LIBERTY IRB, Inc.
A CENTRAL INDEPENDENT REVIEW BOARD

Full Accreditation

MODIFICATIONS TO RESEARCH FORM
(TO BE USED FOR CHANGE OF PRINCIPAL INVESTIGATOR, SUB-INVESTIGATORS, AND/OR COORDINATOR)

	MODIFICATIONS TO RESEARCH FORM
1.	Liberty IRB Tracking Number:
2.	Name of Study:
3.	Name of Principal Investigator: *NOTE: If you are submitting on behalf of multiple investigators, please provide a complete listing of all investigators.*
4.	Is there a change of Principal Investigator? _____Yes _____No If yes, the following documents will need to be submitted to Liberty IRB for review: • Letter from current PI relinquishing responsibility for the study (if feasible – if not explain why signature cannot be obtained) • Letter from new PI accepting responsibility for the study • Letter from sponsor allowing the change • Investigator Declaration – Signed by new PI • Copy of current CV (signed and dated), M/L (if applicable), and copy of Board Certification (if applicable) for new PI • PI Information Sheet – completed for new PI • Indicate training in #7 below • Form 1572 (if applicable) • Contact Liberty for a version of the consent that you can make tracked changes to.
5.	Is there a change of Sub-Investigator(s)? _____Yes _____No If yes, the following will need to be submitted to Liberty IRB for review: • Indicate additions and deletions (can use separate sheet) _____ _____ _____

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<table>
<tr><td></td><td>

- Copy of current CV (signed and dated), M/L (if applicable), and copy of Board Certification (if applicable) for new sub-investigator(s)
- Indicate training in #7 below

</td></tr>
<tr><td>6.</td><td>

Change of coordinator:

- Indicate contact information (name, email and phone)

_____

_____

- Indicate training in #7 below

</td></tr>
<tr><td>7.</td><td>

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:

<table>
<tr><th>TYPE OF TRAINING</th><th>CFR/ HSRP</th><th>GCP</th><th>CCRC/CPI *SEE ABOVE</th><th>COMPLETED IN THE LAST 5 YEARS?</th><th></th></tr>
<tr><td>Principal Investigator</td><td></td><td></td><td></td><td>Yes ◯</td><td>No ◯</td></tr>
<tr><td>Primary Study Coordinator</td><td></td><td></td><td></td><td>Yes ◯</td><td>No ◯</td></tr>
<tr><td>Secondary Study Coordinator</td><td></td><td></td><td></td><td>Yes ◯</td><td>No ◯</td></tr>
<tr><th>TYPE OF TRAINING</th><th>CFR/ HSRP</th><th>GCP</th><th>CCRC/CPI *SEE ABOVE</th><th>COMPLETED IN THE LAST 5 YEARS?</th><th></th></tr>
<tr><td>Sub-Investigator:</td><td></td><td></td><td></td><td>Yes ◯</td><td>No ◯</td></tr>
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Sub-Investigator:				Yes	No
Sub-Investigator:				Yes	No
Sub-Investigator:				Yes	No
Sub-Investigator:				Yes	No
Sub-Investigator:				Yes	No

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; however, a refresher training course must be completed within 6 months..**

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8.	Has the new Principal Investigator or any of the added sub-investigators or study staff ever been convicted of a crime, disciplined by a public or private medical organization, a licensing authority, or are any currently the subject of an investigator? If yes, has the conviction and/or discipline been reported to Liberty IRB previously? **If no, please attach information about the incident and its outcome.**	Yes ☐ No ☐
9.	**Due to the Public Health Service rule on individual financial conflict of interest changing to the DHHS rule on August 24, 2012 the disclosure thresholds have been changed** Is there a financial conflict of interest for the new PI, sub-investigator(s) or study staff? If so, please detail below. With the following definitions in mind: ***Immediate Family*** – means spouse and dependent children ***Financial Interest Related to Research*** – means financial interest in the sponsor, product or service being tested, or competitor of the sponsor or product or service being tested. Does the PI, PI's immediate family, sub-investigator(s), study staff or study staff's family have any of the following? ***Check all that apply*** _____Ownership interest, stock option or other financial interest related to the research unless it meets one of the following: • Does not exceed $5,000 when aggregated for the immediate family • Publicly traded on a stock exchange • No arrangements have been entered into where value of the ownership interests will be affected by the outcome the research • Does not exceed 5%interest in any one single entity when aggregated for the immediate family. _____Compensation related to the research unless it meets one of the following: • Does not exceed $5,000 in the past year when aggregated for the immediate family	Yes ☐ No ☐

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	• Does not exceed 5% interest in any one single entity when aggregated for the immediate family. • No arrangement has been entered into where the amount of compensation will be affected by the outcomes of the research _____Proprietary interest related to the research including but not limited to, a patent, trademark, copyright or licensing agreement _____Board or executive relationship related to the research regardless of compensation ***Note: If any of the above is checked, describe on a separate sheet of paper the financial interest and any steps planned to prevent the financial interest from interfering with the design, conduct, or reporting of the research, including interfering with the protection of participants.*** ***In addition to initial disclosure, the Investigator must notify Liberty IRB whenever his/her financial interests in the study change. Financial conflict of interest should be disclosed to the IRB in writing via a letter from the Investigator to the IRB Chairman.** *If yes, attach explanation.*	

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