

Protocol Review Number: \_\_\_\_\_  
 (Assigned by IRB)



**University of the Pacific  
 Institutional Review Board  
 Human Subjects Activity Review Form**

<b>A. Project Information</b>	
Investigator Name:	
Phone:	
Preferred Mailing Address:	
E-Mail Address	
College/School	
Department	
If Student, Name of Advisor:	
Advisor Dept:	
Advisor Phone:	
If Student, Expected Graduation Date:	
Project Title:	
Review category & number	
When do you plan to begin this study (date/year?)	
What is the expected duration of the study?	
Has this project been reviewed by any other IRB?	
If yes, give date of review(s) and outcomes (attach letter of decision from the IRB)	
Date(s):	
Outcome(s):	

<b>B. Project Support</b>	
<input type="checkbox"/> Funded <input type="checkbox"/> Unfunded	If funded, list source:
If grant proposal: <input type="checkbox"/> pending <input type="checkbox"/> approved	
Does any conflict of interest exist between the funding source and the investigator? <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, describe:

**Investigator Signature and Certification:**

In submitting this proposed project and signing below, I certify that: 1.) I have read and understand the Investigator's Manual on Research with Human Subjects; 2.) I will conduct the research involving human subjects as presented in the protocol and approved by the unit, faculty supervisor (if a student project), and IRB; 3.) I will meet all responsibilities of the research investigator as outlined in the Manual, including obtaining and documenting informed consent and providing a copy of the consent to each subject; 4.) I will present any proposed modifications in the research to the IRB for review prior to implementation; 5.) all conflicts of interest between myself and any funding agencies have been resolved to the satisfaction of the University of the Pacific Office of Sponsored Programs, and, 6.) I will report to the IRB any problems or injuries to subjects.

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

**C. Investigator Status (Check one)**

Student  
To Step V

Faculty  
To Step VI

Administrator  
To Step VI

Other \_\_\_\_\_  
To Step VI

**D. Faculty Supervisor Review:** My signature verifies that 1.) I will supervise this student's research project, and 2.) it complies with federal and University policies regarding protection of human subjects.

Approval: \_\_\_\_\_ Date: \_\_\_\_\_

Proceed to step VI

**E. Unit Review:** The signature below verifies that the project 1.) has been reviewed by the unit, and 2.) complies with federal and University regulations for research with human subjects.

Approval: \_\_\_\_\_ Date: \_\_\_\_\_

*For RGS use only:*

**F. Review Category Assigned**

**A.) Exempt:**

Category numbers:	
Exempt cover letter included:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Consent form approved:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Reviewers Assigned:	1.)
	2.)

**B.) Expedited:**

Category numbers:	
Consent form approved:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Reviewers Assigned:	1.)
	2.)

**C.) Full:**

Exempt cover letter included:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Consent form approved:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Designated Reviewers Assigned:	1.)
	2.)

**G. Institutional Review Board Final Review:**

*(For IRB Use Only)*

Meeting Date:	
Action Taken:	
Proposal Approved	<input type="checkbox"/> Yes <input type="checkbox"/> No
Conditional Approval:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Comments:	
Disapproved:	
Comments:	

**Signature of IRB Chair:**

\_\_\_\_\_ Date: \_\_\_\_\_

**INVESTIGATOR:** Please provide answers to all of the following questions (attach additional pages as needed). Forward 2 copies for Exempt, 3 copies for Expedited proposals, or 12 copies for Full proposals. Also include informed consent forms and other supporting documents as required. Send to Research and Graduate Studies (RGS) for review and approval by the Institutional Review Board. References are found in the Investigator's Manual on Research with Human Subjects, available from RGS.

**I. Purpose and Objectives of the Research**

--

**II. Description of Subject Population(s)**

A.) <u>Who</u> are the subject groups and <u>how</u> are they being recruited?	
B.) What is the maximum # of subjects you will enroll?	
C.) Are you advertising for subjects? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, include a copy of the proposed advertisement. (Refer to Manual Sections V and VIII.)	
D.) What are the criteria for selection and/or exclusion of subjects? (Refer to Manual Sections V and VIII.)	
E.) If special populations are being used, please justify. (Refer to Section X in the Manual).	

### III. Activities Involving Human Subjects

- A.) Describe the activities involving each subject group described in II.A. Include the expected amount of time subjects will be involved in each activity, and where the activities will be conducted.

- B.) How will the data be collected? Check all that apply:

- questionnaires (submit a copy)  
 interviews (submit list of questions)  
 observances (briefly describe)

- standardized tests (list names of tests)

- other (describe)

**IV. Data**

- A.) How will the data be recorded (notes, tapes, computer files, completed questionnaires or tests, etc.)?

- B.) What measures will be taken to eliminate the use of identifiable information, particularly that involving medical records? See list of 18 identifiers listed in HIPAA regulations.

- C.) Who will have access to the gathered data, and how will confidentiality be maintained during the study, after the study, and in reporting of results?

- D.) What are the plans for the data after completion of this study, and how and when will the data be maintained or destroyed?

**V. Benefits, Risks, Costs**

- A.) What are the potential benefits to humanity?

B.) What are the potential benefits to the subjects?

--

C.) What compensation, if any, will be offered to the subjects and how will payment be scheduled throughout the study?

--

D.) Assessment and Description of Risks

1.) What risks to the subject are most likely to be encountered, and at what level?

Type of Risk	Minimal	More than Minimal	Not Sure
Physical	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Psychological (emotional, behavioral, etc. – including anxiety)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sociological (employability, financial, reputation, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Loss of confidentiality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Criminal or civil liability	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Deception	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Economic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (explain)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2.) Describe all risks identified in D1.

--

- E.) What safeguards will you use to eliminate or minimize these risks? If subjects experience adverse reactions, how will they be managed?

- F.) What are the costs, if any, to the subjects (monetary, time, etc.)?

## **VI. Other Compliance Issues**

- A.) If this project may be subject to other regulations, such as state or local laws protecting special populations, or the use of a new drug or device, please identify and discuss.

- B.) If this project involves any of the following activities, requiring consideration by another committee, please check:

- Animal Use and Care
- Radiation Safety (including use of x-rays, microwaves)
- Biological Safety (including recombinant DNA, biohazards)
- Chemical Safety (including hazardous waste materials, chemical carcinogens, flammable, lab safety)

## VII. Informed Consent

A.) How will the study be explained to the subjects, and by whom?

B.) Attach informed consent form(s) you will use in the study (refer to Section IX in the Manual).

C.) Indicate rationale for any special conditions relating to informed consent (e.g., request for approval to obtain oral consent or waiver of documentation). (Refer to Section IX in the Manual)