

**Institutional Review Board  
Durham VAMC Research (151)**

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**PROTOCOL AMENDMENT IRB SUBMISSION FORM**

[rev 06/21/2001]

Date: \_\_\_\_\_ MIRB #: \_\_\_\_\_ Promise #: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Protocol Title:

Research Coordinator: \_\_\_\_\_ Phone: \_\_\_\_\_ Pager: \_\_\_\_\_

Amendment Date: \_\_\_\_\_ Amendment Number/Version: \_\_\_\_\_

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**In order for the IRB to fully evaluate an amendment request, please provide a summary of the modifications from the sponsor/investigator.**

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Check all protocol amendments that apply:

**Consent Form Changes**

*(Provide copy of original consent form and new consent form with highlighted changes)*

**One or more subjects have already provided written or verbal consent to enroll in this study:**

Yes  No

**Inclusion / Exclusion Change**

**Editorial / Administrative Changes**

**New Information Provided to Subjects**

**Therapy Changes**

**Scientific Changes**

**Other** (e.g., closure, suspension, substudy): \_\_\_\_\_

Signature of PI: \_\_\_\_\_ Date: \_\_\_\_\_

IRB Reviewer: \_\_\_\_\_ Approved:  Yes  No Date: \_\_\_\_\_

Comments: \_\_\_\_\_

The Durham VAMC IRB is not connected with, and has no authority over, and is not responsible for human research conducted at any other institution. Separate consent forms, initial reviews, continuing reviews, amendment, and reporting of serious adverse events are required if the same study is conducted at multiple institutions.