APPENDIX H. CLOSE-OUT VISIT REPORT FORMS

DCP PROJECT
CLINICAL SITE CLOSE-OUT VISIT REPORT

I. SITE INFORMATION

Instructions: Please provide the requested information for each of the items listed below. Provide comments whenever necessary or helpful.

Name of Clinical Site:

Protocol Name:

Contract Number:

Date(s) of Visit:

Conducted by:

Clinical Site Personnel Involved with the Study:

NAME	TITLE	AVAILABLE DURING DISCUSSIONS (Y/N)
	Principal Investigator	
	Study Coordinator	
	Pharmacist	
	Other	

Additional Comments:

II. CLOSE-OUT REVIEW

Instructions: Please provide the requested information for each of the items listed below ("Y" = Yes, "N" = No). Please provide comments whenever necessary or helpful.

OBJECTIVE	Y	N	COMMENTS
1. Ensure that all case report forms for each subject have been completed.			
2. Verify that all data have been keyed on-site or all forms have been submitted to the coordinating center. If they have not, discuss the timeline for accomplishing this and document in the comments.			
3. Review the status of all outstanding data edits, queries, or delinquent forms and timeline for their resolution.			
4. Verify that a signed, informed consent is on file for each study participant.			
5. Confirm that the IRB/IEC has been informed of the study closure			
6. Verify that all regulatory and other pertinent documents for the protocol (IRB approvals, consent documents, etc.) are up to date and on file.			
7. Ensure that a progress note is included in each participant's medical record indicating that study participant has ended.			
8. Verify that the investigator has plans to submit the final report to DCP, and that a deadline for completion has been identified.			
9. Ensure that the Principal Investigator understands the requirements for reporting of adverse events for subjects who have completed study.			
10. Ensure that the Principal Investigator and study coordinator have received and understand the requirements for retention of study records.			
11. Ensure that study drug has been returned to the repository.			
12. Ensure that all participant specimens have been shipped according to client specifications.			
13. Ensure that all required Drug Accountability has been reconciled and forms have been completed appropriately.			
14. Determine the disposition of participant specimens, including plans for future shipments or period of time they will be stored onsite.			

CLOSE-OUT REVIEW (continued)

Instructions: Please provide the requested information for each of the items listed below ("Y" = Yes, "N" = No). Please provide comments whenever necessary or helpful.

OBJECTIVE	Y	N	COMMENTS
15. If blinded study drug was used, confirm that the tear-off labels were not opened. For any that were opened, documentation should be obtained noting the reason for unblinding.			
16. Ensure that all unused study drug is returned to the client.			

Additional comments:

Prepared by: Date:

(Signature)