

FINAL STUDY CLOSE-OUT REPORT FORM

A. PROTOCOL INFORMATION:	
Principal Investigator	
Project Title	
Protocol #	

B. STUDY STATUS AT CLOSE OUT:	
1. Provide the reason for closing the study at PHDMC:	
<input type="checkbox"/> Study was completed. <i>(Please complete sections B3 through F.)</i> <input type="checkbox"/> Study was started but closed prior to completion <i>(Please complete sections B2 through F.)</i> <input type="checkbox"/> Study was not started. <i>(Please complete section B2 and section F.)</i>	
2. Please explain why the study was not started or was closed prior to completion.	
3. Did the study involve the collection, storage, or use of any human biological specimens? If yes , please explain what will happen with the specimens at the close of this study.	[] Yes [] No

C. SUMMARY OF STUDY RESULTS:	
1. Please summarize the results of this research project (attach separate page(s) if necessary).	
2. Have there been any presentations or publications resulting from this study? If yes , please describe and cite references.	[] Yes [] No

D. SUBJECT RECRUITMENT AND ENROLLMENT since last initial or continuing review:	
1. Was there any participant contact since the date of the last review? If no , skip to section F. If yes , answer the questions below in this section only for subjects since the initial or continuing review (whichever more recent) .	[] Yes [] No
2. Number of subjects enrolled since the last continuing review (if there has been no continuing review, please record the number of subjects enrolled during the study).	

3. Approximately how many potential subjects have refused participation?	
4. How many subjects have voluntarily withdrawn from participation?	
5. How many subjects have been withdrawn from participation by the PI?	
6. If applicable, provide a brief summary below of any difficulty obtaining/retaining subjects, or obtaining informed consent since the last continuing review.	

E. SIGNIFICANT FINDINGS AND REPORTABLE EVENTS	
<p>Have there been <i>any significant new findings</i> (recent literature or other relevant information) that may affect the risks or benefits associated with the research that should be disclosed to subjects who have participated in the study?</p> <p>If yes, please describe below and describe how you will notify research participants. Submit copies of any materials that you use to notify participants.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

F. PRINCIPAL INVESTIGATOR'S CERTIFICATION:
<p>I certify that all study activity involving participant contact, or use or access to individually identifiable information has ceased and the information provided in this report is complete and correct.</p>

Principal Investigator's Signature

Date

OR

PHDMC Collaborator Signature

Date