



**Research Protocol Amendment Form**

PI Name: \_\_\_\_\_ Reviewer Name: \_\_\_\_\_

Protocol Number: \_\_\_\_\_ Date: \_\_\_\_\_

Project Title: \_\_\_\_\_

Initial Review Level:  Full  Expedited  Exempt

**Form Submission**

In accordance with the federal regulations, the IRB must approve all proposed changes to approved protocols and supporting documents prior to implementation. Amendments are processed within 15 business days of receipt.

**The following documents are required to be submitted with this form to [irb@arizonacollege.edu](mailto:irb@arizonacollege.edu):**

- i. Clean version of the amended protocol
- ii. Clean version of the amended supporting documents

**Contact Information**

Name: _____	Phone: _____
Email: _____	

**Purpose for Amendment(s) (Select all that apply)**

- Update Personnel (Note: if this is the only amendment skip to the personnel change section of this form.)
- Revisions to protocol procedures and/ or supporting documents
- Update regulatory documentation (i.e., funding)

**Amendment Summary**

Provide a summary of the proposed changes to the research protocol and supporting documents and a rationale for all changes in the box below.

Current Status of Research	Participant Enrollment	
<input type="checkbox"/> Research study has not commenced <input type="checkbox"/> Research is subject to active participant enrollment <input type="checkbox"/> Research is closed to participant enrollment	Total number of participants consented	
	Number of active participants	
	Number of completed participants	

Amendments to the Consent Form and Re-consent Plan
Does the proposed amendment(s) change the content of the consent form? <input type="checkbox"/> Yes <input type="checkbox"/> No
<b>If yes, provide the re-consent plan:</b>
<input type="checkbox"/> N/A- no participants have enrolled <input type="checkbox"/> All active and completed participants will be re-consented <input type="checkbox"/> Only select participants will be re-consented <input type="checkbox"/> There are no plans to re-consent participants
Provide rationale for selected consent plan:

Changes to the Risk/Benefit Profile of the Research Study
Provide a statement on whether any components of the proposed amendment(s) pose new or increased risk to participants in the box below.

Personnel Changes					
<input type="checkbox"/> No personnel changes			<input type="checkbox"/> Updating CITI training for existing Personnel <i>Note: must submit CITI training certificate</i>		
<input type="checkbox"/> Adding New Personnel			<input type="checkbox"/> Removing Personnel		
Name	Affiliation	Role in Study	Name	Affiliation	Role in Study

Principal Investigator's Signature: \_\_\_\_\_ Date \_\_\_\_\_