***Amendments/Modifications to Research Protocols***

No changes to an approved protocol can be implemented until the IRB has reviewed and approved the changes. This includes subject recruitment methods, consent form changes, cover letters, instruments/questionnaires, research design, funding source, addition of study site or change in study population, etc.

As with new protocols, you will be notified in writing of the IRB’s review. Please note that an amendment/modification does not change the original approval/termination dates. Your continuing review date will remain the same. The amendment/modification approval is effective within the approval period of the protocol.

Complete the attached Request for Amendment/Modification form and submit it along with a copy of the approval letter for the original protocol application to irb@csuci.edu. Be sure to include supporting documentation if applicable.

### INSTRUCTIONS FOR COMPLETION

1. **Investigator Information Section**

Fill in the title of the research, Principal Investigator, Co-Investigator and IRB Number as noted on the IRB approval letter.

1. **Type of Amendment/Modification**

Check all appropriate boxes and fill in requested information. If the amendment/modification includes a change to the protocol, please submit the revised protocol with changes highlighted. If the amendment/modification includes a change to the consent document, submit two copies of the new consent – one with clean copy and one with changes highlighted. Any revised protocol or consent should have the revision date as a footer on the document.

1. **Explanation and Rationale**

Describe the amendment or modification and provide the reason for the change.

1. **Signatures**

If the co-investigator is a student, the student must sign the form in addition to the faculty PI.

**Institutional Review Board**

**Request for Amendment/Modification to Research Protocols**

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| **Investigator Information** |
| Protocol Title:  |
| Principal Investigator: | Co-Investigator: | IRB Number: |
| **Type of Amendment/Modification** (Check all appropriate boxes) |
| **[ ]  Amendment** (Attach supporting documentation, the revised protocol with changes highlighted.) **[ ]  Informed Consent Change** (Attach two copies. One with changes highlighted and one clean copy.)**[ ]  New Procedures** (Describe any change in risks and benefits)  **[ ]  Change in Investigators** (Include role and contact information)  [ ]  Add investigator [ ]  Delete investigator  [ ]  **Change in Enrollment** Increase#      Decrease#     [ ]  **Change of Site** (Include site permission/IRB approval)  **[ ]  Change in Funding** [ ]  Add source (name)       [ ]  Delete source (name)       **[ ]  Other** (Describe)       |
| **Explanation and Rationale:** (Use additional page if necessary) |
| PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Student Researcher Signature (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **IRB Use Only** |
| Protocol expiration date is not changed by the approval of this modification❒ Full Board Received:❒ Expedited❒ Exempt |