Study Site Monitor Visit Report

Investigator	Sponsor	Protocol number
Date of Visit	Site	Site Address/Phone numbers
		Telephone

Subjects Reviewed

Subject ID	Status (Ongoing/Complete, etc.)	CRF Pages reviewed	CRF Pages retrieved	Comments

Serious Adverse Events (SAEs) /Immediately Reportable Adverse Events (IRAEs)/Safety

Have SAEs/IRAEs occurred since last visit? Comments:	**Yes**	**No**	**N/A**
Have all SAEs/IRAEs follow ups been performed and information obtained?	**Yes**	**No**	**N/A**
Has new relevant information for previously reported SAEs/IRAEs been detected and communicated appropriately?	**Yes**	**No**	**N/A**
Have adverse events other than SAEs/IRAEs occurred since since previous visit?	**Yes**	**No**	**N/A**
Have these adverse events been appropriately recorded?	**Yes**	**No**	**N/A**

Protocol Compliance

Were subjects enrolled eligible for the trial?	**Yes**	**No**	**N/A**
Were protocol compliance issues/violations found?	**Yes**	**No**	**N/A**

Source Documentation Verification/CRF Review

Were CRFs and source documentation verification performed? Comments:	**Yes**	**No**	**N/A**
Were source documents complete and accurate?	**Yes**	**No**	**N/A**
Have required CRFs been completed and appropriately signed by the investigator? Comments:	**Yes**	**No**	**N/A**
Have CRFs been retrieved?	**Yes**	**No**	**N/A**

Comments:

Have data clarifications and queries been resolved? Comment:	**Yes**	**No**	**N/A**

Investigational Drug

Have storage area/conditions been inspected/reviewed?	**Yes**	**No**	**N/A**
Do supplies reconcile with records?	**Yes**	**No**	**N/A**
Have randomization envelopes or blinded labels been opened or missing?	**Yes**	**No**	**N/A**
Are supplies adequate and expiration dates acceptable?	**Yes**	**No**	**N/A**
Has the designated IP been prepared for return or destruction?	**Yes**	**No**	**N/A**

Biological Samples

Were laboratory problems noted?	**Yes**	**No**	**N/A**
Are reference ranges current?	**Yes**	**No**	**N/A**
Are certificates for labs current?	**Yes**	**No**	**N/A**
Are the inventory and shipment records current?	**Yes**	**No**	**N/A**

Regulatory Issues

Are all required documents filed in the Investigator's Files? (See completed Investigators' Site File checklist) Comments:	**Yes**	**No**	**N/A**
Is IRB opinion or approval up to date? Comments:	**Yes**	**No**	**N/A**
Have informed consents been obtained properly? Comments:	**Yes**	**No**	**N/A**

Actions to be completed prior to next monitoring visit: