(Office Symbol) (Date)

MEMORANDUM THRU Director or Detachment Commander, Division of .....

FOR Director, Division of Human Subjects Protection, Walter Reed Army Institute of Research, Silver Spring, MD 20910-7500

SUBJECT: Closeout Report for Human Use Protocol (Insert Protocol Name, WRAIR #, HSRRB Log # - This report should be 1-2 pages in length. It should include a brief abstract as well as the approximate start and end dates of actual data collection)

1. RESEARCH OBJECTIVES: (Describe the protocol objectives in 1-2 sentences. Add dates that are covered by the report. Also, include the approximate dates data collection started and data collection ended).

2. NUMBER OF SUBJECTS ENROLLED/WITHDRAWN/APPROVED: (Tell how many subjects have been enrolled into the protocol. If any subjects withdrew/were withdrawn, state how many and why. Also, state the number of subjects that was originally approved. If modifications have been approved increasing the sample size, please state this and provide dates of approval.)

3. CURRENT LITERATURE: (If there have been any publications, provide a brief summary and any relevance it may have to your research. If there has been no literature, include a statement indicating that a search of the literature revealed no new information of this subject matter. Please include the keywords used to conduct the literature search and any database searches.)

4. SIDE EFFECTS: (Give a brief description of all the side effects observed and their severity. Did any adverse effects occur, and were they expected or unexpected? If any unexpected side effects occurred, state what they are, whether they were reported as required, and if a protocol modification has been/will be submitted to add the side effects to the consent form for future subjects.)

5. SUMMARY OF RESULTS TO DATE: (Give a brief summary of your results in 1-2 paragraphs. If any deviations from the protocol occurred, they should be described and discussed in a separate paragraph under this section of the report. A copy of the original report describing the deviation from the protocol may be attached.). Copies of publications and presentations from this study may be included as attachments.

6. SPECIMEN AND DATA MANAGEMENT: (Give a brief description of how specimens and data are managed. The following items should be addressed: (1) Specify if specimens are currently being stored; (2) If yes, identify where the specimens are being stored and the length of time specimens will be kept; (3) Identify where the database is being kept and by whom; and, (4) Describe the provisions in place in assuring subject confidentiality is maintained.

7. FUTURE PLANS: (Analysis of data? Submission of a new protocol to expand on results?)

8. Be sure to include short summary of the protocol.

(Signature of PI)
(Signature block of PI)