

DATE: August 30, 2017
TO: Robert C. Martin, M.D.
IRB NUMBER: 02.0496
STUDY TITLE: Evaluation of the Genetic Polymorphisms and Expressions as a Predictor of Cancer
REFERENCE #: 646336
REVIEW DATE: 08/29/2017
IRB STAFF CONTACT: Cathy J. Carter, CIP, Senior IRB Analyst, 852-4098, cathy.carter@louisville.edu

The continuation request for this study was reviewed by a Vice-Chair of the Institutional Review Board (IRB) through the expedited review procedure, according to 45 CFR 46.110 and 21 CFR 56.110 since this study falls under Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (healthy non pregnant adults 110lbs or more, no more than 550mL in 8 weeks and no collection more than 2x a week OR other adults and children not exceeding the lesser of 50 ml or 3 ml per kg in an 8 week period and no collection more than 2x a week). **The study now has continued committee approval from 09/23/2017 through 09/22/2018.**

The following items were reviewed and approved:

Submit Continuing Review	Version 4.0	Approved as Submitted	
Study Document Title	Version #	Version Date	Outcome
2017 CR Protocol	Version 3.0	03/30/2016	
2017 CR ICF	Version 13.0	08/10/2017	Approved

In addition, Michael Egger, M.D., and Traci Hayat were added to the study team.

Continuation Review Requirements

You are responsible for submitting a continuation review 30 days prior to the expiration date of your research study. Investigators who allow their study approval to expire have committed significant non-compliance with federal regulations. Such lapses may require reporting to federal agencies, a program audit by compliance auditors to ensure that subjects were not enrolled during the expired period, and may lead to findings of serious and continuing non-compliance if expiration were to occur a second time.

Please begin using your newly approved (**stamped**) consent document on **09/23/2017**. The previous version will no longer be valid.

This action will be reported promptly to the IRB at a scheduled full Board meeting.

If you have any questions, please contact the IRB analyst listed above or the Human Subjects Protection Program office at hspofc@louisville.edu.

Diller Groff, M.D., Vice Chair, Biomedical Institutional Review Board

We value your feedback. Please let us know how we are doing: <https://www.surveymonkey.com/r/CCLHXP>.