UNIVERSITY OF LOUISVILLE

Human Subjects Protection Program Office
MedCenter One – Suite 200
501 E. Broadway
Louisville, KY 40202-1798
Office: 502.852.5188 Fax: 502.852.2164

DATE: November 11, 2016
TO: Susan Galandiuk, M.D.
IRB NUMBER: 97.0361
STUDY TITLE: The Association of Gastrointestinal Disease, DNA Repair and Host Defense Genes
REFERENCE #: 631449

IRB STAFF CONTACT: Name: Sherry Block
Phone: 852-2163
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The continuation request was approved at the full board meeting of 10/27/2016. The stipulations were received by the Human Subjects Protection Program Office and reviewed by the HSPPO staff and was found to be complete.

The following items were reviewed and approved:

Submission Components			
Title	Version #	Version Date	Outcome
Revised ICF dated 10.31.16	Version 1.0	10/31/2016	Approved
Protocol dated 2.13.12	Version 1.0	08/30/2016	Approved
Revised Assent ICF dated 9.1.16	Version 1.0	09/01/2016	Approved

Please begin using your newly approved **(stamped)** consent document on **11/18/2016.** The previous version(s) will no longer be valid.

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 Note: Dr. Dryden is an IRB Committee member. Due to a conflict of interest, he/she was not present for the presentation, discussion, or voting of this protocol.

The initial submission of this study was reviewed and approved contingent upon changes made to the study by the fully convened IRB. The IRB has determined this study can be reviewed in the future through expedited procedures. All future requests for this study should be submitted for expedited review. This study now falls under expedited category (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

If you have any questions, please contact the Human Subjects Protection Program Office at hsppofc@louisville.edu

Sincerely,

Sherry Block, BS, IRB Analyst