

MCHM-DCI

MEMORANDUM FOR Principal/Associate Investigator

SUBJECT: Request for Continuing Review or Project Closure

Enclosed is a progress report form, which must be completed NLT the suspense date two weeks in advance of the expiration date of your approved protocol.

Continuing reviews are mandatory for regulatory compliance. The reviews are due on at least an annual basis for all studies that have not been determined to be exempt. The WBAMC IRB required form is attached. This study is due for review on or before the anniversary of each year the study is active.

The progress report form must be accompanied by a synopsis of study progress to date, a copy of the current consent form in use, and an updated copy of the protocol form (with tracked changes) if there has been an amendment(s) since the original approval of the protocol. You may select the option on the form to request that the IRB either **continue or close** the project. The synopsis must include but is not limited to:

- the number of subject enrolled
- a detailed description of any adverse events (if none, please so state)
- a summary of any recent literature, study findings, amendments or modifications since the past review
- any other relevant information (especially information about a change in perceived risks associated with the study)

Should you need additional information or assistance, please contact this office at 915.569.2485 or via email to wbamc.dci@amedd.army.mil

Lola Norton, DAC
Supervisor, Clinical Protocol Section
Human Protections Administrator
Department of Clinical Investigation
William Beaumont Army Medical Center

STATEMENT OF PROGRESS FOR IRB
(For Use of Reviewing Authority)

Date:

Protocol #

Principal Investigator:

Department:

Title:

Medical Monitor:

Approval Date:

1. This is a request for continuation () closure () of the project identified above.
2. Protocol is: ___Ongoing ___Completed ___Terminated (Explain)
3. Has there been a change of principal investigators?
() Yes (please provide name, rank, department) () No
4. Has there been a change of associate investigators?
() Yes (please provide name, rank, department) () No
5. Number of subjects recruited: _____
6. Number of subjects who withdrew or were dropped (please explain): _____
7. Adverse reactions: () Yes (explain) () No
8. If the protocol is ongoing, please answer the questions below:
 - a. Have you made any changes to the approved protocol?
() Yes* () No
*If yes, you must also submit a formal request for amendment
 - b. Is progress to date satisfactory? () Yes () No
 - c. Are records being adequately maintained and available for review?
() Yes () No
 - d. Are methods to obtain consent satisfactory? () Yes () No
 - e. Are completed consent forms readily available for inspections?
() Yes () No
 - f. Are you requesting modifications to the protocol as approved?
() Yes* () No
*If yes, you must submit a formal request for amendment
9. **Please provide a brief synopsis of study progress and results to date on a separate page. Include a copy of the current consent form in use, and an updated copy of the protocol form (with tracked changes) if there has been an amendment(s) since the original approval of the protocol with this request for an extension of your approval.**

Signature of Principal Investigator

Date

PLEASE FORWARD COMPLETED CONTINUING REVIEW PACKAGE TO CHIEF, DCI
Protocol Section

Signature of IRB Chair or
designated alternate

Date