IRB Protocol #: Click here to enter text. Date: Click here to enter text.

Title of Study: Click here to enter text.

Principal Investigator: Click here to enter text.

Email: Click here to enter text.

Telephone: Click here to enter text.

This application is to seek approval for a modification to a currently approved study. Any proposed changes to previously approved human subjects research must be reviewed and approved by the IRB prior to implementation. This includes modifications to the study, inclusion or exclusion criteria, recruitment methods, research personnel, or any new or revised study materials. Approval is required for all modifications whether initiated by the investigator or external sponsor.

Instructions for Submitting

Include with your submission the items indicated in the list below, where applicable.

Unless otherwise instructed, submit to the same IRB that previously reviewed this study

Include the items indicated, where applicable:

* Check the relevant items below and include one copy of all checked items 1-5 in the order listed.

→ Applications will be considered INCOMPLETE if these instructions are not followed.

|  |  |  |
| --- | --- | --- |
| Check | Item | Total No. of Copies |
|[ ]  1. A concise summary of the requested modification using this form. List and describe each proposed change to aid in IRB review. Add pages as necessary. Provide a concise summary of changes when submitting an updated Investigator Brochure or Master Protocol. | 1 |
|[ ]  2. New or revised consent forms, questionnaires, surveys, recruitment materials, advertisements, etc. One copy should have changes highlighted by underlining, and the other clean copy will be used for stamping. | 1 highlighted1 clean |
|[ ]  3. If you have made substantive changes to the study design or procedures, submit a revised full IRB application with changes highlighted by underlining. If you are making changes only to the first page, just submit that page. | 1 |
|[ ]  4. The sponsor's document describing the amendment, if any. | 1 |
|[ ]  5. If adding personnel, include name, location (HU or specific outside location), role, and email address for each person who should receive electronic copies of IRB correspondence to PI.  | 1 |

1 List and describe each proposed change: Click here to enter text.

2. Is this modification being submitted in response to an unanticipated problem/adverse event or new findings? [ ] yes [ ] no

If yes, explain, including whether these events or findings are relevant to participants’ willingness to continue. Click here to enter text.

3. Do any of the proposed changes increase risk? [ ] yes [ ] no

 If yes, explain. Click here to enter text.

For industry sponsored research (if applicable):

Sponsor’s protocol version #: Click here to enter text. Version date: Click here to enter text.

Investigator Brochure version #: Click here to enter text. Version date: Click here to enter text.

Any other details you need documented on IRB approval: Click here to enter text.

Click here to enter text. Click here to enter text.

Name of Principal Investigator or designee Date

Click here to enter text.

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Signature of Principal Investigator or designee