THE UNIVERSITY OF TULSA

**INSTITUTIONAL REVIEW BOARD**

**TU IRB MODIFICATION REQUEST FORM FOR APPROVED HUMAN SUBJECTS RESEARCH*Please complete this form as thoroughly as possible and submit the Word version electronically to:*** ***researchcompliance@utulsa.edu***

**The following items must be submitted in order to process the Request for Modification:**
 1. A completed TU IRB Modification Request Form
 2. A revised TU 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 researchcompliance@utulsa.edu,918-631-3310.

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| --- |
| **1. PROTOCOL INFORMATION** |
| Protocol No:  |
| Protocol Title:  |
| Principal Investigator:  Department**:** Email:  Phone**:**  |
| **2. 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 risks and/or benefits**  | **[ ]  Change in advertisement(s)** |
| **[ ]  Change in Funding Please describe:** |
| **3. MODIFICATION SUMMARY** |
| **Please provide a summary of the current practices and a summary of the additions/changes you want to make to the protocol. Include a rationale for each change.**

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| --- | --- | --- |
| **CURRENT PRACTICE** | **PROPOSED ADDITIONS/CHANGES** | **RATIONALE** |
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|  |  |  |

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| **4. NEW INVESTIGATORS** *(List any new investigators below)* \*previously submitted to the IRB |
| Name:  | E-mail:  | Is their IRB training current? :[ ]  Yes [ ]  No |
| Name:  | E-mail:  | Is their IRB training current? :[ ]  Yes [ ]  No |
| Name:  | E-mail:  | Is their IRB training current? :[ ]  Yes [ ]  No |
| **5. INVESTIGATORS TO BE REMOVED** (List below any investigators being removed) |
|  |  |  |
|  |  |  |
| **6. PROTOCOL STATUS – Answer all questions below:** |
| Provide an estimated total number of participants currently enrolled in this study - Is this study still open to new subject enrollment? [ ]  Yes [ ]  NoHave there been any complaints, adverse events, unanticipated problems or any participant withdraws related to any of the proposed changes you are currently requesting? [ ]  Yes [ ]  No If yes, please explain.  |
| **7. Newly Revised Documents Attached/Included with this request form** ***(check all that apply)*** |
| [ ]  Revised IRB Application Form (with changes highlighted) | [ ]  Consent Form(s)(with changes highlighted if applic.) |
| [ ]  Survey/Instrument (with changes highlighted if applicable) | [ ]  Other - (with changes highlighted if applicable) |

**SIGNATURES REQUIRED ON THE ESIGNATURE PAGE FOR THIS FORM**

**You can find the** [**eSignature Page**](https://utulsa.edu/wp-content/uploads/2023/04/TU-IRB-Modification-Request-Form-eSignature-Page.pdf) **for the TU IRB QA-QI Form on the TU IRB webpage.**

**The TU IRB acceptable signatures:**

* A secure electronic signature that is digitally generated with date and time and cryptographically bound to the document, such as an Adobe Acrobat digital signature; *or*
* An email with a statement that you have reviewed/approved the form and to use the email as your approval signature; *or*
* Print the eSignature Page, sign/date the form and scan and email it to: researchcompliance@utulsa.edu with your other IRB documents.

**\*The TU IRB cannot accept a typed name using a script font**

**\*\*For instructions on** [**how to set up an electronic signature**](https://utulsa.edu/wp-content/uploads/2023/04/digital-signature-instructions-for-Adobe-Acrobat.pdf)**, please see our step-by-step instructions.**