

RR 403-G

mm/dd/yy

Changes to research may not be initiated prior to IRB approval except as necessary to eliminate apparent immediate hazard to subjects [(45 CFR 46.103(a)(4) and 21 CFR 56.108(a)]; therefore, amendments must be approved by the IRB prior to implementation.

**IRB #** **Date Received**  
**Protocol Title and Number**

Address:

**Principal Investigator**

**Contact person** Phone:  
Address: Fax:  
E-mail:

**Brief description of modification(s): (attached [ ] )**

*(continue on second page, if necessary)*

**Consent form revisions?** [ ] No [ ] Yes

If Yes, attach 1 copy of the revised consent **with changes underlined on original and all copies**

**Protocol amendment?** [ ] No [ ] Yes

If Yes, attach 1 copy of the revised protocol **with changes underlined on original and all copies**

Investigator Brochure amended? [ ] No [ ] Yes

If Yes, attach revised Investigator Brochure

**Should enrolled study subjects be informed of these changes?** [ ] No [ ] Yes

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Report prepared by Date

For IRB Use :

Minor modifications acceptable for expedited review (changes are minor, administrative changes, and/or they do not make the protocol more complex or risky)

Approved full board review IRB Meeting Date

Comments:

Signature of Institutional Review Board Chairperson Date