**FORM 403G AMENDMENT SUBMISSION FORM**

Changes to research may not be initiated prior to IDI REC approval except as necessary to eliminate apparent immediate hazard to participants; therefore, amendments must be approved by the IDI REC prior to implementation.

**IDI REC # Date Received**

**PROTOCOL TITLE AND NUMBER**

Address:

**Principal Investigator:**

Contact personPhone:

Address: Fax:

E-mail:

Brief description of modification(s): (attached )

*(continue on second page, if necessary)*

**Consent form revisions?**  No  Yes

If yes, attach copies of the revised consent **with changes track-changed on original and all copies Protocol amendment?**

No  Yes

If yes, attach copies of the revised protocol **with changes track-changed on original and all copies**

Investigator Brochure amended?  No Yes

If yes, attach revised Investigator Brochure

**Should enrolled study participants be informed of these changes?**  No Yes

Report prepared by Date

**For IDI REC Use:**

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

Major modifications that require full IDI REC review (changes potentially increase risk or make the study more complex)