

## Sample Monitoring Visit Report Form

### MONITORING REPORT

<b>SPONSOR:</b>	<b>PROTOCOL NO:</b>
<b>TEST MATERIAL:</b>	<b>MONITOR(S):</b>
<b>VISIT DATE(S):</b>	<b>PREVIOUS VISIT DATE(S):</b>
<b>INVESTIGATOR NAME/ADDRESS/SITE #:</b>	<b>PERSON(S) CONTACTED:</b>

#### STUDY CONDUCT AND FACILITIES

Item #	Items to be checked	Yes	No	NAP	Other*	See Comments
1.	Informed consent signed and dated prior to subjects participation; correct consent used.					
2.	Subjects meet inclusion and exclusion criteria.					
3.	Case report forms legible, accurate, and complete.					
4.	Case report forms verified against source documentation.					
5.	Study protocol is being followed. Describe protocol deviations/violations in Comments.					
6.	Adverse events documented and reporting requirements fulfilled. Describe SAEs in Comments.					
7.	Case report forms signed by investigator.					
8.	Treatment code present and not inadvertently revealed for any subject					
9.	Test article properly stored and administered.					
10.	Test article accountability maintained and found to be accurate.					
11.	Test article/case report form/other supplies adequate.					
12.	Regulatory documents reviewed by monitor.					
13.	Investigator's study file (including all regulatory documents) properly maintained and complete.					
14.	Investigator has adequate time and fulfills obligations.					
15.	Site facilities and equipment adequate.					
16.	No changes in study personnel.					
17.	Monitoring visit log signed.					
18.	Updates for IRB, laboratory certification and normal ranges obtained as necessary.					

\* Key: NAP = Not Applicable, \*= Must provide comment

All pertinent information must be provided in the **COMMENTS** section. Provide item number with each Comment.

#### SITE STATUS

Total number of patients planned for this site: \_\_\_\_\_

## Sample Monitoring Visit Report Form (continued)

Study No.: \_\_\_\_\_ Investigator: \_\_\_\_\_ Visit Date: \_\_\_\_\_

	Screened	Screen Failures	Randomized	Ongoing	Completed	Withdrawn*		
						AE	Death	Other
Since last monitoring visit								
Total since study start								

\*Comment on Any Withdrawals since Last Monitoring Visit on COMMENTS page

**CRF STATUS**

Patient Number	CRFs Reviewed This Visit	CRFs Collected This Visit*
<b>TOTAL</b>		

\*Explain in Comments any CRFs that were Reviewed but not Collected

**TEST ARTICLE ACCOUNTABILITY**

Test article: \_\_\_\_\_

Shipment Date/# Received	Expiration Date/Lot Number(s)	# Dispensed to Patient	# Remaining at Site	Date/# Returned to Sponsor	Comments
/				/	
/				/	
/				/	

**COMMENTS**

**STUDY CONDUCT AND FACILITIES:**

**CRF STATUS:**

**OTHER:**

Prepared by \_\_\_\_\_ Date \_\_\_\_\_

Reviewed by \_\_\_\_\_ Date \_\_\_\_\_