

Subject # \_\_\_\_\_

**VAMHCS RESEARCH SERVICE  
SOURCE DOCUMENTS AUDIT**

PROTOCOL: \_\_\_\_\_ P.I.: \_\_\_\_\_

AUDITOR: \_\_\_\_\_ DATE: \_\_\_\_\_

REASON FOR AUDIT / PORTION OF AUDIT: \_\_\_\_\_

PHASE/COMMENTS	ITEM	YES	NO	NA/#	
<b>Screening</b>	1.Current version of signed consent?				
	2.Signature, date & time prior to enrollment?				
	3.Subject seemed competent to sign consent?				
	4.All pages initialed?				
<b>Eligibility</b>	5.All pre-enrollment tests & dx's documented?				
	6.Ht / Wt / IBW / age criteria met?				
	7.Lab / VS criteria met?				
	8.Childbearing / lactating restrictions met?				
	9.Other Inclusion criteria met?				
	10.Sbjt ruled-out for exclusion criteria?				
	11.Waiver / exceptions documented?				
	12.Time-Event Screening/Eligibility section completed?				
	<b>Randomization</b>	13.Sbjt randomized accd to protocol?			
		14.Study med dispensed in a timely manner?			
		15.Time-Event Sheet complete?			
	<b>Medications</b>	16.Concomitant meds documented?			
17.Any protocol-prohibited meds given?					
18.Has drug been dispensed properly (time, duration, route,etc)?					
19.Is prescription / med orders / MAR in chart?					
20.Time-Event Sheet complete?					
<b>AE Reporting</b>	21. Any SAEs?				
	22. If yes, were they reported accd to requirements (Sponsor, IRB, etc.)?				
	23. Source documents complete?				
	24. Any AEs?				
	25.If yes, were they reported accd to requirements (Sponsor, IRB, etc.)?				
	26.Source documents complete?				
<b>Endpoints</b>	27.Has the sbjt reached any protocol-defined endpoints?				
	28.If yes, are they documented & followed up properly?				
	29.Time-Event Sheet complete?				
<b>Follow-up</b>	30.Has sbjt missed any visits?				
	31.If yes, are they documented & attempts to contact pt noted?				
<b>Clerical:ID,dates,etc.</b>	32.No clerical errors?				
	33.If errors, how many?				
<b>Problem Resolution Worksheet</b>	34.Worksheet generated? (sched F/U: _____ )				
	35.Problems resolved/answered?				