

CONTINUING REVIEW FORM

1.	Liberty IRB Tracking Number:
2.	Name of Study:
3.	IDE or IND # <input type="checkbox"/> N/A
4.	Name of Principal Investigator:
5.	Original IRB Approval Date:
6.	<p>Action Requested:</p> <p><input type="checkbox"/> Renew for continuing enrollment</p> <p><input type="checkbox"/> Enrollment closed; however (<i>please select one</i>),</p> <p style="margin-left: 20px;"><input type="checkbox"/> Subjects still receiving treatments</p> <p style="margin-left: 20px;"><input type="checkbox"/> Subjects have completed study treatments but continue in follow up</p> <p style="margin-left: 20px;"><input type="checkbox"/> Subject involvement completed but renewal is requested for data analysis</p> <p><input type="checkbox"/> Terminate because:</p> <p style="margin-left: 20px;"><input type="checkbox"/> Study completed and the investigator affirms that:</p> <p style="margin-left: 40px;">➤ The research is permanently closed to enrollment.</p> <p style="margin-left: 40px;">➤ All participants have completed all research-related interventions.</p> <p style="margin-left: 40px;">➤ Collection of private identifiable information is completed.</p> <p style="margin-left: 40px;">➤ Analysis of private identifiable information is completed.</p> <p style="margin-left: 20px;"><input type="checkbox"/> Lack of funding</p> <p style="margin-left: 20px;"><input type="checkbox"/> Safety concerns (<i>include letter of explanation</i>)</p> <p style="margin-left: 20px;"><input type="checkbox"/> Other (<i>please specify</i>)</p> <p style="margin-top: 20px;"><i>Note: If study was canceled or terminated and subjects were enrolled, a detailed explanation of how subjects were followed through to completion must be provided.</i></p>
7.	Indicate number of subjects who have successfully completed the study at your site.

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8.	Have any subjects withdrawn from the study either voluntarily or otherwise? If yes, please complete 8a.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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8a.	For all subjects withdrawn, indicate: <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Subject ID</th> <th style="width: 70%;">Reason for Withdrawal</th> </tr> </thead> <tbody> <tr> <td style="color: blue;">ABC/001</td> <td style="color: blue;">Withdrew consent</td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> </tbody> </table>	Subject ID	Reason for Withdrawal	ABC/001	Withdrew consent									<input type="checkbox"/> N/A
Subject ID	Reason for Withdrawal													
ABC/001	Withdrew consent													

9.	Have there been unanticipated problems or serious adverse events at this site involving risk to subjects? (If you report SAE's in #17 & #18, you should mark yes and include details in 9a.)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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9a.	If question 9 is answered yes, provide the following: <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">Date</th> <th style="width: 20%;">Subject ID</th> <th style="width: 30%;">Description (SAE, etc.)</th> <th style="width: 40%;">Relationship to drug/device</th> </tr> </thead> <tbody> <tr> <td> </td> <td style="color: blue;">ABC/001</td> <td style="color: blue;">Pneumonia</td> <td style="color: blue;">Unrelated</td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Date	Subject ID	Description (SAE, etc.)	Relationship to drug/device		ABC/001	Pneumonia	Unrelated													<input type="checkbox"/> N/A
Date	Subject ID	Description (SAE, etc.)	Relationship to drug/device																			
	ABC/001	Pneumonia	Unrelated																			

10.	Indicate approval date of ICF currently in use: <i>Submit a copy of the ICF currently in use with this form.</i>	
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11.	Is Investigator requesting changes to subject population? <i>If yes, attach explanation.</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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12.	Is Investigator requesting changes in recruitment activities? <i>If yes, attach explanation.</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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13.	Is Investigator requesting changes in consent procedures? <i>If yes, attach explanation.</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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14.	Have there been any significant protocol deviations, which in the opinion of the sponsor or Investigator have increased the risks to the subjects?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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14a.	<p>If question 14 is answered yes, provide the following:</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">Subject ID</th> <th style="width: 45%;">Description of Deviation</th> <th style="width: 30%;">Effect on Subject</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"><i>ABC/001</i></td> <td style="text-align: center;"><i>Improper medication administered</i></td> <td style="text-align: center;"><i>No adverse effect</i></td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Subject ID	Description of Deviation	Effect on Subject	<i>ABC/001</i>	<i>Improper medication administered</i>	<i>No adverse effect</i>										
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15.	Indicate total projected enrollment at your site.																
16.	Indicate number of subjects enrolled to date.																
17.	Indicate total number of SAEs resulting in death.																
18.	Indicate total number of all SAEs reported at this site. (Please list details of SAE's in #9 and 9a.)																

Name of Person Completing Form (contact person for questions):	
Name:	
Title:	
Phone Number:	
Fax Number:	
Email Address:	
Principal Investigator Signature	
Date:	Signature: