APPENDIX G. ANNUAL VISIT REPORT FORMS

DCP PROJECT
PRELIMINARY REPORT OF AUDIT FINDINGS

Name of Clinical Site:	Date(s) of Site Visit:
Principal Investigator:	Westat Team Monitor:
Document Number:	DCP Representative(s) Present:

Instructions: For the following categories, indicate the final assessment for each of the three components of the monitoring visit.

1. Assessing the IRB and Informed Consent Findings:

_____ **Acceptable:** No deficiencies identified.
Few minor deficiencies identified.
Major deficiencies identified during the site visit that were addressed and/or corrected prior to the site visit for which documentation exists and no further action is required.

_____ **Acceptable, Follow-up:** Multiple minor deficiencies identified.
Major deficiencies identified during the site visit, but not corrected and/or addressed prior to the site visit.

_____ **Unacceptable:** Multiple major deficiencies identified.
A single major flagrant deficiency found.
Excessive numbers of minor deficiencies found.

2. Assessing the Accountability of Investigational Agents and Pharmacy Operations:

_____ **Acceptable:** Compliance found for security, drug accountability record forms completed correctly, protocol and drug-specific usage and/or return of study drug in DCP repository.
Non-compliant items identified during the site visit that were addressed and/or corrected prior to the site visit for which documentation exists and no further action is required.

_____ **Acceptable, Follow-up:** Category found non-compliant during the site visit which was not corrected and/or addressed prior to the site visit.

_____ **Unacceptable:** Inability to track the disposition of NCI/DCP supplied investigational **agents**
Multiple non-compliant categories identified.

3. Review of Patient Records:

_____ **Acceptable:** No deficiencies identified
Few minor deficiencies identified.
Major deficiencies identified during the site visit that were addressed and/or corrected prior to the site visit for which documentation exists and no further action is required.

_____ **Acceptable, Follow-up:** Multiple minor deficiencies identified.
Major deficiencies identified during the site visit, but not corrected and/or addressed prior to the site visit.

_____ **Unacceptable:** Multiple major deficiencies identified.
A single major flagrant deficiency found.
Multiple minor deficiencies of a recurring nature found in a majority of the patient cases reviewed.

DCP PROJECT

CLINICAL SITE ANNUAL 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:

Document Number:

Date(s) of Visit:

Conducted by:

DCP Representative(s) Present:

Clinical Site Personnel Present at the Visit:

NAME	TITLE	PRESENT AT DEBRIEFING (Y/N)
	Principal Investigator	
	Study Coordinator	
	Pharmacist	
	Other	

Additional Comments:

II. REGULATORY REVIEW

Instructions: Please provide the requested information for each of the items listed below ("Y" = Yes, "N" = No, "N/A" = Not applicable). Please provide comments whenever necessary or helpful.

DOCUMENTS AND STORAGE	Y	N	N/A	COMMENTS
1. Copy of the protocol and all pertinent amendments on file				
2. Initial IRB/IEC approval of protocol				
3. IRB/IEC approval of most recent protocol amendments				
4. Annual IRB/IEC renewal of protocol				
5. IRB/-approved consent form and all form revisions on file				
6. Adverse Event Safety reports submitted to IRB/IEC				
7. Serious Adverse Event reports submitted to CCSA				
8. Copy of one of the following IRB/IEC compliance documents: IRB/IEC roster, DHHS #, or Assurance #				
9. Research records stored in a secure area				
10. FDA Form 1572 current				
11. Laboratory certification up-to-date				
12. Copy of normal range values for each laboratory used				
13. Investigator's Brochure(s) on file and securely stored				
14. Site Monitoring Visit log up-to-date				
15. Site Personnel Signature log up-to-date				

Additional comments:

III. RECORD REVIEW AND SUMMARY

Instructions: Write the patient identification number for each chart reviewed in column one. Record the visit week to begin review for a specific patient in the second column. Record the last visit reviewed for the specific patient in the third column. In the summary table, provide the requested information for each of the items listed ("Y" = Yes, "N" = No). Please provide comments whenever helpful or necessary.

Total # of Charts Reviewed: _____

SUBJECTS REVIEWED (ID #)	BEGAN REVIEW (AT WEEK)	TO VISIT (INCLUSIVE)

SUMMARY OF FINDINGS FOR SITE MONITORED CASES	Y	N	COMMENTS
1. 100% of informed consents appropriately obtained and documented			As of :____/____/____
2. Participant eligibility verified			
3. Source documentation adequate			
4. Adverse events (including SAEs) appropriately documented and reported			
5. Endpoints correctly reported			
6. Clinical events (i.e., change in patient status, concurrent illness) and concomitant meds recorded on CRFs			
7. Clinical and laboratory evaluations obtained as per protocol			
8. Laboratory samples correctly collected and shipped/stored/evaluated			
9. Source documents and CRFs indicate compliance with protocol treatment and blinding procedure, if applicable			
10. Protocol deviations noted and reported as needed.			

Additional comments:

IV. SITE OPERATIONS ASSESSMENT

Instructions: Please provide the requested information for each of the items listed below ("Y" = Yes, "N" = No, "N/A" = Not applicable). Please provide comments whenever necessary or helpful.

ITEMS EVALUATED	Y	N	N/A	COMMENTS
1. Adequate resources (e.g., facilities, staffing)				
2. Internal quality assurance activities				
3. Participant accrual and retention				
4. Database for study-specific procedures				

Additional comments:

V. STATUS OF PAST FINDINGS: (Have corrections been made to errors which were identified previously?)

VI. DISCUSSION OF CURRENT FINDINGS WITH STAFF: (Include problems identified, if any, and recommendations/action items for corrections.)

VII. **TRAINING CONDUCTED DURING VISIT:** (Include training performed and names of site personnel present at the time of the training.)

VIII. **DISCUSSION OF MONITORING ACTIVITIES AT PARTICIPATING SITES:** (Include problems identified, if any, and recommendations/action items for corrections.)

IX. **ADDITIONAL COMMENTS/IMPRESSIONS OF SITE PERFORMANCE:**

Prepared by: _____ Date: _____

(Signature)