LIBERTY IRB, Inc.
A Central Independent Review Board

Continuing Review Form

	Continuing Review	
1.	Liberty IRB Tracking Number:	
2.	Name of Study:	
3.	Provide IDE, 510K #, IND #, etc.	☐ N/A
4.	Name of Principal Investigator:	
5.	Name of Sub-investigators: **(Provide list on separate sheet of paper of any changes [additions or deletions] to sub-investigators since study initiation or last continuing review [whichever is latest)]. In addition, submit current CV [signed and dated within 2 years] and current Medical License for any additions if IRB not previously notified.)**	
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.	Yes ☐ No ☐
7.	Name and contact information for coordinator (s): Primary: Secondary:	

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8. 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 on Code of Federal Regulations (CFR), training in Human Research Subject Protection (HRSP), and training on Good Clinical Practice (GCPs).

CCRC/ CPI Stands for Certified Clinical Research Coordinator/ Certified Principal Investigator.

Indicate whether or not research training was completed by each of the following (indicate names of coordinators and sub-investigators):

TYPE OF TRAINING	CFR/ HSRP	GCP	CCRC/CPI* SEE ABOVE	COMPLETED IN THE LAST 5 YEARS?	
Principal Investigator	☐	☐	☐	Yes ☐	No ☐
Primary Study Coordinator	☐	☐	☐	Yes ☐	No ☐
Secondary Study Coordinator	☐	☐	☐	Yes ☐	No ☐
TYPE OF TRAINING	**CFR/ HSRP**	**GCP**	**CCRC/CPI*SEE ABOVE**	**COMPLETED IN THE LAST 5 YEARS?**	
Sub-Investigator:	☐	☐	☐	Yes ☐	No ☐
Sub-Investigator:	☐	☐	☐	Yes ☐	No ☐
Sub-Investigator:	☐	☐	☐	Yes ☐	No ☐
Sub-Investigator:	☐	☐	☐	Yes ☐	No ☐

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Type of Training	CFR/ HSRP	GCP	CCRC/CPI*see above	Completed in the Last 5 Years?	
Sub-Investigator:	☐	☐	☐	Yes ☐	No ☐
Sub-Investigator:	☐	☐	☐	Yes ☐	No ☐
Other:	☐	☐	☐	Yes ☐	No ☐
Other:	☐	☐	☐	Yes ☐	No ☐

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.

*Satisfies training requirements

**** If all training has not been completed within the last 5 years the PI, Sub-I or staff member may still participate in this research as long as training has been completed previously; however, a refresher training course must be completed within 6 months.**

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	ACTION REQUESTED	
9.	☐ Renew for continuing enrollment ☐ Enrollment closed; however ***(please select one),*** ○ Subjects still receiving treatments ○ Subjects have completed study treatments but continue in follow up ○ Subject involvement completed but renewal is requested for data analysis 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.*	
10.	Indicate approval date of Informed Consent Form (ICF) currently in use: ***Submit a copy of the <u>first page</u> of all ICF(s) currently in use with this form (including translations).***	
11.	Indicate version date of the most current PROTOCOL:	
12.	Indicate version date of the most current Investigator's Brochure (if applicable):	
13.	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 ☐
14.	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 ☐

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15.	For <u>multi-site</u> **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 ☐
16.	For **device studies**, have annual reports been submitted to Liberty for review (as applicable)? If not, please provide during continuing review.	Yes ☐ No ☐
17.	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 ☐
	CHANGES IN RESEARCH	
18.	Is Investigator requesting changes to subject population (i.e. increase in numbers)? *If yes, attach explanation.*	Yes ☐ No ☐
19.	Is Investigator requesting changes in recruitment activities? *If yes, attach explanation.*	Yes ☐ No ☐
20.	Is Investigator requesting changes in consent procedures? *If yes, attach explanation.*	Yes ☐ No ☐

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	ENROLLMENT HISTORY POPULATION (at your site)	
21.	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 #22.)	
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**).	

22. 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)	
23.	Have there been unanticipated problems or serious adverse events (including deaths) at this site involving risk to subjects **(since the last continuing review)**?	Yes ☐ No ☐
23a.	If question 23 is answered yes, provide the following:	

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

23b.	Indicate total number of **all** SAEs reported at this site **(since beginning of study)**.	

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	SIGNIFICANT PROTOCOL DEVIATIONS	
24.	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 ☐ No ☐
24a.	If question 24 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: