



Purpose: This form is to be used by the principal investigator in requesting a change the study design of an IRB-approved protocol. Any changes made to a study must first be approved by the IRB prior to implementing any change. Failure to notify the IRB of changes or implementing a change before the IRB grants approval is considered noncompliance and will be handled pursuant to the IRB Noncompliance Policy. Submit completed form to [irb@pacific.edu](mailto:irb@pacific.edu).

<b>Lead Researcher/ Principal Investigator (PI):</b>		<b>IRB Protocol Review Number:</b>	
<b>Project Title:</b>			

Proposed Change Information		
<b>1.</b>	<b>Number of subjects enrolled to date:</b>	
<b>2.</b>	<b>Number of subjects to be enrolled in the next 12 months:</b>	
<b>3.</b>	<b>Has there been, or will there be, a change of Investigator or other project staff?</b> <i>If yes, please list the names of personnel and the associated changes below:</i>	
<b>4.</b>	<b>Do you plan to make any changes in this research project?</b> <i>If yes, please explain below:</i>	
Will your Informed Consent form be revised?		
<input type="checkbox"/> No <input type="checkbox"/> Yes                      If yes, please attach a copy of the new form.		

**Investigator Signature:**

I certify that the planned changes in the study will not adversely affect the human subjects and that the use of human subjects is in accordance with federal and University regulations. I will present to the IRB for approval any additional proposed modifications in the research activities prior to implementation.

Signed: \_\_\_\_\_ Date: \_\_\_\_\_  
Print Name: \_\_\_\_\_

**Faculty Advisor Signature (if student project):**

In sponsoring this project, I certify that it has been in compliance with federal and University regulations governing the protection of human subjects, that any revised activities will also be in compliance, and that any additional proposed changes in activities will be submitted to the IRB for review prior to implementation.

Signed: \_\_\_\_\_ Date: \_\_\_\_\_  
Print Name: \_\_\_\_\_

<b>Approved by IRB</b> <input type="checkbox"/> No <input type="checkbox"/> Yes	Date: _____
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