For IRB Use Only

Approval Date:

File Number:

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| Type of Review |  |

**Modification Request**

**Texas State University Institutional Review Board**

**Purpose:** Complete this form when you would like to change the key personnel, data collection sites, protocol (e.g., compensation, study procedures, etc.), and/or Informed Consent/Assent Form in a research study that has already received IRB approval. Submit this form along with copies of any new or modified materials or documents you describe below. If modifications are more extensive than can be easily described on this form, please submit a new IRB application. NOTE: You may not implement any changes to an IRB-approved study until your Modification Request has been approved.

**Filling Out and Saving the Form**

Please type in the blue fields. Check “No” or “Yes” on items #5-9 and elaborate on “yes” answers as indicated. Save this form on your desktop and when ready submit this application along with all supplemental documents to the IRB Office as an attachment. All documents should be saved as First Name or Initial, Last Name, and one-word description, with no extra spaces or special characters other than underscores. Acceptable examples: JohnSmithapplication, J\_Smith\_application.doc, JohnSmith\_consentformEnglish.pdf, JSmithconsentformSpanish.doc

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| **1. IRB Application Number:** |
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| **2. Title of Study** |
| Must be identical to the title of any related internal or external grant proposal. |
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| **3. Investigator (Primary Researcher)** |
| First Name |  | Last Name | Title (i.e. grad student, faculty, ect.) |  |
|   |  |  |  |  |
|  |  |  |
| Degree program/Department | Texas State Email Address | Phone Number |
|   |  |  |  |  |

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| **4. Co-Investigator/ Texas State University Supervising Faculty (if applicable)** |
| First Name | Last Name | Texas State E-mail Address |
|  |  |  |  |  |
|  |  |  |
| Department or University |  | Title (Associate Professor, Professor, Dean, ect) |
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| --- |
| Phone number  |
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| **5. Are there changes in key personnel assisting in the research project?** |
| [ ]  No[ ]  Yes - List changes below and have all new key personnel complete CITI training The CITI course may be accessed by visiting: <https://www.citiprogram.org/>. Names and Texas State Affiliation of new Key Personnel: |
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| Names of Key Personnel to be Deleted: |
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| **6. Are there any additions or changes to sites where the data will be collected?** |
| [ ]  No[ ]  Yes - Identify specific data collection sites or agencies below. In addition, submit a signed letter on official letterhead  approving data collection at each site (other than Texas State University). |
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| **7. Are there any proposed changes to the informed consent/assent forms(s))?**  |
| [ ]  No[ ]  Yes – Provide a *brief* description of and rationale for proposed changes below. In addition, submit a tracked/highlighted *revised* informed consent/assent form(s) showing the changes and a clean copy of the informed consent/assent form(s).  |
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| **8. Are there any proposed changes in the protocol requested (e.g., recruitment procedures, data collection instruments or procedures, compensation)?** |
| [ ]  No[ ]  Yes – Provide a description of and rationale for proposed changes below. In addition, submit copies of any recruitment materials, data collection instruments, etc. that have been modified or added since your last IRB approval of this study. |
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| **9. Are there any proposed changes not described above?** |
| [ ]  No[ ]  Yes – Provide a brief description of and rationale for the proposed changes. |
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**Investigator or Supervising Investigator Certification**

[ ]  By checking this box I am certifying that the revised information provided for this project is correct and that no other procedures or forms will be used. I confirm that no changes will be implemented until I receive written approval for the changes from the Texas State IRB.

The application and all supplementary documents must be submitted together to be processed for review**. Applications submitted will only be valid for 30 days**. If your application expires after 30 days you will need to resubmit another application.

**If you have questions, please contact The Office of Research Integrity and Compliance at (512) 245-2334.**