INSTITUTIONAL REVIEW BOARD
University of South Alabama

Addendum / Amendment / Revision REPORT FORM

Protocol IRB# _____ Principal Investigator: _____
Date Submitted:_____
Project Title: _____

Addendum number/date: _____
(if applicable)

Please attach the required copies for each submission:

' If ***no*** subjects are enrolled since the last IRB renewal:
Submit **two** copies of the following: this form, the addendum, current protocol and investigator brochure (if applicable), the most recent version of the stamped approved consent and the revised consent.

' If subjects ***are*** enrolled since the last IRB renewal:
Submit **thirty** copies of the following: this form, the addendum, the most recent version of the approved IRB stamped consent, the revised consent and **three** copies of the most current protocol and investigator's brochure (if applicable)

NOTE: ***CHANGES SHOULD BE HIGHLIGHTED OR OTHERWISE NOTED ON THE CONSENT FORM AND WITHIN THE PROTOCOL.***

1) List requested changes to the protocol and/or consent form being requested at this time. Please explain; attach additional pages if necessary.

2) Have there been any serious adverse event (on-site) reports since the last IRB approval? ☐ NO ☐ YES
If yes, briefly explain.