HOWARD UNIVERSITY

Office of Regulatory Research Compliance
Institutional Review Board

MODIFICATION FORM

IRB Protocol #: **Date:**

Title of Study:

Principal Investigator: **Email:**

Telephone:

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 on the next page, 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 highlighted 1 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	1

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	page, just submit that page.	
☐	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:

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.

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

If yes, explain.

For industry sponsored research (if applicable):

Sponsor's protocol version #: Version date:

Investigator Brochure version #: Version date:

Any other details you need documented on IRB approval:

Signature of Principal Investigator or designee Date