To:                John Baumann
                  RESEARCH ADMINISTRATION

From:                                          
                  Chair - IRB-04
                  Human Subjects Office
                  Office of Research Compliance – Indiana University

Date:  July 15, 2014

RE:                NOTICE OF APPROVAL - AMENDMENT

Protocol Title:   Sample FDA/VA Protocol
Study #:          1407313285A001 | Y
Funding Agency/Sponsor:    NATIONAL INSTITUTES OF HEALTH
Review Level:     Full
Status:           Approved | Submitted to IRB

Study Approval Date: July 15, 2014
Study Expiration Date: August 18, 2015

The Indiana University Institutional Review Board (IRB) IRB00000219 | IRB-04 recently reviewed the above-referenced protocol. In compliance with (as applicable) 21 C.F.R. § 56.109 (e) and 46 C.F.R. § 46.109 (d), this letter serves as written notification of the IRB’s determination.

The amendment was approved.

Approval of this amendment is based on your agreement to abide by the policies and procedures of the Indiana University Human Research Protection Program and does not replace any other approvals that may be required. Relevant policies and procedures governing Human Subject Research can be found at: http://researchadmin.iu.edu/HumanSubjects/hs_guidance.html.

As a reminder, IRB approval is required prior to implementing any changes or amendments in the protocol, regardless of how minor, except to eliminate immediate hazards to subjects. No changes to the informed consent document may be made without prior IRB approval.

If you submitted and/or are required to provide participants with an informed consent document, please ensure you are using the most recent version of the document to consent subjects.

The study expiration date is noted above. Failure to receive notification from the Human Subjects Office will not relieve you of your responsibility to ensure compliance with Federal Regulations regarding annual review [as applicable, 21 C.F.R. § 56.109(f) and 45 C.F.R. § 46.109(e)].

You should retain a copy of this letter and all associated approved study documents for your records. Please refer to the assigned study number and exact study title in future correspondence with our office. Additional information is available on our website at http://researchadmin.iu.edu/HumanSubjects/.

If your source of funding changes, you must submit an amendment to update your study documents immediately.

If you have any questions or require further information, please contact the Human Subjects Office via email at irb@iu.edu or via phone at (317)274-8289 (Indianapolis) or (812) 856-4242 (Bloomington).
You are invited, as part of ORA’s ongoing program of quality improvement, to participate in a short survey to assess your experience and satisfaction with the IRB related to this approval. We estimate it will take you approximately 5 minutes to complete the survey. The survey is housed on a Microsoft SharePoint secure site which requires CAS authentication. This survey is being administered by REEP; please contact us at reep@iu.edu if you have any questions or require additional information. Simply click on the link below, or cut and paste the entire URL into your browser to access the survey: https://www.sharepoint.iu.edu/sites/iu-ora/survey/Lists/Compliance/IRB_Survey/NewForm.aspx.

/enclosures