

**Tuscaloosa VA Medical Center  
Subcommittee on Human Studies (IRB)**

3701 Loop Road East, • Tuscaloosa, AL 35404 • 205-554-3675 • Fax: 205-554-2877

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**PROTOCOL AMENDMENT IRB SUBMISSION FORM**

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

Date: \_\_\_\_\_ ID: \_\_\_\_\_ Prom#: \_\_\_\_\_  
Principal Investigator: \_\_\_\_\_  
Protocol#: \_\_\_\_\_  
Protocol Title: \_\_\_\_\_

Sponsor: \_\_\_\_\_  
Research Coordinator(s): \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Number of Subjects enrolled to date: \_\_\_\_\_  
Amendment Date: \_\_\_\_\_ Amendment Number / Version: \_\_\_\_\_  
Consent Form Changes: \_\_\_\_\_ Old Version Date: \_\_\_\_\_ New Version Date: \_\_\_\_\_  
*(Provide copy of old consent form and new one with changes tracked/highlighted)*

**PROVIDE A COPY OF THE APPROVED CONSENT FORM AND ALL MODIFIED DOCUMENTS**

- I. Minor Change(s)/Minimal Risk  
Significant Change(s)/Greater Than Minimal Risk (Full Board Review Required)
- II. Summarize and provide a rationale for the change(s). If request involves changes to the consent document, please also list the specific revisions or additions.

Check all that apply, and **provide a justification** for all changes:

- Change in PI/study personnel, consultants, or members of the research team:
- Advertisements:
- Inclusion/Exclusion Changes:
- Editorial/Administrative Changes:
- New Information Provided to Subjects:
- Therapy Changes:
- Scientific Changes:
- Other (e.g., enrollment closure, suspension, sub-study):

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III. Describe how this amendment will affect the risk to benefit ratio for subjects.

IV.  Yes  No Do changes require REVISION OF THE PROTOCOL?  
If **YES**, enclose a complete copy of the revised protocol with all changes **highlighted**/changed text marked.

V.  Yes  No Do changes require REVISION OF CONSENT FORM(S)?  
If **YES**, enclose an original of the revised form(s) and a copy of revised form(s) with changes **highlighted**/changed text marked.

Yes  No Do changes require an ADDITIONAL CONSENT FORM? If **YES**, enclose an original of the additional consent form.

VI.  Yes  No Are changes requested by a STUDY SPONSOR? If **YES**, enclose written verification from the sponsor.

VII.  Yes  No Have subjects been enrolled in this study? If **YES**, describe below how you will notify them of the change(s):

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

***(IRB Use Only)***

More information needed: \_\_\_\_\_

Review on \_\_\_\_\_. Signature of IRB Official/Date: \_\_\_\_\_

Approved on \_\_\_\_\_ as Minimal Risk and Meets criteria: \_\_\_\_\_

Greater than Minimal Risk - Refer to Full Board

I attest that I have no conflict of interest(s) in regard to the research protocol or item reviewed.

\_\_\_\_\_  
Signature of IRB Official \_\_\_\_\_ Date \_\_\_\_\_ Report Amendment to the IRB at the next convened meeting.

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**REQUEST FOR AMENDMENT APPROVAL INSTRUCTIONS & INFORMATION**

Refer to HRPP SOP #4 for full details.

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

Per requirements of 45CFR46.103(b)(4) and 21CFR56.108(a)(3)(4), changes in approved research cannot be initiated without IRB review and approval unless necessary to eliminate apparent immediate hazards to the subjects. Minor changes or amendments that represent minimal risk may be approved by expedited review by the IRB Chairperson and then reported to the full Board at a convened meeting. When a proposed change in a research study is not minor (e.g. procedures involving increased risk or discomfort are to be added), the IRB must review the change at a convened meeting before the change may be implemented. **If you anticipate that your request will require full Board review and approval you should submit this form in accordance with deadlines established for new submissions.** If the overall risk(s) associated with the research as currently approved are either increased or decreased, an updated assessment of the risk(s) must also be provided in Section III. If the risk profile of the research is unchanged, this should be stated.

Minor changes/amendments or corrections/clarifications that represent minimal risks include the following:

Change in PI/study personnel, consultants, or members of the research team (**DO NOT COMPLETE SECTIONS III THROUGH VII**)

Advertisements (**DO NOT COMPLETE SECTIONS III THROUGH VII**)

Change in sequence of follow-up visits

Typographical errors

Minor grammar and format changes

Change in PI phone number in consent

Change in study title

Change in number of subjects to be enrolled

Addition of normal subjects for venipuncture within guidelines

Minor change in compensation

Change in person obtaining consent unless the study was approved under special circumstances

Rearranging (previously approved) text of consent

Addition of or changes to questionnaires (unless sensitive issues)

Deletion of procedures that decrease the risks or burden to subjects

Protocol clarifications that do not result in change to the actual procedures or risk to subject

Changes that do not exceed or increase the risks of the study identified at the initial or continuing review

**THE REQUEST FOR AMENDMENT APPROVAL WILL BE RETURNED IF IT IS INCOMPLETE FOR ANY OF THE FOLLOWING REASONS:**

- The changes are not summarized or changes summarized are not comprehensive.
- The changes are not summarized on the front of this form.
- Appropriate changes have not been highlighted or tracked on applicable document(s).
- The risk benefit assessment section has not been adequately addressed.
- The sponsor (if applicable) verification is not included.
- The appropriate consent(s) is/are not included (if applicable).