipends)? ◯ Yes ◯ No ◯ Not Applicable

If yes, please explain:

8. Has this research been through previous IRB review, or is anticipated to undergo IRB review, at another location (e.g. Veterans Administration, other university, medical center)? ◯ Yes ◯ No ◯ Not Applicable

If yes, please explain:

9. Indicate the **total number of participants** you plan to include or enroll in your study.

Indicate the **age range** of the participants you plan to include or enroll in your study.

10. Will participants include individuals from any of the following groups?

Minors (persons under the age of 18) ◯ Yes ◯ No

Prisoners ◯ Yes ◯ No

Persons with legal guardians, or those otherwise unable to provide informed consent (describe below) ◯ Yes ◯ No

If you answered "Yes" to any of the items in #10, describe the methods you will use to provide the **special protections** to which these groups of participants may be entitled under federal regulation. (Some special protections are listed in 45 CFR 46, available at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.)

11. Name and/or describe the site(s), location(s), or organization(s) from which you will recruit or enroll participants. Please attach any permission request letters you intend to send to the site(s).

12. Describe the process you will use to **recruit or enroll participants** and inform them about their role in the study. Please attach copies of advertisements, flyers, website postings, recruitment letters, oral or written scripts, or other materials used for this purpose. If you use a nomination process, indicate how you will advise participants about who nominated them. If relevant, describe how you will ensure voluntary participation free from coercion.

13. Describe the inclusion and exclusion criteria for your participants and how these will be sensitively communicated to potential participants. What will you say to potential participants who do not meet your inclusion criteria? Please attach copies of any letters or scripts you will use to **exclude potential participants**.

14. Please select "Yes" or "No" as appropriate on the following items. When responding, consider both the **actual and potential risks** that could reasonably be expected to occur during the course of the study.

Disclosure of the participants' responses may place the participants at risk of criminal or civil liability.	◯ Yes	◯ No
Disclosure of the participants' responses may be damaging to their financial standing, employability, or reputation.	◯ Yes	◯ No
Participants may encounter physical risk.	◯ Yes	◯ No
Participants may be subjected to stress beyond that ordinarily encountered in daily life.	◯ Yes	◯ No
Participants may be asked to disclose information they might consider to be personal or sensitive.	◯ Yes	◯ No
Participants may be presented with materials that they might consider to be offensive, threatening, or degrading or they may encounter other forms of psychological or social risk.	◯ Yes	◯ No
The fact that the person participated in research will be reported so that the participant can obtain research credit.	◯ Yes	◯ No
As a result of this research, a permanent record will be created that will contain information (identifiers) that could reveal a participant's identity.	◯ Yes	◯ No

15. If you answered "Yes" to any of the items in #14, please describe and discuss the risk below.

15a. Please describe any **<u>other</u>** risks to participants you have identified and steps you will take to minimize those risks.

15b. Please describe the steps you will take to **minimize those risks and/or ameliorate the impact** of any possible harm you have identified above.

15c. **For studies greater than minimal risk:** Are you providing any information about referrals or other kinds of help in the event a participant experiences distress? If your study is not greater than minimal risk, select "N/A." ◯ Yes ◯ No ◯ Not Applicable

If yes, please describe:

15d. If you have described any risks in #14 or #15 above, please describe how the benefits you described in #8 above outweigh the risks you have described here.

16. Indicate how your data will be used. Select all that apply.

- ☐ Dissertation
- ☐ Publication/Journal Article/Presentation
- ☐ Results released to agency or other organization
- ☐ Pilot Study for Dissertation
- ☐ Results released to participants/parents
- ☐ Results released to employer or school
- ☐ Capstone Project
- ☐ Other:

17. Will you use research assistants during the collection or analysis of your data? ◯ Yes ◯ No ◯ Not Applicable

If you are using research assistants, will you have them sign a confidentiality agreement? ◯ Yes ◯ No ◯ Not Applicable

If using a confidentiality agreement, complete the form (except for the name and signature of the person(s) assisting) and include in the appendices. if you are using a research assistant and are not using a confidentiality agreement, please explain why.

18. Describe the steps you will take to address the confidentiality and/or anonymity of the participants and data. Indicate how you will safeguard data that includes identifying or potentially identifying information (e.g. coding). Indicate when identifiers will be separated or removed from the data. Also, indicate where and how you will **store** the data and how long you plan to retain it. If you are going to dispose of the data, describe how you will dispose of it (e.g. erasure of tapes, shredding of data).

If you will identify the location of the research site in your publications, presentations, etc., discuss this use in your response below and also include that information in your informed consent document and permission request letter.

19. After the research is completed, will you provide a summary of results to the participants or other stakeholders? ◯ Yes ◯ No ◯ Not Applicable

If you answered "Yes," please explain how this will be done. If you answered "No," please explain why.

20. **Informed Consent Form:** Most of the information you have described above must be included, in various ways, in this informed consent.

Have you completed and attached your informed consent form? ◯ Yes ◯ No ◯ Not Applicable

In the space below, **include discussion of <u>how</u> you are providing informed consent to participants.** If you are not including an informed consent form, explain why. If you are not requiring signed informed consent, explain why.

Provide the following information <u>only</u> if it is applicable to your study: Discuss the use of, and the process to obtain, any of the following permissions IF your research requires this documentation: minor's assent, parental permission letter, HIPAA authorization. (If your study includes minors and/or will utilize HIPAA protected data and you are requesting a waiver of documentation, discuss why.)

Signature Page

Title of Study

Principal Researcher:

Researcher Certification

In making this application, I certify that I have read, understand, and will comply with the Fresno Pacific University institutional policies regarding research ethics and human subjects protections, and also with all federal, state, and local laws governing the conduct of my study.

As the principal researcher, I agree that:

1. NO research activities (solicitation/recruitment, enrollment, consent, data collection, etc.) will take place until **after** IRB approval or an exemption determination has been obtained.

2. Furthermore, all other required approvals (institutional, dissertation committee, etc.) will be obtained **before** recruitment and enrollment begins.

3. Following approval, my study will be conducted **exactly** as described in the final IRB approved study documents.

4. I will obtain IRB approval for all recruitment materials **prior to** utilization.

5. I will submit reports on unexpected or serious adverse events (unanticipated problems) experienced by my study participants within 24 hours of their occurrence.

6. I will submit any proposed changes or modifications to the IRB for review and approval **prior to** implementation.

By entering my name and date of application in the spaces below, I certify that I have read and agreed to comply with all requirements set forth by the Fresno Pacific University IRB.

Researcher Name (First, Middle Initial, Last) | Date of Application

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Faculty Approval:

Please ensure faculty approvals have been sent before submitting your IRB application.

Name (First, Middle Initial, Last) of Dissertation Chair, or Faculty Mentor/Advisor | E-mail Address

OFFICE USE ONLY: Approved by: | Date: | Classification:

- exempt
- expeditable
- full review

Comments:

Last updated June 11, 2010