INSTITUTIONAL REVIEW BOARD
(856) 761-3844
Fax: (856) 761-3834

IRB MODIFICATION FORM

1. Study Information

IRB Protocol Number: *Click here to enter text.*
Study Title: *Click here to enter text.*

Principal Investigator (include degree(s)/certifications): *Click here to enter text.*
Co-Investigators (include degree(s)/certifications): *Click here to enter text.*
Study Personnel (include degree(s)/certifications): *Click here to enter text.*

2. Modification Request

Indicate the type of change and/or addition (Check all that apply)

☐ *Advertisements/Recruitment Materials*	☐ *Compensation/Incentive*
☐ *Consent Form(s)/Letter(s)***	☐ *Drugs/Devices/Biologicals***
☐ *Funding Source*	☐ *Change in Principal Investigator**
☐ *Addition/Removal of Co-Investigator(s)**	☐ *Project Title*
☐ *Protocol Document(s)*	☐ *Performance Site(s)*
☐ *Study Instruments (surveys/questionnaires/interview/focus group)***	☐ *Addition/Removal of Study Personnel**
☐ *Subject Enrollment***	☐ *Targeted Population or Selection Criteria*
☐ *Participant Material*	☐ *Local Context Supplement or IRB application*
☐ *Investigator Brochure*	☐ *Number of charts increased***
☐ *Case Forms*	☐ *Study paused or suspended.*
☐ *Adding another language Consent/ Recruitment Material*	☐ *Other Changes (please describe): Click here to enter text.*

**When requesting a change to study team or Principal Investigator, please provide completed COI form, complete CITI training records and ensure delegation of authority log has been updated. Please have the additional co-investigator/study personnel/new principal investigator sign the modification form.*

***Please ensure that a tracked change version and a clean version of any revised items (consent form, study instruments, revised protocol, local context supplement etc.) are attached.*

Does the modification affect the subjects currently enrolled/being treated or in follow-up?

☐ *Yes, please describe your plan for reconsenting/informing the subjects* *Click here to enter text.*
☐ *No*

3. Summary of Changes

For each document being revised, please provide a list of the revisions and the associated rationale or justification for requested revisions. In addition, if AI tools are used, describe whether any study data will be entered into external or cloud-based platforms. Investigators must confirm that no PHI or identifiable data will be entered into non-approved systems unless explicitly authorized, and must describe safeguards to prevent unauthorized disclosure. *Click here to enter text.*

4. Risk/Benefit Profile of the Study

As assessed by the investigator, does the modification request add any new or increase the risk to new or active participants?

☐ *Yes*
☐ *No*

5. Additional Information

If applicable, please attach any documentation from the Sponsor and/or FDA communications.
Click here to enter text.

If this modification is being submitted alongside another submission (ie., Continuation, Reportable Event, etc.), please indicate that here.
Click here to enter text.

If there is any additional information that you wish to include about the study, please include it below.
Click here to enter text.

6. Investigator/Additional CoI/Study Personnel signoff

Signature of PI: _____ *Date:* _____

If applicable, Name of New CoI: Click here to enter text.
Signature: _____ *Date:* _____

If applicable, Name of New Study Personnel: Click here to enter text.
Signature: _____ *Date:* _____