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| 1. **Contact Information** | | | | | | |
| Title of Study: | | | |  | | |
| IRB ID: | | | |  |  | |
| Principal Investigator (PI): | | | |  | | |
|  | |  |
| 1. **Current Study Status (**Indicate YES or NO for activities involving this research at UTSA.**)** | | | | | | |
| **2.1** Have participants been enrolled (consented)? | | | | | | Yes  No |
| * 1. Is the research permanently closed to enrollment of new participants?   (If NO, SKIP to Item #3: Accrual of Participants.) | | | | | | Yes  No |
| **2.3** Have all participants completed all research-related interventions1 and interactions2, including those related to long-term follow-up? | | | | | | Yes  No |
| **2.4** Is all of the collection of information about participants that are both private3 and identifiable4 complete? | | | | | | Yes  No |
| **2.5** Are all of the analyses of information that is both private3 and identifiable4 complete?  (Can be checked YES if another organization will do the analysis.) | | | | | | Yes  No |
| **1***Interaction* means communication or interpersonal contact between investigator and subject.  **2***Intervention* means physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes.  **3***Private* means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.  **4***Identifiable* means the identity of the subject is or may readily be ascertained by the investigator or readily associated with the information by the investigator. | | | | | | |
| 1. **Accrual of Participants** | | | | | |
| **3.1** Will participants currently involved in the research be notified of any changes? | | | | | | Yes  No |
| **3.2** Will former participants be notified of any changes? | | | | | | Yes  No |
| **Brief Summary of the Modification (**OR submit a separate document**)** | | | | | | |
| Enter summary of modifications to the study here. | | | | | |
| **Submission Requirements** | | | | | |
| Provide the following documents with this application:  • All modified and new documents. Use the documents received from the IRB office. Tracked changes will be activated. If not, please make it easy to see the changes using highlighting or underlining. If a modification to the consent document reflects a change to the study protocol, submit a modified protocol.  • A description of how current or former participants will be notified (if you answered yes to 3.1 or 3.2). | | | | | |
| **Investigator Certification** | | | | | |
| **By submitting this form, investigator acknowledges and confirms compliance with "INVESTIGATOR GUIDANCE: Investigator Obligations (HRP-800)" throughout the conduct of the study.** | | | | | |