

November 8, 2012

Dear Sponsor:

Pennington Biomedical Research Center Institutional Review Board has instituted the following policy:

After reviewing the January 2007 OHRP and January 2009 FDA guidance regarding adverse event reporting to Institutional Review Board's, the Pennington Biomedical Research Center Institutional Review Board, effective immediately, will accept only external adverse events that meet the following criteria.

Only those adverse event reports that are:

1. Unexpected, and
2. Serious, and
3. Related to the research study, and
4. Would have implications for the conduct of the study, e.g., requiring a significant and usually safety-related, change in the
 - a. Protocol, or
 - b. Informed consent, or
 - c. Investigator brochure, or
 - d. Device labeling

Thank you for your cooperation with this policy.

Sincerely,



Paula Geiselman, Ph.D.
Institutional Review Board Chair
Pennington Biomedical Research Center