|  |
| --- |
| ***Completed by IRB:*** |
| **IRB PROJECT #:**  |
| **[ ]  Expedited Review (if required by IRB):** **.** |
| **[ ]  Full Review:** **.** |
| **[ ]  Revised:** |



**Institutional Review Board (IRB)**

**RESEARCH CONTINUATION FORM**

**PLEASE NOTE: If submitting a revised form, please check the Revised box above and highlight ALL CHANGES in yellow.**

|  |  |  |
| --- | --- | --- |
| **Responsible Project Investigator:**  | **Phone:**  | **Email:** |
|        |        |       |

|  |  |  |
| --- | --- | --- |
| **Name of Investigator (if different):** | **Phone:**  | **E-mail:** |
|        |        |       |

|  |  |
| --- | --- |
|  **Department/Program:** | **Sponsor (if funded):** |
|       |       |

|  |  |  |
| --- | --- | --- |
|  **Title of Project:**  | **Project Start Date:** | **End:** |
|        |        |       |

**1. What type of continuation is being requested?**

[ ]  Extension of study requested **without** protocol or study modifications

[ ]  Extension of study requested **with** protocol and study modifications

[ ]  Extension of study requested for other reason. Please explain:

**2. Has this project enrolled any participants yet?**  [ ]  Yes [ ]  No

 If yes, how many? **\_\_\_\_\_\_**

**How many more will be enrolled? \_\_\_\_\_\_**

If no participants have been enrolled, please list the reason(s) why data collection has not

commenced:

**3. Was an adverse event report filed for this study during the past year?** [ ]  Yes [ ]  No

If yes, were steps taken to effectively manage the event? [ ]  Yes [ ]  No

If yes, please explain how procedures have been changed to minimize the risk and manage any

future event.

NOTE: An adverse event is defined as any experience that has taken place during the course of a research

project, which, in the opinion of the investigators, was harmful to a subject participating in the research,

 increased the risks of harm in the research, or had an unfavorable impact on the risk/benefit ratio. The

investigator does not necessarily have to feel that an adverse event was *caused by* research participation in

order for it to merit reporting to the IRB. All adverse events should be reported to the IRB within 24

hours of the PI learning of the event; see IRB Policies and Procedures.

**4. Do you plan any change(s) to your protocol as data collection continues?** [ ]  Yes [ ]  No

If yes, please explain in **question 5**, below.

**5. Please indicate which types of changes you intend to make to your protocol:**

 a) Addition or deletion of key personnel? [ ]  Yes [ ]  No

b) Changes to advertisements, notices, flyers, or other

 recruitment materials or procedures? [ ]  Yes [ ]  No

 c) Changes to the study design? [ ]  Yes [ ]  No

 d) Changes to enrollment criteria? [ ]  Yes [ ]  No

 e) Changes in data collection methods? [ ]  Yes [ ]  No

 f) Changes to the risk/benefit ratio? [ ]  Yes [ ]  No

g) Changes to the consent form, assent sheets, or any study

 information sheets? [ ]  Yes [ ]  No

 h) Any other changes that relate to how participants are treated? [ ]  Yes [ ]  No

If yes to any of the items listed above, please explain the nature of these changes and the rationale for making the changes:

**Please sign below where indicated and return this form, along with a copy of the IRB approval letter for the original protocol application and any revised documents, to** **irb@csuci.edu****.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator’s Signature Date