

**Request for Continued Approval of Human Use**  
(Submit with Abstract\*, Protocol, and Consent Form)

1. Principal Investigator: \_\_\_\_\_
  2. Project Title: \_\_\_\_\_
  3. Date initially approved: \_\_\_\_\_ Last approval (Continuing review date): \_\_\_\_\_
  4. Project Status:
    - \_\_\_\_\_ Project has terminated.
    - \_\_\_\_\_ Project is active, but no human subjects are currently enrolled.
    - \_\_\_\_\_ Project is active and human subjects are being used.
    - \_\_\_\_\_ Project is permanently closed to new enrollments and research remains active for follow-up of subjects or the collection of data only. The IRB will be notified when the project has completely terminated.
    - \_\_\_\_\_ Project is closed, but the collection or analysis of private identifiable information continues.
  5. Date last patient entered \_\_\_\_\_
  6. A signed consent form is in my files for each subject entered into this study \_\_\_Yes \_\_\_No
  7. A signed consent form is in the medical record of each VA subject entered into this study. \_\_\_Yes \_\_\_No
  8. A copy of the consent form has been given to each subject entered. \_\_\_Yes \_\_\_No
  9. TVAMC subjects: # screened \_\_\_\_\_; # actively enrolled \_\_\_\_\_; total # enrolled \_\_\_\_\_.
  10. One or more TVAMC subjects have claimed injury from participating in this study. \_\_\_Yes \_\_\_No
  11. Unanticipated problems involving risks to participants or other have occurred. \_\_\_Yes \_\_\_No
  12. Serious adverse events (SAEs) have occurred at TVAMC. \_\_\_Yes \_\_\_No
    - a. Adverse Drug Events (ADEs) have occurred at TVAMC. \_\_\_Yes \_\_\_No
    - b. Expected Adverse Events (EAEs) have occurred at TVAMC. \_\_\_Yes \_\_\_No
    - c. Unexpected Adverse Events (UAEs) have occurred at TVAMC. \_\_\_Yes \_\_\_No
  13. SAE have occurred at any other sites. \_\_\_Yes \_\_\_No \_\_\_N/A
    - a. ADEs have occurred at any other sites. \_\_\_Yes \_\_\_No \_\_\_N/A
    - b. EAEs have occurred at any other sites. \_\_\_Yes \_\_\_No \_\_\_N/A
    - c. UAEs have occurred at any other sites. \_\_\_Yes \_\_\_No \_\_\_N/A
  14. Have all serious or unexpected adverse events been reported as required. \_\_\_Yes \_\_\_No
  15. Is each study subject's response to the investigational procedure being documented in the progress notes of the medical record? \_\_\_Yes \_\_\_No \_\_\_N/A
  16. Has new information changed the risks or benefits? (i.e. if an investigational drug is being used, has information from the Sponsor changed the risks or benefits?) \_\_\_Yes \_\_\_No \_\_\_N/A
- If "Yes" please explain.**

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17. Are there female subjects participating in the TVAMC study? \_\_\_\_\_ If so, how many? \_\_\_\_\_
  18. Provide a Table of number and percent of subjects from racial groups, ethnic groups, and vulnerable populations (include specific category of vulnerable populations.

19. How many subjects have been exited from the study early? \_\_\_\_\_ Why?

20. Are subjects being paid for participation in the study? \_\_\_Yes \_\_\_No

If so, how much? \_\_\_\_\_

Please state the rationale for this compensation: \_\_\_\_\_

**FOR SPONSORED STUDIES: Please include sponsor site monitoring visit forms and multi-center trial reports with continuing review application.**

21 Are there any relevant multi-center trial reports? \_\_\_\_Yes \_\_\_\_No

22. Have any sponsor site monitoring visits occurred? \_\_\_\_Yes \_\_\_\_No

a. If so, did the site monitor sign in and out at the IRB Office prior to meeting with the PI or other responsible investigator? \_\_\_\_Yes \_\_\_\_No (If no, explain briefly)

b. Were any suspicions or concerns of serious non-compliance discovered? \_\_\_\_Yes \_\_\_\_No

c. If so, were the concerns found during the monitoring visit appropriately addressed and the appropriate facility officials and committees notified as required by facility policy?  
\_\_\_\_Yes \_\_\_\_NO

d. If concerns were found during the monitoring visit, what remedial action or penalties for non-compliance occurred? \_\_\_\_N/A (If b is no)

Signature of Principal Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of Research Asst.: \_\_\_\_\_ Date: \_\_\_\_\_

**\*SUBMIT ORIGINAL AND 14 SETS OF THE FOLLOWING:**

- Request for Continued Approval of Human Use form
- Stamped approved copy of Abstract\*, Protocol, and Consent Form
- Tracked copy of Abstract, Protocol, and Consent Form
- Clean copy of Abstract, Protocol, and Consent Form
- Table summary of all SAEs, ADEs, EAEs, UAEs, unanticipated problems involving risks to participants or others, complaints about the research, protocol deviations, and amendments or modifications with continuing review application.
- Site monitoring visit forms
- Multi-center trial reports

**\*Updated Abstract must include "FINDINGS."**