**INSTRUCTIONS:**  **BLUE** text indicates sample text or suggestions from TC IRB and can be freely edited out. **BLACK** text must be kept in the final document, unless you justify otherwise. Please ensure the final document is saved in all **BLACK** text and delete template text before submitting to TC IRB.

**To**: Teachers College Institutional Review Board, IRB@tc.edu

**From**: {Name of PI, Affiliation}

**Contact**: {Contact Information}

**Protocol Title**: {Title of Study}

**Regarding**: {Document Updates and Research Staff Changes (label requested changes)}

**Date:** {January 1, 2021}

**IRB Protocol #:** {19-123}

The researcher(s) for this project would like to make the [following minor [or major] changes to this protocol](https://www.tc.columbia.edu/institutional-review-board/how-to-submit/modification/): [*Provide a summary of what the reviewers should expect when reviewing this modification. For example:*]

1. Research staff change
2. New recruitment materials
3. Revised study measures
4. Increase participant recruitment
5. Translated study documents and translation verification form

Below is a detailed summary of the requested changes: [*Elaborate on the context more; tell the story of the changes, so reviewers understand why this modification is being requested; explain how it might impact the risk to participants.* ]

The protocol was modified to address the following points: [*Itemize and elaborate on the list provided in the first section, as it applies to your proposed changes. For example:*]

1. **Research staff change**
   1. [*First and Last Name, email, and research role (e.g., research assistant, external researcher, etc.)*]
   2. [*Ensure all new research staff are CITI trained within the last three years and staff members’ CITI training certificates are uploaded in each staff member’s own MyTC/PI Documentation*]
2. **New recruitment materials**
   1. [*Describe what is changed or added*]
   2. [*Ensure all recruitment materials have the TC IRB number on them*]
   3. [*Upload a copy of each new material or upload a tracked changes and clean version for review*]
3. **Revised study measures** 
   1. [*Describe what has changed and how*]
   2. [*Specify if these modifications change the risk level of the study*]
   3. [*Adjust the consent form (parent permission or assent form) and the IRB application if the new measures change the timing of study activities*]
   4. [*Upload a copy of each new material or upload a tracked changes and clean version for review*]
4. **Increase in participant recruitment** 
   1. [*Describe what has changed and how*]
   2. [*Specify if these modifications change the risk level of the study*]
   3. [*Adjust the consent form (parent permission or assent form) and the IRB application if the new measures change the timing of study activities*]
   4. [*Upload a copy of each new material or upload a tracked changes and clean version for review*]
5. **Translated Documents**
   1. [*Specify the languages into which the materials have been translated (e.g., Spanish, Mandarin)*]
   2. [*List all translated documents (e.g., consent forms, recruitment materials, study measures)*]
   3. [*Confirm that translated documents are accompanied by a Translation Verification Form signed by the translator and PI*]
   4. [*Describe how the inclusion of translated documents impacts participant recruitment, risk assessment, or study logistics, if applicable*]
   5. [*Upload the completed Translation Verification Form for each language*]
   6. [*Include clean versions of the translated documents, ensuring consistency with the content, style and readability of the IRB-approved English versions*]

List the file names of the revised uploaded documents: [*When submitting a modification, please consolidate the changes into one Modification memo and one Modification record. Do not create multiple Modification records to upload additional documents. To upload additional files, click on the context menu in TC Mentor IRB to the left of the file type label. For changes made to existing documents, please upload a tracked changes and a clean version of each document. For translated documents, only clean or final versions are required.*

|  |
| --- |
| *Name all files following this format:*   * Document Title TrackedChanges\_IRBProtocolNumber * Doc Title\_Final\_IRBProtocolNumber * Doc Title\_ (Translated Language) Translation\_IRBProtocolNumber |

**Sample file naming**

1. Application\_TrackedChanges\_19-123
2. Application\_Final\_19-123
3. Consent Form\_TrackedChanges\_19-123
4. Consent Form\_Final\_19-123
5. Learning Survey\_Final\_19-123
6. Recruitment Flyer\_Spanish Translation\_19-123
7. Verbal Consent\_Spanish Translation\_19-123