THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
105 Mason Farm Road
Medical Building #52
CB #7097
University of North Carolina at Chapel Hill
Chapel Hill, North Carolina 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
Federalwide Assurance (FWA) #4801

To: Robert Sandler
Medicine-Gastroenterology

From: Biomedical IRB

Approval Date: 2/20/2015
Expiration Date of Approval: 2/01/2016
RE: Notice of IRB Approval by Full Board Review
Submission Type: Initial
Study #: 14-3156

Study Title: Risk factors for microscopic colitis

This submission has been approved by the IRB for the period indicated.

Study Description:

Purpose: Microscopic colitis is an increasingly common cause of diarrhea. The purpose of the study is to learn more about risk factors.

Participants: Individuals referred for clinically indicated colonoscopies for diarrhea.

Procedures (methods): Potential participants will be sent a brochure describing the study and will be called by a research assistant to answer questions. On the day of colonoscopy those who are interested in participating will be consented. Consented subjects will have blood drawn through the IV catheter placed for the colonoscopy, will have research biopsies taken during colonoscopy and will be interviewed by phone at a later date.

Regulatory and other findings:

This approval includes a limited waiver of HIPAA authorization to identify potential subjects for recruitment into this research study, as allowed under 45 CFR 164.512. This temporary waiver provides access to protected health information (PHI) to confirm eligibility and facilitate initial contact, after which consent and HIPAA authorization will be sought when applicable. Access and use is limited to the minimum amount of PHI necessary to review eligibility criteria and to contact potential subjects.

Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

Your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/index.cfm?event=home.dashboard.irbStudyManagement&irb_id=14-3156.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at http://irbis.unc.edu.

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records).

The current data security level determination is Level III. Any changes in the data security level need to be discussed with the relevant IT official. If data security level II and III, consult with your IT official to develop a data security plan. Data security is ultimately the responsibility of the Principal Investigator.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
Joseph Galanko, Medicine-Gastroenterology
Beth Jaeger, Center for Gastrointestinal Biology and Disease
John Woosley, Pathology and Lab Medicine - Clinical