



# Study Close-out Visit Report

<b>Monitor:</b>		<b>Investigator:</b>	
<b>Product Name:</b>		<b>Site Number:</b>	
<b>Protocol Number:</b>		<b>Visit Date(s):</b>	
<b>Sponsor:</b>			

Site Personnel Contacted	Title/Responsibility

Summary Report/Accomplishments	Y	N	N/A	Needed Actions/Comments
<b>Study Close-out Procedure Discussion</b>				
<b>Regulatory Documents Review</b>				
<i><b>IRB</b></i>				
-Initial approval and amendment approval present?				
-Annual reviews present?				
-All SAEs reported to the IRB?				
-Notified of Study Discontinuance?				
<i><b>Informed Consent</b></i>				
-Are all IRB-approved ICs present?				
<b>FDA form 1572 present?</b>				
<i><b>Case Report Forms</b></i>				
-Are all CRFs collected?				
-Are all queries resolved?				
<i><b>Curriculum Vitae all present?</b></i>				
-Principal Investigator?				
-Others as listed on the FDA form 1572?				
<i><b>Laboratory Certifications and Normals</b></i>				
-Are there certifications for the entire study period?				
-Did any of the Normals change?				
<b>Patient Log</b>				
<b>Monitoring Log</b>				
<b>Nature of FDA Inspection</b>				
<i><b>Retention of Records</b></i>				
-If the investigator moves, who will be a contact?				
<b>Study Supplies</b>				
Have all investigational materials been returned?				
Collect signed Investigational Material Accountability				
Have all supplies been discarded?				



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**Other Issues:**

**Action Items:**



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Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name (printed): \_\_\_\_\_

Signature of Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

Name (printed): \_\_\_\_\_