Tulsa Community College

**INSTITUTIONAL REVIEW BOARD**

**MODIFICATION REQUEST FORM FOR APPROVED HUMAN SUBJECTS RESEARCH**C***omplete this form and submit electronically to:*** ***irb@tulsacc.edu******.***

**The following items must be submitted in order to process this request for modification:**
 1. This completed TCC IRB Modification Request Form
 2. A revised TCC IRB application form with changes highlighted
 3. All IRB documents that are being modified with changes highlighted and/or any new documents

For additional information contact the IRB at irb@tulsacc.edu.

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| --- |
| **PROTOCOL INFORMATION** |
| Protocol No:  |
| Title of Protocol:  |
| Principal Investigator:  Department**:** Email:  Phone**:**  |
| **TYPE OF MODIFICATION***(check all that apply and attach copies of all updated documents with highlights)* |
| **[ ]  Change in Investigators** | **[ ]  Change in location of research** |
| **[ ]  Change in study design** | **[ ]  Change in participant activity** |
| **[ ]  Change in participant cost or compensation** | **[ ]  Change in recruitment method** |
| **[ ]  Change in participant population** | **[ ]  Change in consent form(s)** |
| **[ ]  Change in funding source**  | **[ ]  Change in advertisement(s)** |
| **[ ]  Change in risks and/or benefits** | **[ ]  Other, describe****:**  |
| **MODIFICATION SUMMARY** |
| **Provide a summary of the current practices, a summary of the additions/changes you want to make to the protocol, and a rationale for each change.**

| **CURRENT PRACTICE** | **PROPOSED ADDITIONS/CHANGES** | **RATIONALE** |
| --- | --- | --- |
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| **NEW INVESTIGATORS** (List any new investigators below)  |
| Name:  | E-mail:  | Is their human subjects training current? [ ]  Yes [ ]  No |
| Name:  | E-mail:  | Is their human subjects training current? [ ]  Yes [ ]  No |
| Name:  | E-mail:  | Is their human subjects training current? [ ]  Yes [ ]  No |
| **INVESTIGATORS TO BE REMOVED** (List below any investigators being removed) |
|  |  |  |
|  |  |  |
| **CURRENT PROTOCOL STATUS** |
| Provide an estimated total number of participants enrolled in this study - Is this study still open to new subject enrollment? [ ]  Yes [ ]  NoHave there been any complaints, adverse events, unanticipated problems, deviations, or any participant withdrawals related to any of the proposed changes you are currently requesting? [ ]  Yes [ ]  No If yes, please explain.  |
| **MODIFIED DOCUMENTS** Attached/Included with this request form *(check all that apply)* |
| [ ]  Revised IRB Application (with changes highlighted) | [ ]  Consent Form(s) (with changes highlighted if applicable) |
| [ ]  Survey/Instrument (with changes highlighted if applicable) | [ ]  Other - (with changes highlighted if applicable) |
| [ ]  Human subjects training document(s) |  |
| **PRINCIPAL INVESTIGATOR’S ASSURANCE** |
| * I certify that the information provided in this IRB modification request is complete and accurate.
* I understand that I cannot initiate any changes to my approved protocol prior to having received IRB approval of the requested modification.

PI Signature **­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Date:Printed name **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**\*Sponsor’s Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:      (**\*REQUIRED – if Co-PI is a student**)Printed name **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

 Protocol No: **\_\_\_\_\_\_\_\_\_\_\_\_\_** Principal Investigator: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**TCC IRB Office use:**

Date Received Modification Request: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Modification Request Approval Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**IRB Approving Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**