

SITE INFORMATION CHANGE SUBMISSION FORM

Complete this form when submitting changes to site information for previously approved Principal Investigators. *We accept study submissions by email, fax or mail.

1.	Sponsor:	Protocol No.:
2.	Principal Investigator:	
3.	Please indicate the current status of the study at your site: (choose only one) <input type="checkbox"/> Study not initiated / no active subjects yet <input type="checkbox"/> Open to Enrollment with _____ active subjects (indicate # of active subjects) <input type="checkbox"/> Closed to Enrollment with subjects still active and/or in follow-up <input type="checkbox"/> Study related activity completed (no active subjects and enrollment closed); however site is to remain open	
4.	Please indicate the effective date of the information change(s) you are submitting: <i>*If the effective date noted above is in the <u>past</u>, please provide a rationale for the delay in reporting:</i>	
5.	Please indicate the type of information change you are submitting: (check all that apply) <input type="checkbox"/> Physical Site Address Change (please complete section 6) <input type="checkbox"/> Site Name Change (please complete section 6) <input type="checkbox"/> Phone Number(s) for Subject Use Change (please complete section 7) <input type="checkbox"/> Site Location Removal (please complete section 8) <input type="checkbox"/> Subject Compensation Change (please complete section 9)	
<p><i>Unless all study related activity is completed at your site, Alpha IRB will revise the site's informed consent form(s) (ICF) and provide new IRB approved version(s) with updated information. If additional changes to the ICF(s) are needed, please submit a tracked changes copy of your current ICF(s) in Word format for review. You can request a copy of the site's Word format ICF(s) by contacting Alpha IRB.</i></p>		
<p><i>If adding a <u>new</u> study location, please instead complete a 'Study Submission Form: Additional Study Location' For a change of Principal Investigator, please instead complete a 'Change of Principal Investigator Form'</i></p>		
6.	Previous address and/or Site name: NEW address and/or Site name: <i>*If the <u>physical site address</u> has changed, please also complete questions A through F below (you do not need to complete A through F if <u>only the site name</u> has changed).</i>	
A.	Does the site have adequate resources, including staff to conduct this study? <input type="checkbox"/> Yes <input type="checkbox"/> No - if no, explain:	
B.	What resources are available at this site to treat emergencies, if they occur? (check all that apply) <input type="checkbox"/> BLS certified personnel <input type="checkbox"/> Emergency medication <input type="checkbox"/> ACLS certified personnel <input type="checkbox"/> Crash cart <input type="checkbox"/> Emergency response team within facility <input type="checkbox"/> Access to 911 <input type="checkbox"/> Other (please describe): <input type="checkbox"/> N/A; explain:	
C.	Name of the nearest emergency facility to be used in the event of an emergency: Distance of emergency facility from this study site: _____ miles	

D.	Are there any state or local laws that you are aware of that might impact or influence the conduct of the study? <input type="checkbox"/> No <input type="checkbox"/> Yes – Please describe:																												
E.	Are there community attitudes that may adversely affect subjects in this study? <input type="checkbox"/> No <input type="checkbox"/> Yes - If yes, describe attitudes and how they may affect subjects:																												
F.	Are there any changes to privacy/confidentiality measures from what was previously reported? <input type="checkbox"/> No <input type="checkbox"/> Yes – please describe:																												
7.	Revised phone number to be added to consent form(s): Revised 24 Hour phone number to be added to consent form(s):																												
8.	Site name(s) being removed from consent form(s): Site address(es) being removed from consent form(s): Do you continue to have adequate resources, including staff, to conduct this study? <input type="checkbox"/> Yes <input type="checkbox"/> No - if no, explain:																												
9.	<p>Please outline the new compensation schedule below:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 5px;"> <thead> <tr> <th colspan="4" style="text-align: center;">Subjects will be compensated as indicated below:</th> </tr> <tr> <th style="width: 30%;">Visit Number / Type (e.g. Screening, Visit 4, Visits 1-3,etc.)</th> <th style="width: 20%;">Amount</th> <th style="width: 30%;">Visit Number / Type (continued)</th> <th style="width: 20%;">Amount (continued)</th> </tr> </thead> <tbody> <tr> <td></td> <td style="text-align: center;">\$</td> <td></td> <td style="text-align: center;">\$</td> </tr> <tr> <td></td> <td style="text-align: center;">\$</td> <td></td> <td style="text-align: center;">\$</td> </tr> <tr> <td></td> <td style="text-align: center;">\$</td> <td></td> <td style="text-align: center;">\$</td> </tr> <tr> <td></td> <td style="text-align: center;">\$</td> <td></td> <td style="text-align: center;">\$</td> </tr> <tr> <td colspan="4">Total potential compensation for study visits: \$</td> </tr> </tbody> </table> <p><i>*You may list more than one visit number per line. Attach additional pages if needed.</i></p>	Subjects will be compensated as indicated below:				Visit Number / Type (e.g. Screening, Visit 4, Visits 1-3,etc.)	Amount	Visit Number / Type (continued)	Amount (continued)		\$		\$		\$		\$		\$		\$		\$		\$	Total potential compensation for study visits: \$			
Subjects will be compensated as indicated below:																													
Visit Number / Type (e.g. Screening, Visit 4, Visits 1-3,etc.)	Amount	Visit Number / Type (continued)	Amount (continued)																										
	\$		\$																										
	\$		\$																										
	\$		\$																										
	\$		\$																										
Total potential compensation for study visits: \$																													
A.	Form of Payment: <input type="checkbox"/> Check <input type="checkbox"/> Cash <input type="checkbox"/> Gift Certificate/Card – list type (e.g. Visa): <input type="checkbox"/> Other:																												
B.	When will subject receive his/her compensation? (choose only one) <input type="checkbox"/> At each completed study visit <input type="checkbox"/> At the subjects final study visit <input type="checkbox"/> Within <indicate #> weeks of subjects final study visit <input type="checkbox"/> Other – please describe:																												
C.	This compensation change will affect: (choose only one) <input type="checkbox"/> New enrollees only <input type="checkbox"/> Current and new enrollees <input type="checkbox"/> Other - Please explain:																												
D.	Please provide a brief, but detailed rationale/reason for the compensation change:																												

By signing this form, I am confirming that I am the Principal Investigator (PI) or the PI's designee authorized to submit on behalf of the PI and that the PI is aware of the information contained in this submission. I certify that the information provided in the application is true and correct.

**Principal Investigator (or Designee)
Printed Name**

Title (for Designee):

**Principal Investigator (or Designee)
Signature**

Date: _____