



LIBERTY IRB

An Independent Central IRB



Continuing Review/Closure 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.	Name of Sub-investigators:																																				
6.	Name and contact information for coordinator:																																				
7.	<p>Liberty IRB requires all investigators and their research staff to be qualified by training and experience to conduct research. Clinical research training should include training in Code of Federal Regulations (CFR)/Human Research Subject Protection (HRSP) <u>and</u> training in Good Clinical Practice (GCPs). Indicate whether or not research training was completed by each of the following:</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Type of Training</th> <th style="text-align: center;">CFR/HRSP</th> <th style="text-align: center;">GCP</th> <th style="text-align: center;">CCRC/CPI*</th> </tr> </thead> <tbody> <tr> <td>Principal Investigator</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Primary Study Coordinator</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Secondary Study Coordinator</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Sub-Investigator _____</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Sub-Investigator _____</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Sub-Investigator _____</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Other: _____</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Other: _____</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table> <p>Note: Liberty IRB is a participating organization in the Collaborative Institutional Training Initiative (CITI). Investigators using Liberty as their central IRB can meet the training requirement through CITI. Please email or call for information on how to access the CITI training if you are interested.</p> <p>* Satisfies training requirements</p>	Type of Training	CFR/HRSP	GCP	CCRC/CPI*	Principal Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Primary Study Coordinator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Secondary Study Coordinator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sub-Investigator _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sub-Investigator _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sub-Investigator _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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ACTION REQUESTED	
8.	<input type="checkbox"/> Renew for continuing enrollment <input type="checkbox"/> Enrollment closed; however (<i>please select one</i>), <ul style="list-style-type: none"> <input type="checkbox"/> Subjects still receiving treatments <input type="checkbox"/> Subjects have completed study treatments but continue in follow up <input type="checkbox"/> Subject involvement completed but renewal is requested for data analysis <input type="checkbox"/> Terminate because: <ul style="list-style-type: none"> <input type="checkbox"/> Study completed and the investigator affirms that: <ul style="list-style-type: none"> ➤ The research is permanently closed to enrollment. ➤ All participants have completed all research-related interventions. ➤ Collection of private identifiable information is completed. ➤ Analysis of private identifiable information is completed. <input type="checkbox"/> No subjects have been enrolled <input type="checkbox"/> Lack of funding <input type="checkbox"/> Safety concerns (<i>include letter of explanation</i>) <input type="checkbox"/> Other (<i>please specify</i>) <p>Note: <i>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>
9.	Indicate approval date of ICF currently in use: <p><i>Submit a copy of the <u>first page</u> of all ICF(s) currently in use with this form (including translations).</i></p>
CHANGES IN RESEARCH	
10.	Is Investigator requesting changes to subject population (i.e. increase in numbers)? <div style="text-align: right;">Yes No</div> <div style="text-align: right;"><input type="checkbox"/> <input type="checkbox"/></div> <p><i>If yes, attach explanation.</i></p>
11.	Is Investigator requesting changes in recruitment activities? <div style="text-align: right;">Yes No</div> <div style="text-align: right;"><input type="checkbox"/> <input type="checkbox"/></div> <p><i>If yes, attach explanation.</i></p>
12.	Is Investigator requesting changes in consent procedures? <div style="text-align: right;">Yes No</div> <div style="text-align: right;"><input type="checkbox"/> <input type="checkbox"/></div> <p><i>If yes, attach explanation.</i></p>



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ENROLLMENT HISTORY					
13.	Description		Number of Subjects	<input type="checkbox"/> N/A	
	A. Indicate projected enrollment (per sponsor)				
	B. Indicate number of subjects who were screen fails (i.e., those who signed consent forms)				
	C. Indicate subjects withdrawn (either voluntarily or otherwise). Does not include screen fails. (Provide details in #14.)				
	D. Indicate number of subjects currently active in study.				
	E. Indicate number of subjects who have successfully completed study at your site.				
	F. Indicate number of subjects enrolled since beginning of study (Sum of B through E).				
14.	For all subjects withdrawn, indicate:			<input type="checkbox"/> N/A	
	Subject ID		Reason for Withdrawal		
	<i>(Sample)ABC/001</i>	<i>Withdrew consent</i>			
		<i>You may attach a separate sheet of paper.</i>			
UNANTICIPATED PROBLEMS or SERIOUS ADVERSE EVENTS (SAE's)					
15.	Have there been unanticipated problems or serious adverse events (including deaths) at this site involving risk to subjects (since the last continuing review)?		Yes <input type="checkbox"/>	No <input type="checkbox"/>	
15a.	If question 15 is answered yes, provide the following:			<input type="checkbox"/> N/A	
	Date	Subject ID	Description (SAE, etc.)		Relationship to drug/device
	<i>Sample</i>	<i>ABC/001</i>	<i>Pneumonia</i>		<i>Unrelated</i>
15b.	Indicate total number of all SAEs reported at this site (since beginning of study).				



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SIGNIFICANT PROTOCOL DEVIATIONS																	
16.	Have there been any significant protocol deviations (since the last continuing review), which in the opinion of the sponsor or Investigator have increased the risks to the subjects?	Yes <input type="checkbox"/> No <input type="checkbox"/>															
16a.	If question 16 is answered yes, provide the following:																
	<table border="1"> <thead> <tr> <th>Subject ID</th> <th>Description of Deviation</th> <th>Effect on Subject</th> </tr> </thead> <tbody> <tr> <td><i>(Sample)ABC/001</i></td> <td><i>Improper medication administered</i></td> <td><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>(Sample)ABC/001</i>	<i>Improper medication administered</i>	<i>No adverse effect</i>										
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Name of Person Completing Form (contact person for questions):	
Name:	
Title:	
Phone Number:	
Fax Number:	
Email Address:	
	Principal Investigator Signature
Date:	Signature: