

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

508 Fulton Street · Durham, NC 27705 · Phone: (919) 286-6926 · Fax: (919) 286-6824

MISCELLANEOUS IRB SUBMISSION FORM

Date: _____ MIRB #: _____ Promise #: _____

Principal Investigator: _____

Protocol Title:

Research Coordinator: _____ Phone: _____ Pager: _____

Check one or more of the following:

Consent Form Change not related to SAE or Protocol Amendment
(attach copy of old consent form and new consent form with highlighted changes)

Old version date: _____ New version date: _____

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

Yes No

Reconsent required? Reasons for requiring or not requiring reconsent?

Advertisement(s) / Recruitment Letter(s)

Include:

Investigator's Name, Purpose of Research, Criteria for Eligibility, Brief List of Benefits (e.g., no-cost health examination), Location of Research and Contact Person

Safety Update Summaries

Update Number: _____ Update Date: _____

Are consent form changes required? Yes No

List Commonalities noted (e.g., renal failure – 5, chest pain -3): _____

PI Change

Specify (include letter from sponsor acknowledging change, if applicable): _____

Investigator Brochure Update (attach update summary and copy of consent form)

Other Specify: _____

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.

