Appendix G

Annual Visit Report Form

DCP PROJECT
PRELIMINARY REPORT OF MONITORING FINDINGS

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

Instructions: For the following categories, indicate the final assessment for each of the 3 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 Participant 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 participant cases reviewed.

REPORTING DEFICIENCIES

Directions: For each participant chart reviewed, record the total number of deficiencies (major or lesser) for each category. If there were no major or lesser deficiencies identified for a particular category, record a zero (0) in the appropriate cell.

Number of participant cases reviewed: _____

Comments:

DEFICIENCY CATEGORY	MAJOR	LESSER	COMMENTS
Disease Outcome			
Eligibility			
General Data Quality			
IRB			
Informed Consent			
Pharmacy			
Toxicity			
Treatment			
Total			

DCP PROJECT

CLINICAL SITE ANNUAL (INTERIM) VISIT REPORT

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:

NCI Protocol 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	
	Site Coordinator	
	Pharmacist	
	Other	

Additional Comments:

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 Number, or Assurance Number				
9. Research records stored in a secure area				
10. Form FDA 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 Signature/Delegation of Responsibilities form up to date				
16. DCP approval on file of all protocol versions				
17. Supporting documentation including Medical Licenses and CVs current				
18. Training Logs available listing Human Subject Protection Training for all staff listed on the site signature/delegation of responsibilities form				

Additional comments:

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: _____

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

SUMMARY OF FINDINGS FOR SITE MONITORED CASES	Y	N	N/A	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 (e.g., 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				
11. DCP OC-RDC data recorded accurately when compared to source documents and CRF entries				

Additional comments:

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				
5. RDC training records for all staff entering or reviewing study data in DCP OC-RDC				

Additional comments:

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

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

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

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

ADDITIONAL COMMENTS/IMPRESSIONS OF SITE PERFORMANCE:

Prepared by: Date:

(Signature)