

**IRB Amendment/Modification/Extension Request Form**

Federal regulations require that any changes to IRB-approved research, during the period for which approval has already been given, must be reviewed and approved by the IRB prior to implementation (except where necessary to eliminate apparent immediate hazards to human participants).

Prior to implementation of the study with the proposed changes, the SMUIRB must approve modification/amendment/extension requests to an IRB approved research protocol. This Amendment/Modification/Extension Request form should be completed and submitted to SMUIRB administrator, Jamie Hirota jhirota@samuelmerritt.edu. As part of your Amendment/Modification/Extension request, include in this email a **revised/updated protocol application and revised appendix materials** (consent forms, recruitment flyers, etc.), which should reflect the changes summarized in the Amendment/Modification/Extension request form.

**Please use the Track Changes in Word to show the changes made in the previously approved materials. Please submit revised documents separately. Do not copy and paste other documents into this form.**

**Date:**

1. **Project Title:**

 **IRB Initial Approval Number and Date:**

1. **List the name and Faculty/Students/Staff status of the person(s) conducting the research. (CITI training certificates must be submitted for each member of the research team)**
	1. **Principal Investigator(s):**
	2. **Department:**
	3. **Others:**
2. **Project Period:**
3. **Funding**
	1. **Agency:**
	2. **Amount Awarded:**
4. **Summarize the amendment/modifications/extension.**
5. **Does this amendment/ modification/extension impact the level of risk?**

**Yes / No
If yes, how?**

**By signing this form, the Principal Investigator and the preparer of this form (if other than the Principal Investigator) certify that he/she has disclosed to the SMU IRB all relevant information that might impact the risk to benefit analysis of this study.**

**Preparer’s Name**  **Date:**

 Printed

**Preparer’s signature** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator’s signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**