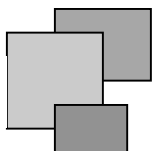


Fax or Mail this form to:



Ethical Review Committee, Inc.

14400 E. 42nd St., Suite 240

Independence, MO 64055

Phone: 816.421.0008 ♦ Fax: 816.356.2227

**SPONSOR CLOSE OUT REPORT FORM**

This form is to be completed and signed by the sponsor of the study upon sponsor decision to close the protocol. To close out a study, all subjects must have completed the entire study and all follow-up periods. If enrollment is closed, but there are still subjects participating in the study, the study cannot close out until participation is complete.

<b>ERC #:</b>	<b>Sponsor Name:</b>	<b>Protocol #:</b>
<b>Coordinator:</b>	<b>Phone:</b> (    )    -	<b>Fax:</b> (    )    -
<b>Protocol Title:</b>		

<u>If the ERC has any questions regarding the completion of this form, who should be contacted?</u>		
<b>Name:</b>	<b>Phone:</b> (    )    -	<b>E-Mail:</b>

**Section A: Reason for Study Closure** *(Please check all that apply)*

All subject intervention, follow-up, and data analyses are concluded.

Research never commenced.

Sponsor requests closure: *Please explain:*

Protocol closed due to unanticipated problems, DSMB decision, FDA action, etc.

*Please explain and attach any additional information:*

Other:

**Section B: Site Involvement**

**1** How many total sites were approved to conduct study?  
-----  
How many sites were approved by the ERC to conduct this study?

**2** How many sites were closed prior to study closure?  
How many of those sites were administratively closed by the sponsor?  
*Please identify and explain the reasoning for closing each site:*

**Section C: Subjects Consented**

Please read this section CAREFULLY and complete all questions as instructed. Failure to complete this section correctly will result in additional reporting requirements and may cause your request for closure to be delayed or even disapproved.

<b>A. How many subjects have completed the entire study (including all required study visits and any required follow-up visits)?</b>	<b>Answer to A</b>
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<b>B. How many subjects signed an Informed Consent Form and then discontinued prior to completion of the study (for any reason including withdrawals, SAE, AE, screen failure, etc.)</b>	<b>Answer to B</b>
--	--------------------

<i>Of those subjects in answer B, were any consented but discontinued before treatment and/or</i>	<input type="checkbox"/> No <input type="checkbox"/> Yes
---	--

study procedures began (i.e.: screen failures)?	
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If yes, how many?	
Of those subjects in answer B were any discontinued due to an SAE or AE?	<input type="checkbox"/> No <input type="checkbox"/> Yes
-----	
If yes, you are required to identify the subject number and provide a description of the event for each:	
Of those subjects in answer B, did any discontinue for any other reason(s) or were any lost to follow-up?	<input type="checkbox"/> No <input type="checkbox"/> Yes
-----	
If yes, you are required to identify the subject number and provide a description of the event for each:	

<b>C. How many total subjects have signed an Informed Consent Form?</b>	<b>Answer to C</b>
---	--------------------

Was informed consent obtained from all enrolled subjects prior to performing any study procedures?  No  Yes

If no, an explanation is **required**\*:

\*Note: No investigator may involve a subject without legally obtaining informed consent of the subject or the subject's legally authorized representative. If this has taken place, the site where the violation has occurred will need to complete the ERC's Violation Report form.

**THE FOLLOWING FORMULA MUST WORK-OUT OR YOUR REPORT WILL NOT BE ACCEPTED:**

Answer to A:	+	Answer to B:	=	Answer to C:
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Section D: Study Completion	
1	What is the record retention policy for this protocol? Where will the data be stored?
2	What is the sponsor plan for the collected data (i.e.: publishing, companion study, etc.)?
3	Does the sponsor feel that the study successfully accomplished the purpose it intended? <i>Explain how the study did or did not accomplish its intent:</i>
4	What is the expected date of study closure?

Name of Person Preparing This Application \_\_\_\_\_ Title \_\_\_\_\_

Signature of Person Preparing This Application \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_