|  |
| --- |
| **DSU IRB**  **ADDENDUM TO PREVIOUSLY APPROVED APPLICATION** |
| **INSTRUCTIONS:**   1. ***This form is to be used whenever ANY change is made to an aleady approved IRB application*** 2. ***The IRB does not accept handwritten versions of this form. You must submit typed versions to prevent errors and delays due to legibility problems.*** 3. ***Your review may be delayed if we need to obtain clarification from you because information listed below differs from the information listed in supporting documents.*** 4. ***Please check the DeSales IRB website to ensure you are completing the most current version of this form.*** |

1. **Research Study Title**: \_     \_\_  
   **PI Name:** \_     \_\_
2. **RESEARCHERS & TEAM MEMBERS:**

Please list below:

1. Any individuals who are no longer members of the research study
2. Any new indiviuals who that will be involved in overseeing the research process, consent process, report generation, data collection and/or data analysis in this research study.

ONLY list those individuals for whom their status has **changed**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Department or External Location** | **Title**  **(PI, Co-PI, faculty investigator, student investigator, research coordinator, external consultant)** | **Contributions to the Research Study**  **(responsible for student investigators, subjects, data analysis, consent process, data collection, etc.)** | **Status**  **(No longer invoved OR new team member)** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

* The PI must ensure each member of this research study has completed CITI training in the protection of human subjects. Training must be current and completed prior to submission of this application and copies must be submitted to the IRB. Has each new member of the team completed this training?

YES

NO

1. **RESEARCH STUDY INFORMATION**
2. Has a change been made to the aims or methods of this research project?

YES

NO

If YES then please describe the change(s) below in detail.

\_\_     \_\_\_

1. Has the funding changed in any way for this research study? For example, are you receiving any new grants from other parties to conduct this research or will the research be completely funded by the University?

YES

NO

If YES then please describe the change(s) in funding below in detail.

\_\_\_\_     \_\_\_\_

1. **RESEARCH SITE LOCATION INFORMATION**

If you or your research team members will be conducting the research at a new site, complete and attach the Additional Site form at the end of this document for each additional site.

Have you added any additional research sites?

YES

NO

**V. RECRUITMENT, CONSENT, AND SUBJECT PAYMENT INFORMATION**

1. 1.Has a change been made to the process of recruiting participants for this research project?

YES

NO

If YES then please describe the change(s) below in detail.

\_\_     \_\_\_

**VI. PRINCIPAL INVESTIGATOR CONFIRMATION OF IRB REQUIREMENTS**

The PI must assure that IRB of the following by signing in the space provided below:

* The answers in this form are accurate.
* I will read and abide by all of the DSU IRB requirements and correspondence I receive.
* If one or more of the IRB requirements are not acceptable, I understand that I may ask the IRB to reconsider its requirements, but may not enroll subjects until the issue is resolved in a manner acceptable to the IRB.
* Confirm that you have included all of the following that are applicable to the changes in your approved research project by checking the boxes:

New/Updated consent form

New/Updated assent form

New/Updated recruitment materials

New/Updated recruitment screening materials

New/Updated data collection instruments

Conflict of Interest (COI) Forms for each new research team member

CITI Training Certificate for each new research team member

Current healthcare professional license showing expiration date for new reserach team members (if applicable)

Letter of Permission for new non-DeSales institution

For each new site, please copy, complete and attach the Additional Site Listing form.

Print Name of PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**To submit your addendum to the IRB for review:**

* Obtain PI’s signature on this form.
  + Scan the entire addendum with all attachments and create ONE file in pdf format with the following filename structure:

PI last name followed by 3-4 key words from the title of the research study\_Addendum

*Ex. Starling\_ReadingScrambledWords\_Addendum.pdf*

* + The PI must email the addendum to [IRB@desales.edu](mailto:IRB@desales.edu)
* In the email subject line write the filename:

*Ex. Starling\_ReadingScrambledWords\_Addendum*

* In the email text write the full title of the research study:

*Ex. Effects of Context Cues on Reading Scrambled Words*

* Attach the addendum in ONE file in pdf format.