



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

**RECEIVED**Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

OCT 21 2010

August 27, 2010

INDEPENDENT  
REVIEW CONSULTINGErica J. Heath, President  
Independent Review Consulting, Inc., IRB  
100 Tamal Plaza, Suite 158  
Corte Madera, CA 94925-1168

Dear Ms. Heath:

The purpose of this letter is to acknowledge your letter of April 6, 2010, which was in response to the Warning Letter issued July 29, 2010. Your response included the additional actions you have taken to prevent recurrence of similar conditions in the future. Your corrective actions may be verified during a future inspection.

*19 EH*  
*August 6, 2010 EH*

The Division of Bioresearch Monitoring has developed introductory training modules in FDA regulated device clinical research practices, which are available on the FDA website. The modules are for persons involved in FDA regulated device clinical research activities. These modules are located at the following website address:  
<http://www.fda.gov/Training/CDRHLearn/ucm162015.htm>

Sincerely yours,

Anne T. Hawthorn, J.D.  
Chief  
Special Investigations Branch  
Division of Bioresearch Monitoring  
Office of Compliance  
Center for Devices and  
Radiological Health