Institutional Review Board

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AMENDMENT APPLICATION

To ensure an accurate and streamlined review of your Amendment Application, please provide the following information:

1. Provide a brief explanation stating what is being proposed and where in the protocol and/or consent changes were made. Please state if you are requesting an increase in enrollment.

Click here to enter text.

2. Explain the rationale/justification for the change.

Click here to enter text.

3. State what impact the change has on risks to participants. If the changes present no additional risks to participants, please provide a statement to indicate so.

Click here to enter text.

4. Please list the total number of participants enrolled in the research to date (this includes all participants who have participated since the project was initially approved). Please state whether the changes will require re-consent. If the changes will not require re-consent, please state why. Please indicate if this project was previously approved for a waiver of consent below.

Click here to enter text.

5. Clearly state whether the change has an impact on the scientific integrity of the study, (i.e. decreases, increases, no impact).

Click here to enter text.

6. List the documents included with the application that have been modified (consent forms, flyers, data collection forms, surveys). State what has been changed in each modified document.

Click here to enter text.

7. If adding a student and their project (in the domain of the currently approved project), please request the addition of their name to the Approval Letter. If adding a student, faculty, or staff member to your application, please be sure to have this person link a valid, CITI Training record to the submission.

Click here to enter text.

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NOTE (1): Upload any modified documents with this amendment application.

NOTE (2): The consent forms in your approved IRBNet PACKAGE must be used. When creating or editing your consent form, please provide the most recent IRBNet package number at the bottom, right corner of the consent form. This ensures you are using the most "up-to-date" version of the form.

To find your IRBNet package number, go to the MY PROJECTS tab and click on the title of your project. In the PROJECT OVERVIEW page, your IRBNet package number will be listed at the top, next to your project title.

NOTE (3): NIH Funding - Any change in research activities that would result in an increased risk to human subjects will require prior NIH approval before implementation. Please speak to your program officer.

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