

Clinical Science Research and Development Data Monitoring Committee Report (To Be Attached to VHA Forms 10-0455 and 10-0455a)

A. Study Title:

B. Date Report Completed:

C. Principal Investigator, VAMC Site:

D. Site Investigator Name(s):

Last Name, First Name	VAMC #	VAMC Location

E. For each site listed above please complete Trial Enrollment Information:

In the table below, show the actual versus expected recruitment rates for the current reporting period for each site (as applicable)

Total for all Sites			
Expected Enrolled	Actual Enrolled	Completed Expected	Completed Actual
Site: (INSERT NAME)			
Expected Enrolled	Actual Enrolled	Completed Expected	Completed Actual
Site: (INSERT NAME)			
Expected Enrolled	Actual Enrolled	Completed Expected	Completed Actual
Site: (INSERT NAME)			
Expected Enrolled	Actual Enrolled	Completed Expected	Completed Actual
Site: (INSERT NAME)			
Expected Enrolled	Actual Enrolled	Completed Expected	Completed Actual
Site: (INSERT NAME)			
Expected Enrolled	Actual Enrolled	Completed Expected	Completed Actual

F. Explain recruitment losses

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G. Serious Adverse Events (SAEs), Adverse Events (AEs), and Unexpected Problems (UPs) (add rows as needed)

Participant Event	SAE, AE, or UP	Date	VAMC	Study Group	Reportable with in 5 days

H. SAEs, AEs, and UP Totals

Total SAE for Reporting Period	
Total AE for Reporting Period	
Total UP for Reporting Period	
Cumulative SAE	
Cumulative AE	
Cumulative UP	

I. Amendments to Study during Reporting Period

- (1) Summary of any Approved/Submitted Study Amendments to IRB
- (2) Summary of Approved/Submitted Study Amendments CSR DMC
- (3) Summary of Study Amendments Planned during next reporting period

J. Attach any communications directed to CSR&D (sponsor) & the response (if applicable)