



**MODIFICATIONS TO RESEARCH FORM
(TO BE USED FOR MODIFICATIONS TO PROTOCOL, CONSENT, AND/OR INVESTIGATOR
BROCHURE)**

MODIFICATIONS TO RESEARCH	
1.	Liberty IRB Tracking Number:
2.	Name of Study:
3.	Name of Principal Investigator: <i>NOTE: If you are submitting on behalf of multiple investigators, please provide a complete listing of all investigators.</i>
MODIFICATIONS TO PROTOCOL	
4.	Does this change include a protocol change (i.e., amendment, revised protocol, administrative change, etc.)? <ul style="list-style-type: none"> • Indicate Version # and Date – • Provide rationale for change if not already included in summary of changes. <i>(Use separate sheet.)</i> <p><i>Submit a copy of a tracked version of the revised protocol or a detailed summary of changes.</i></p>
	Yes No
MODIFICATIONS TO CONSENT	
5.	Does this change include a revision to the consent? <i>Contact Liberty for a version of the consent that you can make tracked changes to.</i>
	Yes No
MODIFICATIONS TO INVESTIGATOR BROCHURE	
6.	Does this change include a revision to the Investigator Brochure? <ul style="list-style-type: none"> • Indicate Version # and Date – <p><i>Submit a copy of a tracked version of the revised brochure or a detailed summary of changes.</i></p>
	Yes No



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FINANCIAL CONFLICT OF INTEREST		
6.	<p>Have there been any changes to the financial conflict of interest for the PI, sub-I(s), or study staff? If so, please detail below.</p> <p>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. 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.</p> <p>Does the PI, PI’s immediate family have any of the following? Check all that apply</p> <p><input type="checkbox"/> Ownership interest, stock option or other financial interest related to the research unless it meets one of the following:</p> <ul style="list-style-type: none"> • 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. <p><input type="checkbox"/> Compensation related to the research unless it meets one of the following:</p> <ul style="list-style-type: none"> • Does not exceed \$5,000 in the past year when aggregated for the immediate family • 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 <p><input type="checkbox"/> Proprietary interest related to the research including but not limited to, a patent, trademark, copyright or licensing agreement</p> <p><input type="checkbox"/> Board or executive relationship related to the research regardless of compensation</p> <p>Note: If any of the above is checked, describe on a separate</p>	Yes No



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<p><i>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.</i></p> <p>*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.</p>	
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Name of Person Completing Form (contact person for questions):	
Name:	
Title:	
Phone Number:	
Fax Number:	
Email Address:	
Date:	Signature: