

**METHODIST HEALTHCARE
INSTITUTIONAL REVIEW BOARD**

Revision/Amendment for Research Project

WHEN TO USE THIS FORM: Any changes made to any part of a research project (i.e. protocol revisions/ amendments, revisions to informed consent, advertising requests, advertising for subjects, updated investigational brochures, additions or deletions to the investigational team, etc.) must be submitted to the MHIRB for appropriate action. Exception to this rule is when a change reduces or eliminates immediate hazards to study subject; the change(s) may be implemented prior to MHIRB approval. However, the MHIRB must be promptly notified within five working days of the change.

**If there are changes to the informed consent, please attach 1 copy of the current consent form, with changes marked, and a clean copy of the revised consent form that will be stamped with the new MHIRB approval date.*

Name of protocol: _____

MHIRB # _____

Principal Investigator: _____ **Address** _____

Change to (check all that apply):

Study procedures Administrative Informed Consent* Other (explain)_____

1. Identify the change(s) to project (i.e. Amendment #, protocol version date, etc.): _____
2. Describe the proposed change(s) and rationale for the changes. For amendments with extensive changes, summarize these changes on this form. Supporting documentation, i.e. letter from sponsor, amendment, revised protocol, etc.) must be attached. _____
3. Does the change(s) affect the risk to study subjects?
 No
 Yes (justification required) _____

Investigator Signature

Date

Do not write below this line – for MHIRB use only

The Methodist Healthcare Institutional Review Board has reviewed the above referenced amendment/revision. These changes are:

- Approved** (*Approval does not alter expiration date of project*)
- Approved pending conditions** (see attachment)
- Disapproved** (see attachment)

MHIRB

Date