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***](mailto: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](mailto:researchcompliance@utulsa.edu),918-631-3310.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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.**   |  |  |  | | --- | --- | --- | | **CURRENT PRACTICE** | **PROPOSED ADDITIONS/CHANGES** | **RATIONALE** | |  |  |  | |  |  |  | | | | | | |
| **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  No Have 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](mailto: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.**