LIBERTY IRB, Inc.
A Central Institutional Review Board

Closure Form

	Closure	
1.	Liberty IRB Tracking Number:	
2.	Name of Study:	
4.	Name of Principal Investigator:	
5.	Name and contact information for coordinator:	
6.	Has either the Principal Investigator's or Sub-Investigator's conflict of interest changed since the study was approved or since the last continuing review date (whichever is later). Refer to Principal Investigator Information Sheet for guidance. (Please describe any changes on separate sheet of paper.)	Yes ☐ No ☐
	ACTION REQUESTED	
7.	_____Terminate because: _____Study completed and the investigator affirms that: • 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. _____No subjects have been enrolled _____Lack of funding _____Safety concerns *(include letter of explanation)* _____Other *(please specify)* **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.***	

LIBERTY IRB, Inc.
A Central Institutional Review Board

CLOSURE FORM

8.	Has there been any new and relevant information, published or unpublished, since the last IRB review, especially information about risks associated with the research? (If so, please describe on a separate sheet of paper.)	Yes ☐	No ☐
9.	Have there been any complaints about the research from subjects enrolled at the local site since the last IRB review? (If so, please provide information on separate sheet of paper.)	Yes ☐	No ☐
10.	For multi-site **drug studies**, have all Data Safety Monitoring Reports or Steering Committee Reports been submitted to Liberty for review (as applicable)? If an annual (or quarterly) report is available, please ensure it has been submitted for review.	Yes ☐	No ☐
11.	For device studies, have annual reports been submitted to Liberty for review (as applicable)?	Yes ☐	No ☐
12.	Have there been any relevant regulatory actions occurring since the last review that could affect safety and risk assessments (i.e., withdrawal or suspension from marketing in any country on the basis of safety, reports of recalls and device disposition, etc.)	Yes ☐	No ☐

LIBERTY IRB, Inc.
A Central Institutional Review Board

Closure Form

	ENROLLMENT HISTORY POPULATION (at your site)	
13.	Description / Number of Subjects	

Description	Number of Subjects
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:

Subject ID	Reason for Withdrawal
(Sample)ABC/001	*Withdrew consent*
	You may attach a separate sheet of paper.

	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)**? **If YES, List Below:**	Yes ☐ No ☐
15a.	If question 15 is answered yes, provide the following:	

Date	Subject ID	Description (*SAE, etc.*)	Relationship to drug/device
Sample	*ABC/001*	*Pneumonia*	*Unrelated*

LIBERTY IRB, Inc.
A Central Institutional Review Board

Closure Form

	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? **If YES, List Below:**	Yes ☐ No ☐
16a.	If question 16 is answered **yes**, provide the following: Subject ID Description of Deviation Effect on Subject	

(Sample)ABC/001	*Improper medication administered*	*No adverse effect*

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