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: carmen-schaar-walden@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 Carmen Schaar-Walden at carmen-schaar-walden@utulsa.edu or call 918-631-3310.

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### 1. PROTOCOL INFORMATION

<table>
<thead>
<tr>
<th>Protocol No:</th>
<th>Protocol Title:</th>
<th>Principal Investigator:</th>
<th>Department:</th>
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### 2. TYPE OF MODIFICATION

- [ ] 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, 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.

<table>
<thead>
<tr>
<th>CURRENT PRACTICE</th>
<th>PROPOSED ADDITIONS/CHANGES</th>
<th>RATIONALE</th>
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### 4. NEW INVESTIGATORS

(List any new investigators below)

*previously submitted to the IRB

<table>
<thead>
<tr>
<th>Name:</th>
<th>E-mail:</th>
<th>Is their IRB training current?</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>
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 applicable)

  □ Survey/Instrument (with changes highlighted if applicable)  □ Other - (with changes highlighted if applicable)

8. 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 this requested modification.

PI Signature __________________________________________ Date: ______

Printed name __________________________________________

*Faculty Mentor’s Signature __________________________________________ Date: ______

(*REQUIRED - if PI is an Undergraduate or Graduate Student)

Printed name __________________________________________

NOTE: **Please make sure to sign and date this form by either inserting an electronic signature or by printing this form, signing/dating it and then scanning it and emailing it to: carmen-schaar-walden@utulsa.edu.
Protocol No: ____________  Principal Investigator: ____________

TU IRB Office use:

Date Received Modification Request: ________________

Modification Request Approval Date: ________________

IRB Approving Signature: ______________________________

Printed name ________________________