



James Ramsey, Ph.D.
President
University of Louisville IRB
500 S. Preston Street, Room 230
Louisville, KY 40202

Dear Dr. Ramsey:

Between September 9, 2009 and September 11, 2009, Ms. Cassandra Winters, representing the Food and Drug Administration (FDA), inspected the Institutional Review Board (IRB) at University of Louisville. The purpose of this inspection was to determine whether the IRB procedures for the protection of human subjects complied with Title 21 of the Code of Federal Regulations (CFR), parts 50 and 56. These regulations apply to clinical investigations of products regulated by FDA.

From our review of the establishment inspection report and the documents submitted with that report, we conclude that the IRB adhered to the applicable statutory requirements and FDA regulations governing the protection of human subjects.

For helpful information on human subject protections, please visit the following FDA web page:

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm>

We appreciate the cooperation shown to FDA Investigator Winters during the inspection. Should you have any questions or concerns regarding this letter or the inspection, please contact me by letter at the address given below.

Sincerely,

{See appended electronic signature page}

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cc: William M. Pierce, Ph.D.
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Laura Clark, M.D.
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/s/

KEVIN A PROHASKA
05/27/2010