

CSUF - Institutional Review Board

Renewal Request for Continued Approval

for Research Project Using Human Subjects

IMPORTANT INFORMATION ABOUT IRB RENEWAL APPLICATIONS: If you wish to continue your research study involving the use of human subjects or collecting data your project must be reviewed by the IRB before the project's expiration date. Please submit this renewal request at least 30 days prior to the project expiration date.

Any changes to the protocol which have occurred since the initial review or the last renewal/approval date must be reported in this renewal request. University and federal guidelines prohibit the use of human subjects beyond the IRB approval expiration date.

Please answer in shaded areas the following questions:

A. Basic Protocol Information	
Principal Investigator Faculty <input type="checkbox"/> Student <input type="checkbox"/>	
If student, indicate Faculty Advisor	
Project Title	
Department	
Email Address	
Protocol Expiration	
If protocol is more than 5 years old and remains active, please explain reason:	

Do you wish to make any changes for collecting data, recruitment of subjects or research personnel in this study? If yes, please explain in progress report.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Are you requesting any changes in the consent form?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Will requested changes, if applicable or future research activities increase risk to subjects beyond those previously approved?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Have there been any adverse events? If yes, explain in progress report.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Has any agency (e.g., FDA or OHRP) or sponsor audited, inspected or otherwise monitored activity in this study during the past approval period?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Has there been any change in funding? If yes, name the sponsor:	Yes <input type="checkbox"/> No <input type="checkbox"/>

In addition to the above-referenced questions, please also provide the following with your renewal request:

1. Progress Report (250 words or less) summarizing the progress of your data collection and/or any adverse circumstances that you may have encountered while involving human subjects and/or collecting data. Any other changes (i.e., change in consent form) should also be included in this report.
2. A blank copy of the current consent form used in your study. (If the consent form has been changed and requires approval, attach a clean copy and a highlighted copy (which shows changes). We will stamp and approve the non-highlighted version of your consent for use with your renewed approval.)