

### Amendment Approval Request Form

Total IRB requires that amendments to the protocol be submitted with a tracked changes or redlined version clearly showing ALL changes to the protocol from the previous version approved by Total IRB.

<b>I. STUDY INFORMATION</b>	
Protocol Number:	
Protocol Title:	
Sponsor name and/or Funding Agency:	

<b>II. AMENDMENT INFORMATION</b>	
1. Version date of Protocol Amendment:	
2. Protocol Amendment is: <input type="checkbox"/> Attached; tracked changes are within main document. <input type="checkbox"/> Attached; tracked changes are attached in separate document.	
3. Do amendment changes affect the protocol title, number or sponsor name? <div style="text-align: center;"> <input type="checkbox"/> Yes                      <input type="checkbox"/> No           </div>	
4. Do amendment changes affect the existing compensation schedule for subjects? <div style="text-align: center;"> <input type="checkbox"/> Yes                      <input type="checkbox"/> No           </div>	
5. Is amendment due to updated safety information? <div style="text-align: center;"> <input type="checkbox"/> Yes*                      <input type="checkbox"/> No           </div> <p style="margin-left: 20px;"><i>* If yes, attach updated Investigator Brochure, DSMB report, or other related documentation.</i></p>	
6. Summary of Changes*: <p style="margin-left: 20px;"><i>* Attaching separate document to summarize changes is acceptable.</i></p>	

### III. INFORMED CONSENT FORM

1. Do changes to the protocol amendment require changes to informed consent form?

Yes\*                       No

*\* **Attach revised consent form.** All changes must be made from current Total IRB approved consent form using a MS Word tracked changes version for review.*

2. Have any other study documents that require IRB approval been revised?

Yes\*                       No

\* If yes, indicate documents revised and attach:

### IV. PERSON COMPLETING FORM

I certify that the information contained in this form is complete and accurate and that no facts have been suppressed or misstated. I am requesting for Total IRB to review the information submitted and provide approval or disapproval information. I understand that Total IRB has the authority to oversee this study and suspend the research study if necessary to protect the rights and welfare of the study subjects. I agree to provide all information requested to conduct of this study on time. I understand that if information is not provided, Total IRB may suspend the study. I agree to conduct the study in accordance with the conditions above.

\_\_\_\_\_

**Form Completed By**

\_\_\_\_\_

**Date**

\_\_\_\_\_

**Title, Company**

**Phone:**

**Email:**